

Global atlas of medical devices

WHO medical devices technical series



Global atlas of medical devices

(WHO Medical device technical series)

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| Austria | - | - | - | - | - | - | - | - | 298 |
| Azerbaijan | - | - | - | - | - | - | - | - | 300 |
| Belarus | - | - | - | - | - | - | - | - | 302 |
| Belgium | - | - | - | - | - | - | - | - | 304 |
| Bosnia and Herzegovina | - | - | - | - | - | - | - | - | 306 |
| Bulgaria | - | - | - | - | - | - | - | - | 308 |
| Croatia | - | - | - | - | - | - | - | - | 310 |
| Cyprus | - | - | - | - | - | - | - | - | 312 |
| Czech Republic | - | - | - | - | - | - | - | - | 314 |

| | | | | | | | | | |
|--|---|---|---|---|---|---|---|---|-----|
| Denmark | - | - | - | - | - | - | - | - | 316 |
| Estonia | - | - | - | - | - | - | - | - | 318 |
| Finland | - | - | - | - | - | - | - | - | 320 |
| France | - | - | - | - | - | - | - | - | 322 |
| Georgia | - | - | - | - | - | - | - | - | 324 |
| Germany | - | - | - | - | - | - | - | - | 326 |
| Greece | - | - | - | - | - | - | - | - | 328 |
| Hungary- | - | - | - | - | - | - | - | - | 330 |
| Iceland | - | - | - | - | - | - | - | - | 332 |
| Ireland | - | - | - | - | - | - | - | - | 334 |
| Israel | - | - | - | - | - | - | - | - | 336 |
| Italy | - | - | - | - | - | - | - | - | 338 |
| Kazakhstan | - | - | - | - | - | - | - | - | 340 |
| Kyrgyzstan | - | - | - | - | - | - | - | - | 342 |
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| Malta | - | - | - | - | - | - | - | - | 352 |
| Monaco | - | - | - | - | - | - | - | - | 354 |
| Montenegro | - | - | - | - | - | - | - | - | 356 |
| Netherlands | - | - | - | - | - | - | - | - | 358 |
| Norway | - | - | - | - | - | - | - | - | 360 |
| Poland | - | - | - | - | - | - | - | - | 362 |
| Portugal | - | - | - | - | - | - | - | - | 364 |
| Moldova, Republic of | - | - | - | - | - | - | - | - | 366 |
| Romania | - | - | - | - | - | - | - | - | 368 |
| Russian Federation | - | - | - | - | - | - | - | - | 370 |
| San Marino | - | - | - | - | - | - | - | - | 372 |
| Serbia | - | - | - | - | - | - | - | - | 374 |
| Slovakia | - | - | - | - | - | - | - | - | 376 |
| Slovenia | - | - | - | - | - | - | - | - | 378 |
| Spain | - | - | - | - | - | - | - | - | 380 |
| Sweden | - | - | - | - | - | - | - | - | 382 |
| Switzerland | - | - | - | - | - | - | - | - | 384 |
| Tajikistan | - | - | - | - | - | - | - | - | 386 |
| Turkey | - | - | - | - | - | - | - | - | 388 |
| Ukraine | - | - | - | - | - | - | - | - | 390 |
| United Kingdom of Great Britain and Northern Ireland | - | - | - | - | - | - | - | - | 392 |

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| Bhutan | - | - | - | - | - | - | - | 400 |
| Democratic People's Republic of Korea | - | - | - | - | - | - | - | 402 |
| India | - | - | - | - | - | - | - | 404 |
| Indonesia | - | - | - | - | - | - | - | 406 |
| Maldives- | - | - | - | - | - | - | - | 408 |
| Myanmar | - | - | - | - | - | - | - | 410 |
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| Sri Lanka | - | - | - | - | - | - | - | 414 |
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| Brunei Darussalam | - | - | - | - | - | - | - | 426 |
| Cambodia | - | - | - | - | - | - | - | 428 |
| China | - | - | - | - | - | - | - | 430 |
| Fiji- | - | - | - | - | - | - | - | 432 |
| Japan | - | - | - | - | - | - | - | 434 |
| Kiribati | - | - | - | - | - | - | - | 436 |
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| Marshall Islands | - | - | - | - | - | - | - | 442 |
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| Viet Nam | - | - | - | - | - | - | - | 470 |



Preface

Health technologies are essential for a functioning health system. Medical devices in particular are crucial in the prevention, diagnosis and treatment of illness and disease, as well as patient rehabilitation. Recognizing this important role of health technologies, the World Health Assembly adopted resolution WHA60.29 in May 2007. The resolution covers issues arising from the inappropriate deployment and use of health technologies, and the need to establish priorities in the selection, regulation, assessment and management of health technologies, specifically medical devices. By adopting this resolution, delegations from Member States acknowledged the importance of health technologies for achieving health-related development goals; urged expansion of expertise in the field of health technologies, in particular medical devices; and requested that the World Health Organization (WHO) take specific actions to support Member States.

To determine the key areas that require support for the development or improvement of health technology programmes in countries and regions, the first WHO Baseline Country Survey on Medical Devices was developed in 2009, launched in February 2010 and was updated with a re-launch in November 2013. Since then, annual updates have been undertaken. The results of the survey provide detailed information on the availability of specific medical devices, policies, guidelines, standards and services for medical device assessment, management and regulation, and also designate a focal point for health technologies responsible for medical devices in the ministry of health of each respondent country.

For this publication, the information has been processed into a comprehensive database and is displayed in country profiles and maps reflecting the global status quo. In addition, each topic of the survey is introduced by a summary conveying its importance and standing in the health care domain. This publication serves to share the acquired knowledge and resources among the participating Member States, to record and to make visible the current situation, challenges, and problems, and to facilitate decision making on national, regional and global levels. It is intended for use as a reference by decision-makers in ministries of health, nongovernmental organizations and academic institutions involved in health technology at the district, national, regional or global levels. It is planned that supplementary information will be added to upgrade the country profiles annually. These country profiles incorporate facts indicating the national status of medical devices in areas such as: medical device policies, regulations, selection, inventories, production, consumption, access and their use by health care health workers, patients, academia and biomedical engineering resources. The aim of this publication is to raise awareness and bring evidence of the indispensable safe and good use of appropriate, affordable and quality medical devices in health care delivery to achieve better health outcomes.

Methodology

The Baseline Country Survey on Medical Devices was conceptualized and realized by the Diagnostic Imaging and Medical Devices team within the WHO Department of Essential Health Technologies. In 2010, the countries' Ministries of Health or related missions were contacted through a circular letter (including the WHA60.29 resolution) and were asked to nominate a health technology focal point and to complete a web-based survey in one of the six official languages. As countries had not been approached with a similar request before, no structures were in place to easily provide this information to WHO. It took almost two years before 145 countries had submitted a filled-in questionnaire. In 2013, the survey was re-launched by the Policy, Access and Use team of the Essential Medicines and Health Products Department, by contacting the focal points for an update and resending to missions and WHO country offices, with the intention to update the collected information and also to obtain data from countries that had not answered the first survey. These efforts resulted in the final participation of 177 countries. Results were analysed, evaluated and published in the WHO Medical Devices website and in

the WHO Global Health Statistics report. Other surveys have taken place since the first launch of the Baseline Country Survey on Medical Devices using the information and focal points presented in this survey, for example the “Survey on access to medical devices in low-resource settings”¹.

It should be noted that all information published here has been provided by the ministries of health by way of official channels. All data presented in this publication were reviewed in 2014 and are available on different pages of the WHO website as indicated in the following table:

| Information | Location WHO website | Link |
|---|--------------------------------------|---|
| Country profiles | Medical devices website | http://www.who.int/medical_devices/countries |
| Global static maps | Global health observatory | http://www.who.int/gho/health_technologies/medical_devices |
| Global interactive maps | | |
| Metadata information | | |
| Selected indicators for the World Health Statistics | World health statistics publications | http://www.who.int/gho/publications/world_health_statistics |

Definitions

Recognizing that there are multiple interpretations for the terms listed below, for the purposes of this publication they are defined as follows:

Health technology: The application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of life.² It is used interchangeably with the term health care technology.

Medical device: An article, instrument, apparatus or machine that is used in the prevention, diagnosis or treatment of illness or disease, or for detecting, measuring, restoring, correcting or modifying the structure or function of the body for some health purpose. Typically, the purpose of a medical device is not achieved by pharmacological, immunological or metabolic means.³

Medical equipment: Medical devices requiring calibration, maintenance, repair, user training, and decommissioning – activities usually managed by clinical engineers. Medical equipment is used for the specific purposes of diagnosis and treatment of disease or rehabilitation following disease or injury; it can be used either alone or in combination with any accessory, consumable, or other piece of medical equipment. Medical equipment excludes implantable, disposable or single-use medical devices.⁴

Declarations of interests

Conflict of interest statements were collected from all contributors to and reviewers of the document. No conflicts of interests were declared.

1 This survey was the basis for the publication “Local Production and Technology Transfer to Increase Access to Medical Devices: addressing the barriers and challenges in low- and middle-income countries”, WHO 2012, ISBN 9789241504546.

2 Definition as used in the World Health Assembly 60.29, 2007.

3 Definition by the Global Harmonization Task Force: “Definition of the Terms ‘Medical Device’ and ‘In Vitro Diagnostic (IVD) Medical Device’”, GHTF/SG1/N071:2012. <http://www.imdrf.org/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n071-2012-definition-of-terms-120516.pdf>

4 http://www.who.int/medical_devices/publications/med-dev-policies/en/



Acronyms and abbreviations

| | |
|------|--|
| AFR | WHO African Region |
| AMR | WHO Region of the Americas |
| BCS | Baseline Country Survey on Medical Devices |
| EMR | WHO Eastern Mediterranean Region |
| EUR | WHO European Region |
| GDP | gross domestic product |
| GHO | Global Health Observatory |
| GIHT | Global Initiative on Health Technologies |
| HDI | Human Development Index |
| HTA | health technology assessment |
| HTM | health technology management |
| MDG | Millennium Development Goal |
| MoH | ministry of health |
| NGO | nongovernmental organization |
| SEAR | WHO South-East Asia Region |
| UN | United Nations |
| WB | World Bank |
| WHO | World Health Organization |
| WHS | World Health Statistics |
| WPR | WHO Western Pacific Region |

Executive summary

The Global Atlas of Medical Devices offers a new perspective on the global status of national medical device policies and the availability of medical device information, regulations, assessments, procurement and donation guidelines, as well as the density of high cost medical equipment and guidance documents available at country level.

Recognizing the important role of health technologies, in particular of medical devices, the World Health Assembly adopted resolution WHA60.29 in May 2007 and subsequent resolutions have been approved in the following years, related to the importance of medical devices regulations, evaluation and use as well as the medical devices required for essential interventions like surgery. The resolutions cover issues arising from the inappropriate deployment and use of health technologies, as well as the need to establish priorities in the selection, regulation, assessment and management of health technologies and specifically, medical devices. To determine the key areas of country or regional health technology programmes requiring support for development or improvement, the first Baseline Country Survey on Medical Devices was developed in 2009 and launched in February 2010 and was updated with a re-launch in November 2013. A total of 177 countries responded. In 2015, in response to resolution WHA67.23 on health interventions and technology assessment, WHO launched a global health technology assessment survey conducted by government or national institutes. Subsequently, in 2016, resolution WHA67.20 on the regulatory strengthening of medical products, including medical devices, led to a study analysing medical devices regulatory frameworks. The results of both the study and the global survey regarding medical devices have been included in this document.

For the purposes of this publication, the information collected by the surveys and studies has been processed into a comprehensive database that includes statistical analyses of more than 100 aspects related to medical devices evaluated with respect to welfare indicators such as World Bank income groups, health expenditure, Human Development Index and WHO regions. The results are displayed in regional tables, country profiles, diagrams, charts and maps reflecting the global status quo. The country profiles incorporate facts indicating the national status of medical devices in areas such as: policies, regulations, selection, inventories and lists of medical devices by health care facilities or by diseases, and also include nominated focal points in the ministries of health. The survey results reveal areas in which guidelines, documents and process policies are lacking and also serve as an important information archive to which Member States can refer and compare best practices. This information archive also provides a valuable basis for future studies.

The aim of this publication is to raise awareness and bring evidence of the indispensable safe and good use of appropriate, affordable and quality medical devices in health care delivery to achieve better health outcomes.



1

Context and
background

1.0 General perspectives

Global health challenges are becoming more and more complex with the duality of infectious disease outbreaks and the global burden of non-communicable diseases, especially in low- and middle-income countries. To provide quality, affordable and appropriate health care services, resilient health care systems are needed that include trained health workforces, information systems, financing mechanisms, infrastructure, medicines and technologies. The need to prevent diseases, diagnose early and treat effectively under the Universal Health Coverage mandate of the Sustainable Development Goals⁵ calls for safe, effective, and appropriate medical devices (see Fig. 1.0-1).

Sustainable Development Goal 3: “Ensure healthy lives and promote well-being for all at all ages”

- **By 2030, reduce by one third premature mortality from non-communicable diseases through prevention and treatment and promote mental health and well-being.**
- **Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all.**

Figure 1.0-1: Selected Sustainable Development Goal 3 targets for which medical devices are needed

Recognizing the important role of health technologies, in particular medical devices, the World Health Assembly has adopted several resolutions that mandate WHO to assess the needs for, and provide guidance with regard to the goal to improve selection, regulation, assessment and management of medical devices. The first resolution on health technologies by the World Health Assembly was passed in 2007 (WHA60.29).

However, as of 2009, there was no data available depicting the status of medical devices. The Global Atlas of Medical Devices is the outcome of the first Baseline Country Survey on Medical Devices. The project began in 2010 and has been updated regularly in order to provide information on the global situation regarding medical devices, as instructed in the WHA resolutions (further detail in section 1.1). In 2014, as a response to the WHA67.23 and WHA67.20 resolutions, assessments, surveys and data collection exercises on both the medical devices regulatory process and the health technology assessment process were undertaken, and the results are presented alongside the results of the Baseline Country Survey in sections 3.2 and 3.3 respectively.

This publication presents the first assessment of the availability of information, policies, regulations, procurement and donation guidelines and density of high cost medical equipment and guidance documents at country level. The data has been used already to elaborate on the guidelines and tools that are requested by WHA in 2007, specifically for low- and middle-income countries, for example, the guidance documents in the WHO Medical Devices Technical Series on development of policies, health technology assessment, procurement, donations and inventories¹ and publications on priority medical devices for reproductive, maternal, new born and child health.⁶

This information is presented as it was reported by the nominated focal points on health technologies in the ministries of health in the countries, and thus it may not be complete. The information contained in this publication was accurate as of 2015 and was compiled in previous years. To update the results, further data needs to be regularly collected with regards to all the different aspects of health technologies.

⁵ <https://sustainabledevelopment.un.org/sdgs>

⁶ http://www.who.int/medical_devices/publications/interagency_med_dev_list/en/



1.1 Need for global information and WHA resolutions on health technologies

To facilitate health care decision-making on national, regional and global levels, there is a need for comprehensive information as well as clear rules and guidelines:



The field of medical devices is large, diverse, competitive, and highly innovative. This is an area of great promise, sometimes spectacular promise, sometimes seductive promise. It is also an area with a number of problems and pitfalls, some familiar, others unique. As many have noted, the field of medical devices requires, and deserves, its own unique agenda. Health officials and hospital managers in all countries, at all levels of development, need guidance.



—Dr Margaret Chan, WHO Director-General, Thailand, November 2010⁷

In May 2007, resolution WHA60.29 on “Health Technologies” was approved. ⁱⁱ It mandates that WHO deliver a global program of work, especially concerning the policies and guidelines with regard to the goal to improve selection, regulation, assessment and management of medical devices. It specifically urges Member States:

- *“to collect, verify, update and exchange information on health technologies, in particular medical devices, as an aid to their prioritization of needs and allocation of resources”;*
- *“to formulate as appropriate national strategies and plans for the establishment of systems for the assessment, planning, procurement and management of health technologies, in particular medical devices, in collaboration with personnel involved in health-technology assessment and biomedical engineering”;* and
- *“to establish where necessary regional and national institutions of health technology, and to collaborate and build partnerships with health-care providers, industry, patients’ associations and professional, scientific and technical organizations”.*

WHA60.29 requests the Director-General of WHO:

- *“to work with interested Member States ... on the development , in a transparent and evidence based way, of guidelines, and tools, including norms, standards and a standardized glossary of definitions relating to health technologies in particular medical devices”;* and
- *“to develop methodological tools to support Member States in analysing their needs and health systems prerequisites for health technologies, in particular medical devices”.*

In 2014, a second World Health Assembly resolution was approved on “regulatory system strengthening for medical products”, WHA67.20. For the purposes of this resolution, medical products included medicines, vaccines, diagnostics and medical devices.ⁱⁱⁱ It states the importance of the regulation of medical devices for better public health outcomes and to increase access to safe, effective and quality medical products, and acknowledges the need to support the area of medical devices. It specifically urges Member States:

- *“ to strengthen national regulatory systems, to engage in global, regional and subregional networks of national regulatory authorities, and to promote international cooperation, as appropriate;”*

and requests the Director-General of WHO:

- *“ to prioritize support for establishing and strengthening regional and subregional networks of regulatory authorities, as appropriate, including strengthening areas of regulation of health products that are the least developed, such as regulation of medical devices, including diagnostics; and to support the building-up of effective national and regional regulatory bodies and networks. To report in five years to the WHA on the implementation”.*

⁷ Excerpt from the opening address at the WHO First Global Forum on Medical Devices. Bangkok, Thailand, 9–11 September 2010 (http://www.who.int/dg/speeches/2010/med_device_20100909/en/index.html, accessed Jan 2016).

Also in 2014, a third related resolution was approved on “Health Intervention and Technology Assessment in support of Universal Health Coverage”, WHA67.23.^{iv} It specifically requests the Director-General of WHO:

- *“to assess the status of health intervention and technology assessment in Member States in terms of methodology, human resources and institutional capacity, governance, linkage between health intervention and technology assessment units and/or networks with policy authorities, utilization of assessment results, and interest in and impediments to strengthening capacity”.*

Additional recent resolutions recognize the need for affordable, available medical devices to deliver important programmes such as management of non-communicable diseases or essential surgery. In 2015, a resolution was approved on “Strengthening emergency and essential surgical care and anaesthesia as a component of universal health coverage” (WHA68.15). It requests the Director-General of WHO:

- *“to support Member States in the development and implementation of policies and regulations for ensuring access to quality, safe, efficacious and affordable essential medicines, [...], medical devices, and diagnostics that are used in emergency and essential surgical care and anaesthesia”.*

Since 2015, in further efforts beyond this publication, new studies have been and are being conducted by WHO, searching for complementary and updated information, particularly on policies, regulatory processes, assessments and procurement processes in each Member State, as well as on availability of technologies, biomedical engineers and technicians, and on pricing policies. These studies will lead to new evidence on how to better manage health technologies and will also indicate the most urgent gaps needing to be filled, especially with regard to capacity building.

1.2 Objectives

The objective of the Global Atlas of Medical Devices is to present a perspective on the global status of health technology policies. The results of the global survey reveal where guidelines, documents and process policies are present. The results also serve as an information archive that Member States could refer to. It also functions as a valuable basis for future studies.

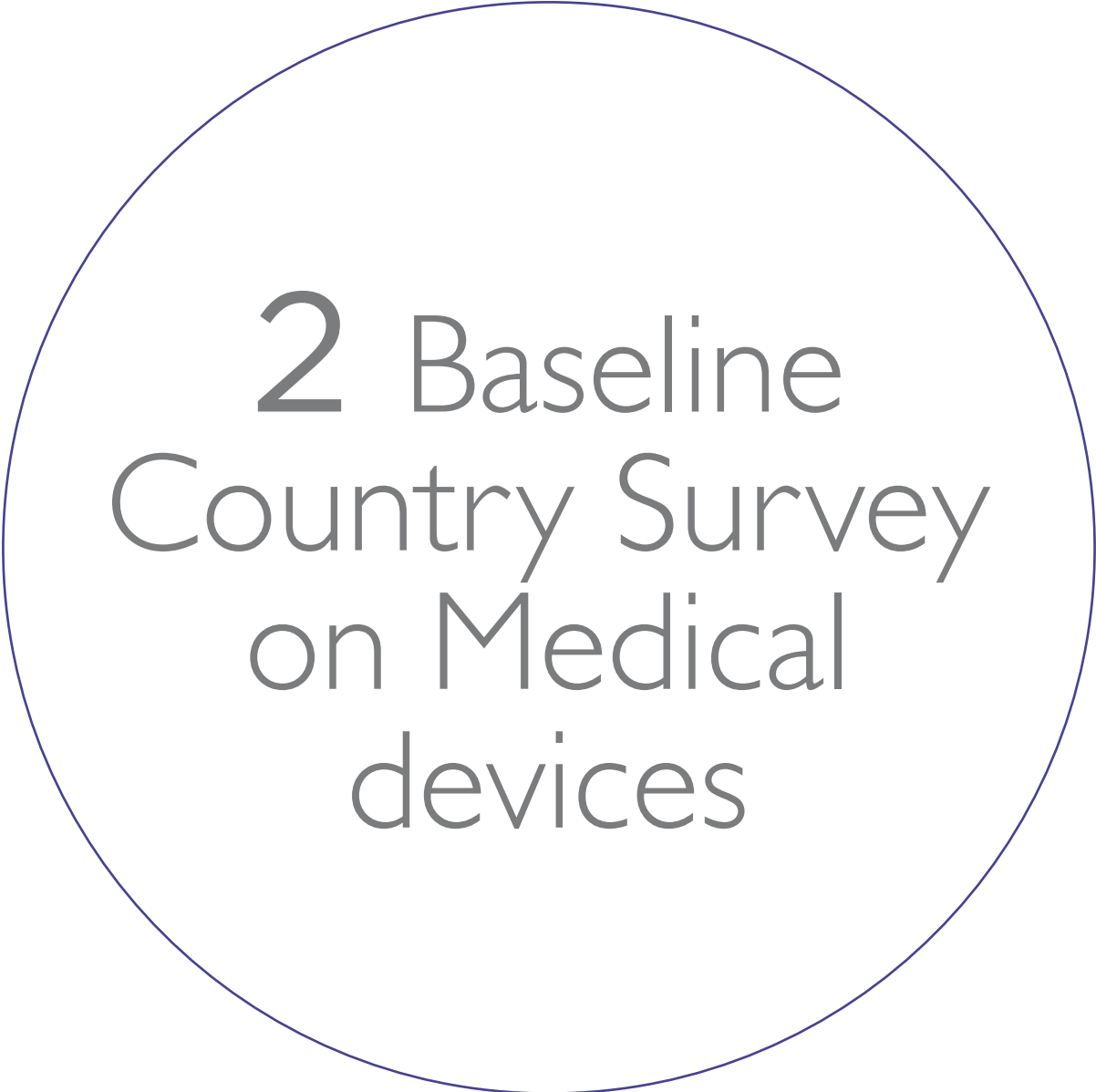
WHO hopes that based on the information available in this publication, more studies will be initiated in this area, where data for policy making are needed. Much is still to be done to attain better access, availability, and use of quality, safe, and affordable health technologies, in particular medical devices, for health care procedures as needed. One proposed new study area is to search for specific indicators and measure annual trends in order to track the status or advancement of the situation related to health technologies – in particular, medical devices – for each Member State. This would be the foundation to support each country appropriately in their efforts to improve the medical device programme in their health plans and therefore support prevention of disease, early diagnosis, effective treatment and better health care for the population, especially the underserved one, who requires our full commitment.

i WHO Medical Devices Technical Series publications: http://www.who.int/medical_devices/links/en/; http://www.who.int/medical_devices/management_use/en/, accessed April 2016.

ii http://www.who.int/healthsystems/WHA60_29.pdf, accessed April 2016.

iii http://apps.who.int/gb/ebwha/pdf_files/WHA67/A67_R20-en.pdf, accessed April 2016.

iv http://apps.who.int/gb/ebwha/pdf_files/WHA67/A67_R23-en.pdf, accessed April 2016.



2 Baseline
Country Survey
on Medical
devices

2.1 Introduction

The Baseline Country Survey (BCS) on Medical Devices was launched in February 2010, concluded in November 2011, and updated in November 2013. The 2013 survey has been conducted by Essential Medicines and Health Products (EMP) department.

The Health Technology resolution WHA60.29, from May 2007, has laid the foundations for a continuous effort to enhance availability and better use of health technologies which will contribute to the strengthening of health systems based on the primary healthcare reforms for universal coverage and better health service delivery.

The BCS on Medical Devices is designed to establish availability of policies, guidelines, standards, and services for assessment, management and regulation of health technology in Member States. Additionally, it is WHO's intention to determine key areas to support the development of health technology programmes in regions and countries, as well as to share knowledge and information among Member States.

The survey is a health technology monitoring tool and has four main objectives:

- To capture the requirements of Member States for tools, guidelines, standards and services in biomedical/clinical engineering, the requirements for health technology assessment, and the status of development of health technology programmes dedicated to medical devices in Member States;
- To disseminate collected knowledge to Member States;
- To facilitate both the sharing of information and resources among participating countries and better-informed decision making on national, regional and global levels; and
- To develop a database of health technology information collected from the participating countries, in order to provide valuable input to various stakeholders and decision makers on regional, national and global levels.

2.2 Methodology

Drawing upon knowledge and experience from previous projects at the WHO, the work of experts in various countries, and the pivotal guidance of the WHA resolutions, a list of essential parameters for health technology was created to inform the design of the survey. Consequently, the following ten topics were incorporated in a comprehensive six-section questionnaire for the BCS on Medical Devices:

- national policy on health technology
- regulatory agencies
- national health technology assessment unit
- national health technology management units
 - » o medical device incorporation
 - » o medical devices inventory and maintenance
- medical device nomenclature system
- national lists of medical devices
- health care facilities
- medical equipment.

Moreover, to improve accessibility and ease of use by Member States, the questionnaire was designed to be available in six official WHO languages: Arabic, Chinese, English, French, Spanish and Russian, and in three possible formats:

- as a web-based tool with Datacol WHO software, available using unique country username and password;
- as hard copy or electronic pdf copy available via post or email; and
- as an excel fill-in tool, delivered via email.



The BCS on Medical Devices follows a six-step process to have the country's survey questionnaire filled in by the corresponding ministry in charge of health technology:

1. WHO sends the official documentation to the country's ministry of health containing the following documents:
 - Request letter for appointment of an official health technology focal point within the corresponding country's Ministry.
 - World Health Assembly Health Technologies resolution: WHA 60.29.
 - Hard-copy of survey questionnaire including three appendices: glossary, supplementary explanations and corresponding WHO contacts.
2. The ministry of health designates the official health technology focal point within the corresponding country's ministry and communicates this to WHO.
3. WHO contacts the official health technology focal point and sends her/him the corresponding questionnaire in the format and language as requested by the health technology focal point.
4. The health technology focal point acts as a survey coordinator, and she/he coordinates and ensures the whole survey's completion by identifying and instructing a group of experts for the different survey's topics within the ministry of health or partner institutions.
5. The health technology focal point submits/sends the completed questionnaire back to WHO within the established deadline.
6. WHO verifies the information and could re-contact the Health Technologies Focal Point to ensure the accuracy, precision and completeness of the submitted/sent data and information.

2.3 History and Collection

The BCS on Medical Devices was launched in February 2010 when country ministries of health, corresponding missions, and WHO regional and country offices were contacted in order to obtain the nomination of the official health technology focal point within the ministry of health, and subsequently the corresponding completed survey questionnaire (see six-step process above).

2.3.1 Country Profiles 2010-2011

From February 2010 to November 2011 the country survey questionnaires from 145 Member States were gathered and revised. The main outcome of this data collection process was the publication "*Baseline Country Survey on Medical Devices 2010*"ⁱ containing 145 country profiles.

In addition to this publication, an excel database was constructed to store all data and information collected through the 145 completed survey questionnaires.

In the following years, 2011 to 2014, close communication was maintained between the official country health technology focal points, WHO Health Technology country focal points, and WHO Health Technology regional advisers in order to constitute a Global Health Technology Network (GHTN) that fosters communication on data outcomes/trends, and facilitates the sharing of valuable information, knowledge, country data, WHO publications, workshops and events and expertise. This global network ensures that both the database and the corresponding lists of health technology focal points are reliable and up to date.

2.3.2 Country Profiles 2013-2014 update

From November 2012 to December 2014 the BCS on medical devices 2010 was updated by two means:

- For the 145 countries that had participated in the 2010 survey, WHO contacted the existing official health technology focal points and followed steps 3 to 6 of the survey's six-step process.
- For countries that had not previously participated in the survey, WHO contacted the ministries of health and

corresponding missions as well as WHO regional and country offices in order to obtain the nomination of the official health technology focal point within the ministry of health, and subsequently the corresponding completed survey questionnaire (by following the survey's six-step process as explained above).

During this period, the country survey questionnaires from 177 Member States were collected and verified.

The main outcome of this data collection process is the publication at hand that contains the Baseline Country Profiles on Medical Devices 2013-2014: 177 country profiles (91% of all 194 Member States), including global facts, regional facts and maps reflecting the global status quo.

In addition to this publication, a comprehensive excel database was created to store all data and information collected through the 177 complete survey questionnaires.

Currently, the Global Health Technology Network is up to date; in the future, WHO plans to maintain the communication and data/information/knowledge verification processes with the 177 and more nominated country health technology focal points, several WHO Health Technology country focal points, and the six WHO Health Technology regional advisers in each of the Regional Offices.

To facilitate exchange of knowledge and experience between countries and communication among relevant stakeholders in general, this publication includes focal points' contact details, as well as those of other contacts within national institutions, responsible for different health technology fields (see chapter 4). It should be noted that contact details might be outdated due to turn over of posts.

2.4 Response rate

The BCS on medical devices 2013-2014 update contains 177 submitted questionnaires (91% of 194 Member States) that had nominated a health technology focal point within the corresponding ministry; and that had answered at least the set of essential mandatory questions.

As shown in Fig. 2.4-1, the response rate for the first eight main topics from the survey questionnaire was considerably high: 90% to 99%. There were two topics: health care infrastructure and medical equipment, with response rates of around 70%. These differences in response rates could be explained by the fact that the last two topics involved strictly quantifiable parameters that were only attainable through a centralized information system. Moreover, several potential scenarios are related to this issue: the required information in the country is not collected in a centralized manner, the health technology focal point in the country could not obtain the information, or the country had previously no designated specialist on healthcare technology to oversee the centralized collection of data.

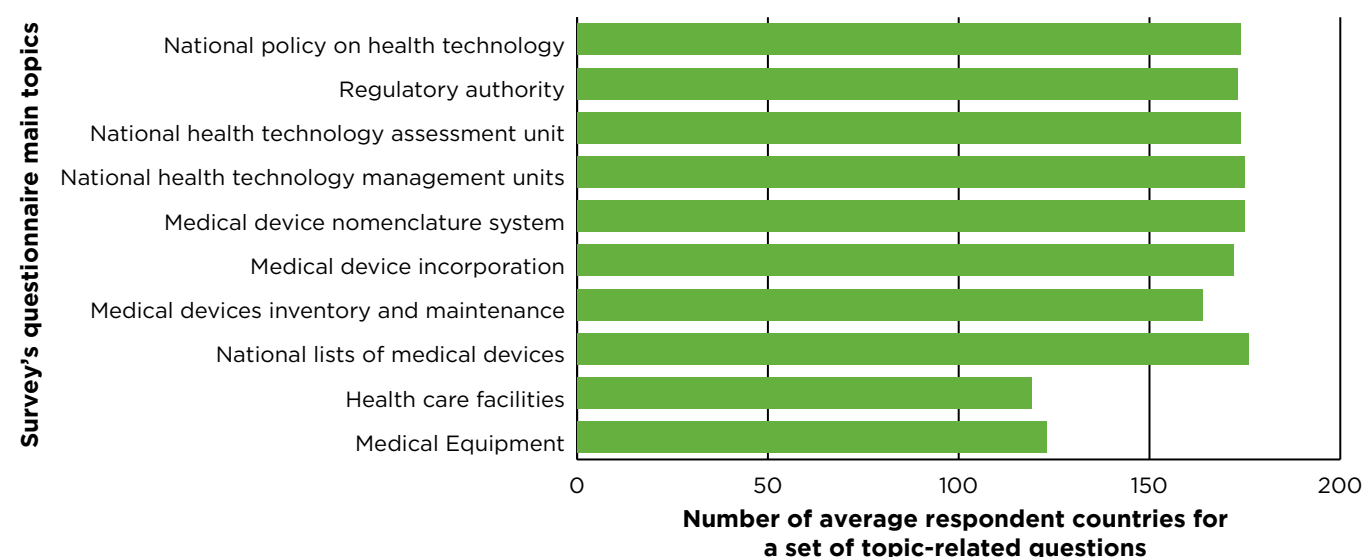


Figure 2.4-1: Respondent countries per BCS's questionnaire main topics



2.5 Strengths and Limitations

In this section, some strengths and limitations of the Baseline Country Survey are identified and discussed.

Strengths:

- The BCS on medical devices collects data directly from the country's ministry of health that typically has the most up-to-date and reliable data on most of the survey questionnaire.
- The data from the BCS is continuously verified by the corresponding nominated official health technology focal points in the ministry of health; the latter are regularly invited to participate in relevant WHO health technology meetings, Global Forum events and related discussions, and receive information from WHO listserv on medical devices including publications.
- The BCS on medical devices questionnaire is available in six languages and three formats; its content has been repeatedly revised and updated over the previous four years. Consequently, the survey in its current form is designed to be accessible, comprehensible, and user-friendly for the corresponding ministry of health focal points.

Limitations:

- The information included in the BCS on medical devices is dependent on the corresponding ministry of health focal point who is responsible for coordination of ministry of health-associated experts. Although WHO applied several verification tools, the included data reflects the information provided by the local ministry of health and might therefore contain a certain degree of bias.
- The BCS on medical devices relies on the ministry of health's health technology focal point having access to up-to-date country data and information. However, sometimes this latest information is not available in the corresponding ministry of health and therefore the answers to the questionnaire might not reflect the latest trends.
- The BCS on medical devices envisages updates on a two-year basis; consequently changes that occur during that two-year period might not be fully reflected in the WHO database.
- The responsible persons for all of the topics can change at any moment, and then the information needs to be updated accordingly.

2.6 Outcomes and applications

The BCS on medical devices contains essential health technology data and information that - as stated in the four main objectives (see section 2.1) - need to be shared among the participating countries, facilitating decision-making on a national, regional and global level.

This section lists the main outcomes and publications that made use of the BCS on medical devices 2010-2011 as well as its 2013 update.

Publications

World Health Statistics (WHS)

The WHS reports are an annual WHO compilation of health-related data for its 194 Member States containing indicators that provide a comprehensive summary of the current status of national health and health systems in crucial topics. WHS is an integral part of WHO's ongoing efforts to provide enhanced access to comparable high-quality statistics on core measures of population health and national health systems.

Several health systems indicators related to healthcare infrastructure and technologies were taken from the corresponding BCS on medical devices for the World Health Statistics publications in the years 2010 to 2015 (including 2011, 2012, 2013 and 2014, for more details see the corresponding publications at http://www.who.int/gho/publications/world_health_statistics/en/).

The Global Health Observatory (GHO)

The Global Health Observatory is a data repository and analysis on global health priorities. Each theme page provides information on the global situation and trend highlights, using core indicators, database views, major publications and links to relevant web pages on the theme. The BCS on medical devices contributes on a regular basis to update the data, facts, maps, and publications concerning health technologies themes under the health systems topic (GHO is available at http://www.who.int/gho/health_technologies/medical_devices/en/).

Surveys:

Local Production and Technology Transfer to Increase Access to Medical Devices

Other surveys have taken place since the first launch of the Baseline Country Survey on Medical Devices using the information and focal points presented in this survey, for example the “survey on access to medical devices in low-resource settings” that was the basis for the publication “Local Production and Technology Transfer to Increase Access to Medical Devices: addressing the barriers and challenges in low- and middle-income countries”.ⁱⁱ

Desk survey on global status of medical device regulation

During 2015/2016, WHO performed a desk survey on the current status of regulatory systems for medical devices in 194 WHO Member States. Information on the status of a legal framework for medical devices was collected from online sources (National Regulatory Authority websites, ministry of health websites, etc.) or by directly contacting WHO focal points or other country representatives who were identified by referring to the entries in the BCS.

Global Atlas of Health Technology Assessment by National Authoritiesⁱⁱⁱ

In compliance with the mandate of the WHA67.23 Resolution on Health Technology Assessment, in 2015, WHO did a global survey on health technology assessment as conducted by government or national institutions. The survey had five broad sections that aimed to measure the utilization of HTA in public sector decision making, the scope of HTA and availability of guidelines, the institutional capacity and human resources supporting HTA, the governance of HTA processes and the requirements for strengthening HTA capacity.

Other:

Global Initiative on Health Technologies (GIHT)

The GIHT aims to help make available the benefits of health technologies, particularly to communities in resource-limited settings. It makes use of the BCS on medical devices that contributes on a regular basis to update country data and information about policies, guidelines, lists, and other important data and information fundamental for health technologies capacity building within either countries or low-resource settings.

GIHT is available at http://www.who.int/medical_devices/appropriate_use/en/. In addition, a searchable database facilitates access to country essential information (GIHT database is available at the Essential Medicines and Health Products Information Portal, <http://apps.who.int/medicinedocs/en/>).

- i Baseline Country Survey on Medical Devices 2010. World Health Organization 2011. http://apps.who.int/iris/bitstream/10665/95785/1/WHO_HSS_EHT_DIM_11.01_eng.pdf (accessed June 2015)
- ii Local Production and Technology Transfer to Increase Access to Medical Devices: addressing the barriers and challenges in low- and middle-income countries, WHO 2012, ISBN 9789241504546.
- iii Global Survey on Health Technology Assessment by National Authorities – Main findings. World Health Organization 2015. http://www.who.int/health-technology-assessment/MD_HTA_oct2015_final_web2.pdf



3

Global topics
and facts

3.0 Introduction

In this chapter, the results of the Baseline Country Survey on Medical Devices (BCS) are presented. Each section is dedicated to one of the survey's key areas and is divided into three parts: introduction to the topic, global facts and further reading. The introductions serve to give a broad overview about the topic, its importance, challenges and standing. The global facts subsections portray the current global situation in the key areas based on selected indicators. Maps and figures illustrate the outcome of the survey from different angles, for example analyzed by income groups or by WHO regions. Eventually, under further readings, a selection of publications and websites points the reader to suitable sources for further exploration of the corresponding topics.

As explained in detail in chapter 2, the key areas were determined by WHO in the quest to support the development of health technology programs in regions and countries following the Health Technologies resolution WHA 60.29 from May 2007. Based on the extracted data and information from the BCS update, the sections report the status of these areas from a global perspective. Additional sources, such as the Global Health Observatory, the World Bank data repository and other world databases, were consulted to obtain selected indicators (see Annex 4: indicators and sources).

3.0.1 Data processing, analysis, and display

The data extraction and treatment was done as follows:

1. First, the country data were collected as explained in section 2.2, which describes the methodology of the Baseline Country Survey on Medical Devices.
2. Next, the data were exported to a data file and cleaned, treated and corrected for inconsistencies with the SPSS version 20 statistical program.
3. A semi-automatic excel⁸ tool was developed to process all extracted baseline country survey indicators (more than two hundred indicators) into tables according to different criteria such as regions, World Bank income groups, etc. This tool is adapted to recalculate the indicators' specific tables each time a country submits new data/information.

Figures and graphics were produced using the tables' contents with the objective to best represent the survey's outcome. The official WHO maps were developed using the following procedures:

- Developed with ESRI ArcMap 9.3 program
- Developed with the official WHO Global template used after 2011 which includes South Sudan member state
- Developed following the WHO guidelines for official WHO Global Maps.

3.0.2 Global participation

The global atlas facts and outcomes are based on the participation of 177 Member States out of a total of 194 Member States, i.e. a response rate of 91%. For a detailed overview please refer to section 2.4. Fig. 3.0-1 visualizes all participating Member States.

Note on all maps: *The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted lines on maps represent approximate border lines for which there may not yet be full agreement.*

8 Microsoft Office Professional Plus 2010 version

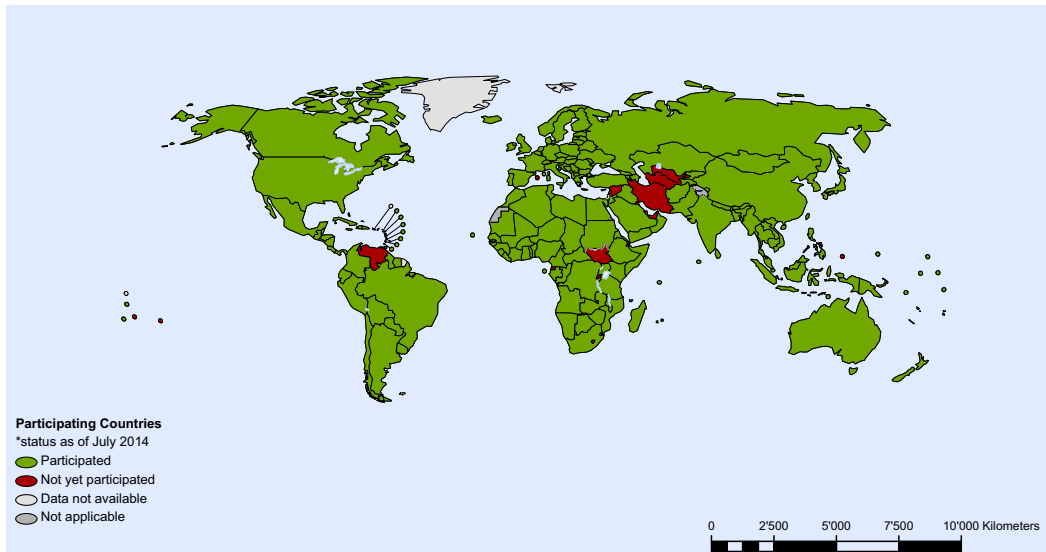


Fig. 3.0-1. Country participation in the Baseline Country Survey of Medical Devices 2013 update

The survey’s participation by income groups was relatively balanced across the four groups ranging from 89% to 94% (see Fig. 3.0-2). However, analyzing the participation data in terms of WHO regions revealed similar participation for five of the six regions, EUR, AMR, AFR, WPR, SEAR⁹ (ranging from 89% to 100%), and a considerably lower participation for the EMR region (71%) (see Fig. 3.0-3).

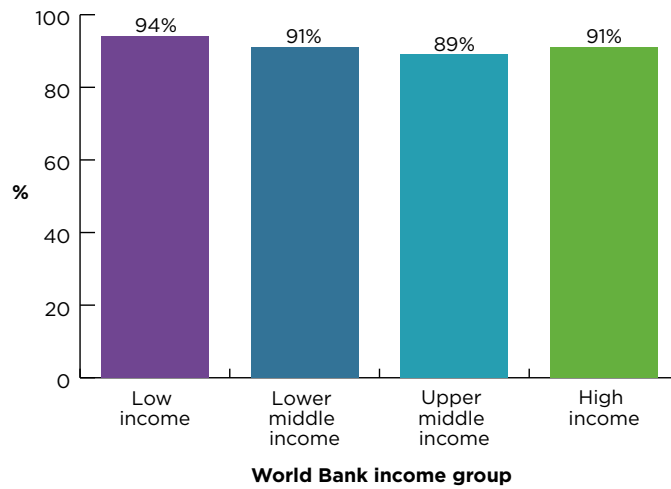


Fig. 3.0-2. Distribution of survey’s participation by World Bank income groups

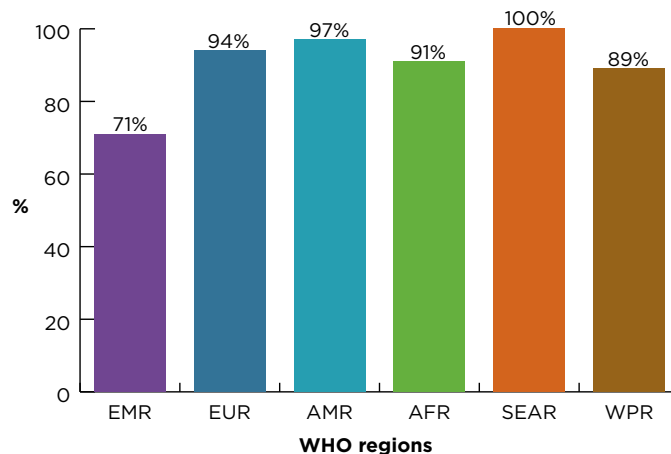


Fig. 3.0-3. Distribution of survey’s participation by WHO regions

⁹ For list of acronyms please refer to the start of this publication.

3.1 National policy on health technology

3.1.1 Introduction

A good national health system leads to quality health coverage for all people by targeting the population's needs and delivering universal health care. However, health systems are complex, manifold and intricate. In order to help build an effective and robust health system, WHO strongly encourages the development of national health policy frameworks that - when implemented - lead to reduced morbidity and mortality, reduced risks and threats to health, and reduced inequity in health (including improved health for women and children)ⁱ. Policies are primarily a set of standard protocols that are tailored to the national health needs, conditions and environment, and that serve as directives and guidelines on all levels of the health system. A national health policy framework includes a vision, a situation analysis, policy directions, strategies to overcome challenges, a policy implementation plan, and the leadership and governance required to achieve sustainability.

Health technologies are essential for a functioning health system, and medical devices in particular are crucial in the prevention, diagnosis, and treatment of illness and disease as well as in patient rehabilitation. An effective national health plan includes one (or more) sections on health technologies, with governmental units enacting health technology policies. The World Health Assembly, in resolution WHA60.29, acknowledged the need “to formulate as appropriate national strategies and plans for the establishment of systems for the assessment, planning, procurement and management of health technologies in particular medical devices, in collaboration with personnel involved in health-technology assessment and biomedical engineering”, as well as the need to provide technical guidance in implementing policies on health technologies.ⁱⁱ Fig. 3.1-1 illustrates how the global agenda and mission of WHO relate to the health systems, resulting in equitable access to safe and quality medical devices through the implementation of national health policies.



Fig. 3.1-1. Linking the global health agenda to improve medical device access via national health plans (WHA: World Health Assembly, MDG: Millennium Development Goals, SDG Sustainable Development Goals)



The array of medical devices, their uses, the settings in which they are applied, and all components of the medical device life cycle require rigorous policies. Robust policies guide health workers in their decisions and actions on each level from daily hospital routines to high-rank decision-making that impacts the future of health care in a country. The policies need to be adapted to the individual health sector functions in order to guarantee the best use of resources and serve the unique needs of the population according to local or national priorities.

Development of policies is a challenging task and requires input from many stakeholders such as academia, patients' organizations, professional organizations, specifically from biomedical engineers. Policy makers need to promote and implement useful strategies to ensure that national strategies and action plans for medical devices directly match public health priorities. This means planning medical device programmes in accordance with policies and protocols that result in equitable access to safe, appropriate and high-quality medical devices. Policies should include guidance for the rational selection of medical technology that best serves the needs of the target population, and should identify the financial and human resources to best use those technologies. Furthermore, policies should promote the safe and appropriate use of devices during their life cycle. The four areas of the medical device agenda that are above all involved in the implementation of health technology policies are:

- research and development: to develop medical technologies based on population needs (role of academia and industry);
- regulation: to authorize products to legally enter the local market;
- health technology assessment: to select the medical devices that could be used for packages of interventions or public procurement or positive lists; and
- health technology management: from selection to procurement, logistics, delivery systems and appropriate use.

Fig. 3.1-2 shows the relationships and interactions underpinning the medical device agenda and the dependence of successful functioning of each of these areas on the principles of safety, quality, universal coverage, and equity. Fig. 3.1-3 shows in more detail how these areas (including sub-areas) are linked in a health system and which supporting areas are closely involved, such as nomenclature and medical device lists.



Figure 3.1-2: The medical device agenda within a national health policy.

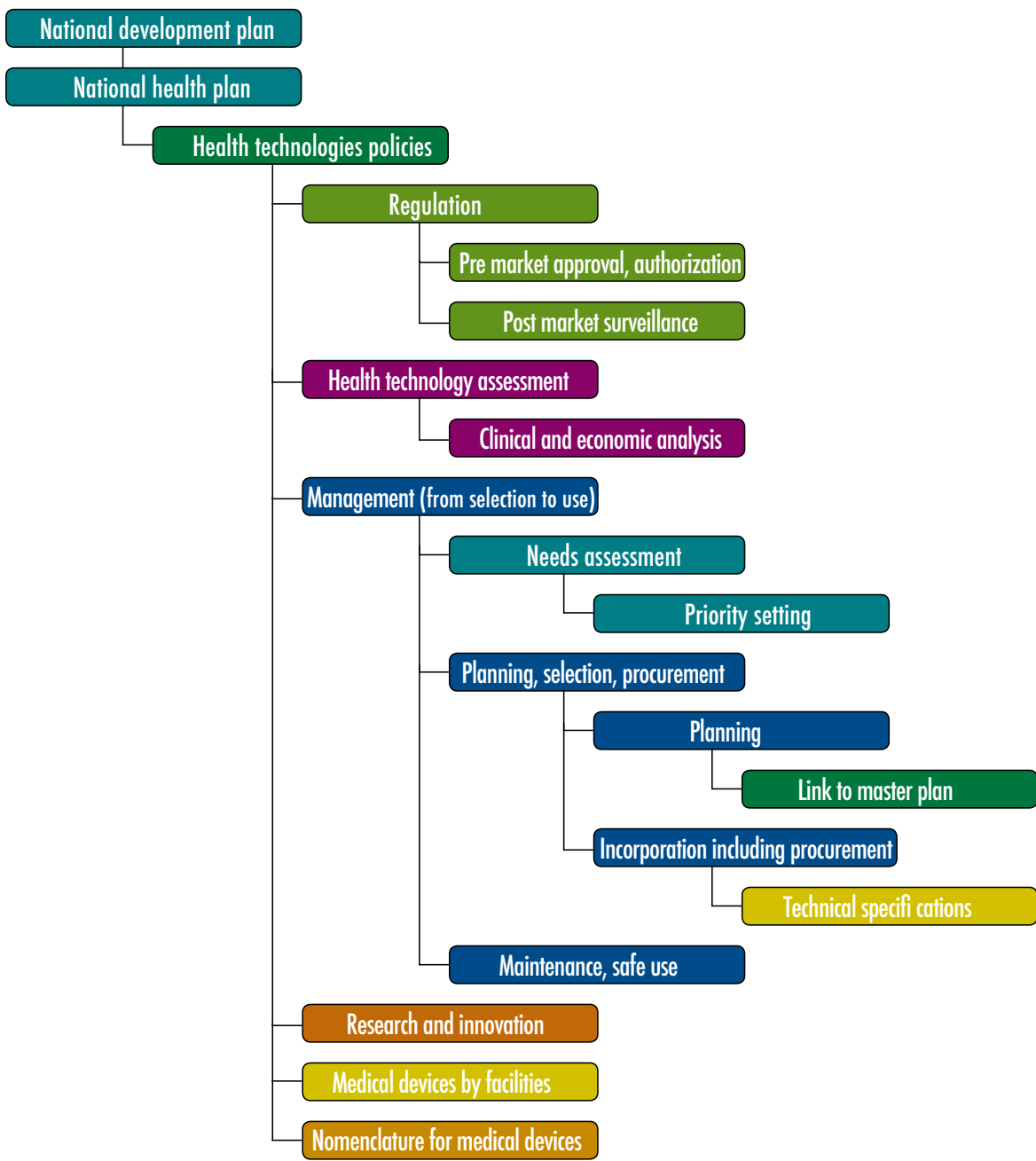


Figure 3.1-3: Areas of implementation for health technology policies

Only when all of the four areas are planned, well supported and coordinated, the overall programme can reach its desired improved health outcomes. The thorough implementation of a national health technology policy framework facilitates this process.



3.1.2. Global facts

The Baseline Country Survey on Medical Devices collected information on the presence of national health technology policies of medical devices globally. Overall results are visualized in Fig. 3.1-4.

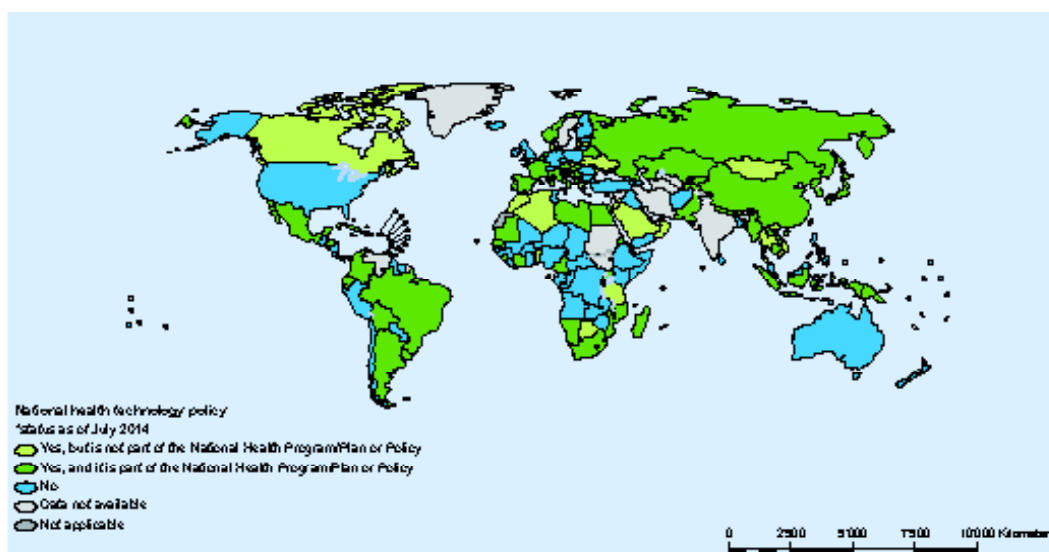


Fig. 3.1-4. Global map of national health technology policies of medical devices

From the 177 country survey respondents, 174 provided information on the subject of health technology (medical devices) policy. In total, 90 Member States (52% of 174) do not have a health technology (medical devices) policy and 83 Member States (48% of 174) do have such a policy. The latter is further subdivided into countries where this policy is part of the National Health Program (35%), countries where it is not (12%) and countries that did not specify this information (1%) as shown in Fig. 3.1-5.

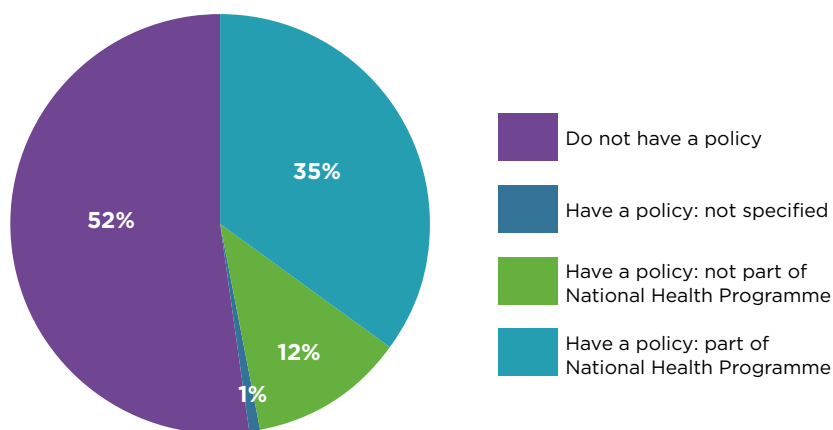


Fig. 3.1-5. Health technology policy in member states

This data was also analyzed with respect to World Bank income groups (Fig. 3.1-6). More than half of low to middle income countries do not have any health technology policy (from 124 respondent low- to middle-income economies), while 65% of high-income countries have a health technology policy (28 out of 49 respondent countries).

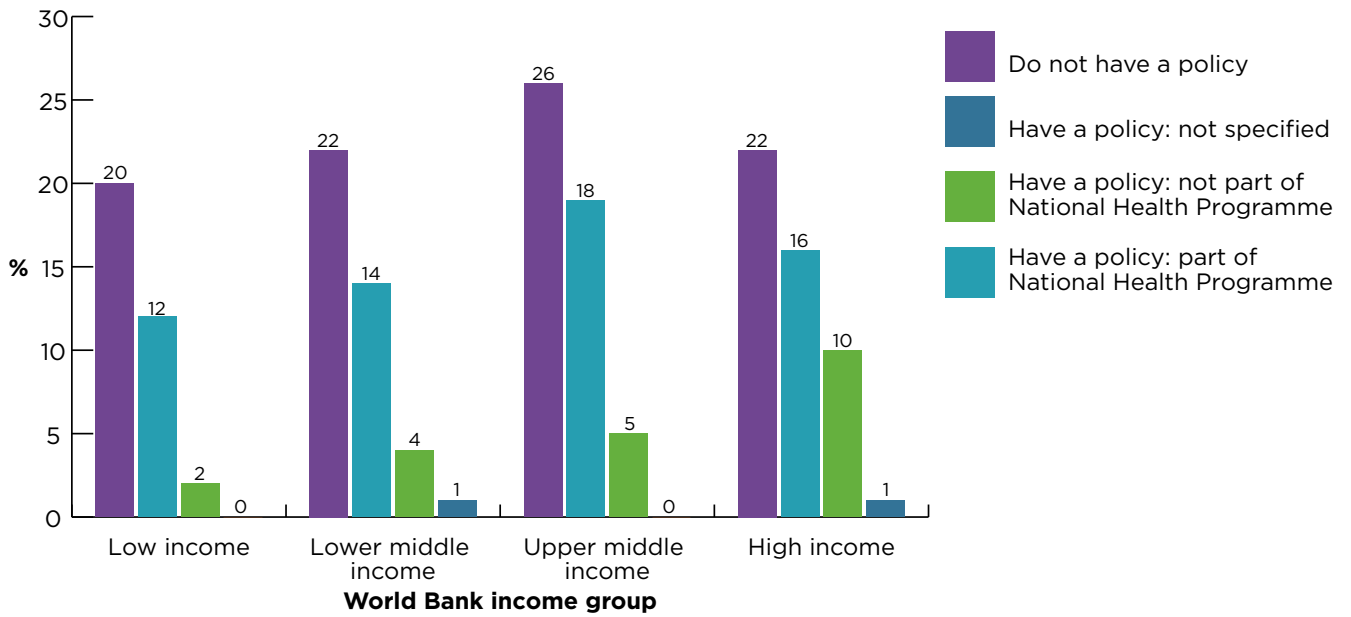


Fig. 3.1-6. Presence of a health technology policy by World Bank income group

Presenting this data with respect to WHO regions shows that more than 55% of countries from the three regions AFR, AMR, WPR have no health technology policy (with 101 respondent countries across the three regions) as shown in Fig. 3.1-7. The regions EMR, SEAR and EUR have national health policies in around 60% of respondent countries.

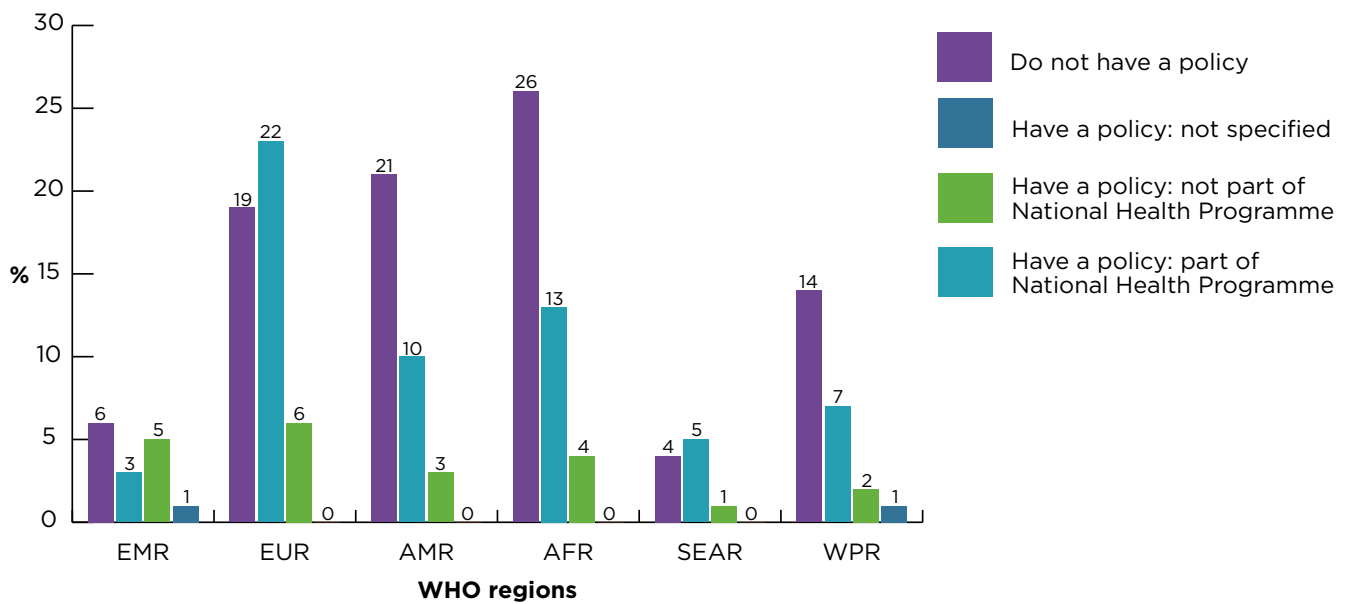


Fig. 3.1-7. Presence of a health technology policy by WHO region



A direct relationship between the Human Development Index (HDI)¹⁰ and countries with health technology policies was observed as follows: the higher the HDI, the higher the proportion of countries having a national health technology policy (Fig. 3.1-8). Countries with low HDI (i.e. lower income, education and life expectancy) also often lack health technology national policies (only 38% of the respondent countries in this group have such policies).

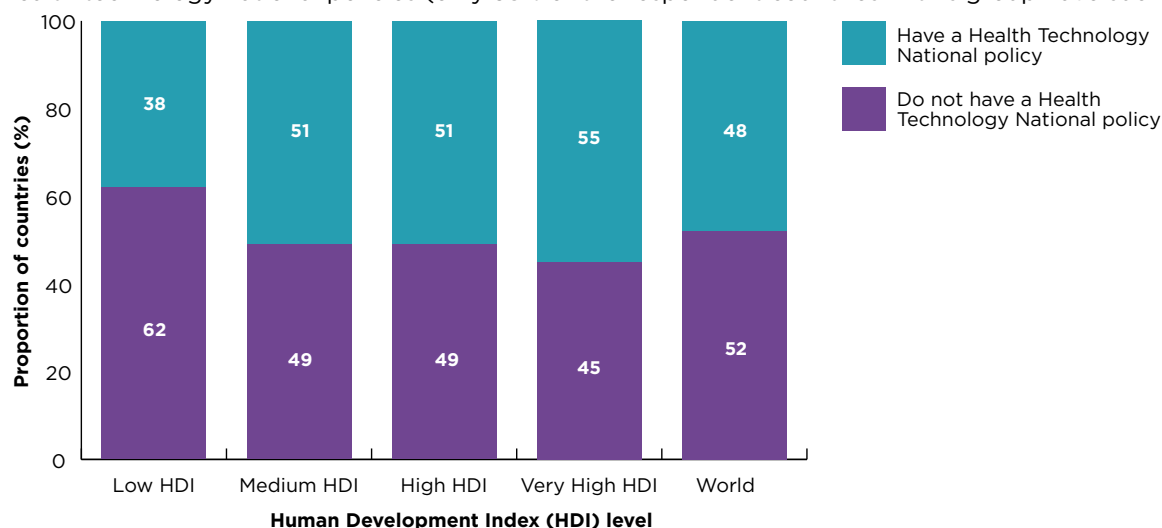


Fig. 3.1-8. Presence of a health technology national policy by Human Development Index (HDI) groups

Please find some examples of policies for medical devices in figure 3.1-9.

| Country | Link to policy | Language |
|------------|---|----------|
| Canada | http://www.cadth.ca/media/policy_forum_section/1_health_tech_strategy_1.0_nov-2004_e.pdf | English |
| France | http://social-sante.gouv.fr/ | French |
| Luxembourg | http://www.legilux.public.lu/leg/a/archives/2009/0054/a054.pdf | French |
| Mexico | http://www.cenetec.salud.gob.mx/descargas/PAES/PEDM.pdf | Spanish |

Fig. 3.1-9. Examples of policies for medical devices

3.1.3 Further Readings

The following documents and websites contain further relevant information on the development of national health technology policies:

Documents:

- Development of medical device policies. WHO Medical Device Technical Series.ⁱⁱⁱ
- Alliance for Health Policy and Systems Research. Systems thinking for health systems strengthening.^{iv}

Sites:

- Health Partners International: “How to Manage” series of health care technology guides.^v

Endnotes:

- Development of national health plans and strategies, Provisional Agenda Item 10, High-Level Preparatory (HLP) Meeting for the 63rd Session of WHO/SEA Regional Committee WHO/SEARO, New Delhi, 28 June - 1 July 2010.
- Resolution WHA60.29 on “Health Technologies, 2007. http://www.who.int/healthsystems/WHA60_29.pdf, accessed April 2016.
- Development of medical device policies. WHO Medical Device Technical Series, 2011. http://www.who.int/medical_devices/publications/med-dev-policies/en/
- Alliance for Health Policy and Systems Research. Systems thinking for health systems strengthening. Geneva, World Health Organization, 2009.
- Temple-Bird C et al. ‘How to Manage’ series of health care technology guides. St Alban’s, Ziken International (Health Partners International), 2005 (<http://resources.healthpartners-int.co.uk/resource/how-to-manage-series-for-healthcare-technology>)

¹⁰ The Human Development Index (HDI) is a composite statistic of life expectancy, education, and income indices used to rank countries into four tiers of human development. The breakthrough for the HDI was the creation of a single statistic, which was to serve as a frame of reference for both social and economic development. The HDI sets a minimum and a maximum for each dimension, called goalposts, and then shows where each country stands in relation to these goalposts, expressed as a value between 0 and 1. Very High: quartile .805, High HDI: quartile .715, Medium .535, low below.

3.2 Regulation of medical devices

3.2.1. Introduction

Regulation of medical devices is a means of reducing potential health risks as much as possible and enabling patient access to high quality, safe and effective medical devices while restricting access to those products that are unsafe or ineffective. When appropriately implemented, regulating medical devices contributes to better public health outcomes.

WHO has a mandate, as outlined in the World Health Assembly (WHA) Resolution 60.29 on Health technologies which encourages “Member States to draw up national or regional guidelines for good manufacturing and regulatory practices, to establish surveillance systems and other measures to ensure the quality, safety and efficacy of medical devices and, where appropriate, to participate in international harmonization”⁹.

The 67th WHA in 2014 adopted Resolution 67.20 on regulatory system strengthening for medical products¹⁰. It stresses the importance of the regulations for medical devices as one of the medical products, for better public health outcome and to increase access to safe, effective and quality medical products. The complete text of the resolution is available in the 6 WHO official languages. Please refer to Fig. 3.2-1 for some important notes referring to medical devices in Resolution WHA67.20.

WHA Resolution 67.20:

- URGES Member States: to strengthen national regulatory systems, to engage in global, regional and subregional networks of national regulatory authorities, and to promote international cooperation, as appropriate; and
- REQUESTS the Director-General WHO: to prioritize support for establishing and strengthening regional and subregional networks of regulatory authorities, as appropriate, including strengthening areas of regulation of health products that are the least developed, such as regulation of medical devices, including diagnostics; and to support the building-up of effective national and regional regulatory bodies and networks.

Fig. 3.2-1. Notes referring to medical devices in the WHA 67.20 resolution “Regulatory system strengthening for medical products”

3.2.2 Global facts

In contrast to the other parts of this publication, the analyses presented in this section are based on a desk survey that WHO performed on the current status of regulatory systems for medical devices in 194 WHO Member States during 2015/2016. Information on the status of a legal framework for medical devices was collected from online sources (National Regulatory Authority (NRA) websites, ministry of health websites, etc.) or by directly contacting WHO focal points or other country representatives. Exclusively officially promulgated regulations and/or guidelines by the Member States and/or their agencies were considered. Data was translated, reviewed and categorized into key elements of medical device regulation.

When information on medical devices regulations was available, it was categorized as “YES”. Any response from a country representative indicating that they did not have a legal framework for medical devices was categorized as “NO”. Information not found and any non-responses were indicated as “Non-Available”. The outcome of the desk survey is presented below.

⁹ http://www.who.int/medical_devices/resolution_wha60_29-en.html

¹⁰ http://apps.who.int/gb/ebwha/pdf_files/WHA67/A67_R20-en.pdf



To begin with, the global picture of the current status of medical device regulation is visualized in Fig. 3.2-2.

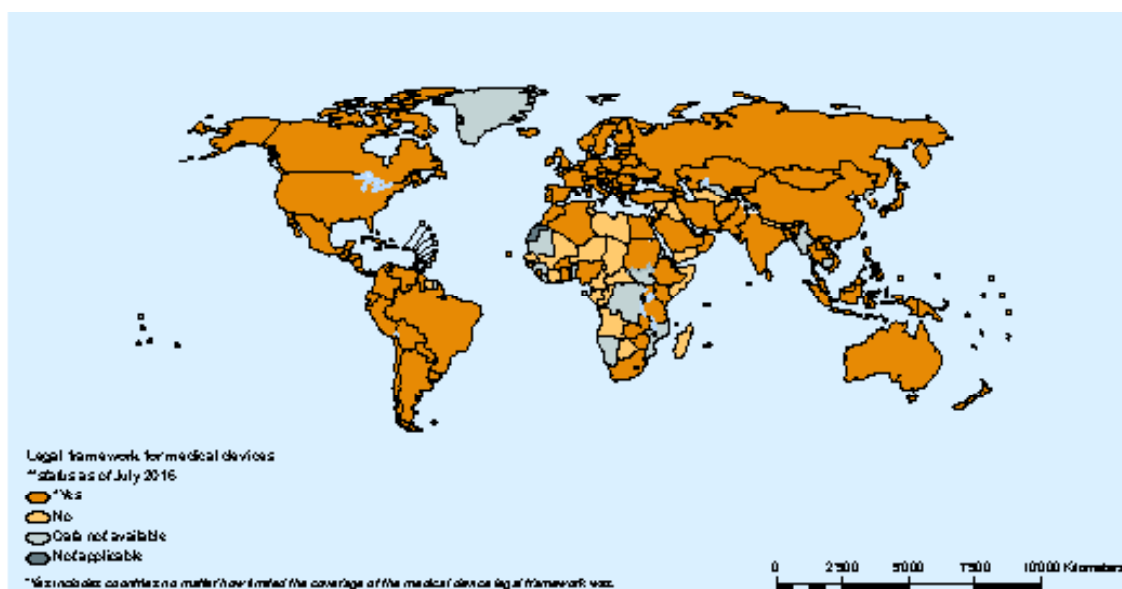


Fig. 3.2-2. Global current status of medical device regulations; existence of a national legal framework for medical devices

In total, 113 out of 194 Member States scored positive on having a legal framework for medical devices, no matter how limited their regulation is. The survey found 53 countries do not have a regulation for medical devices. For 28 Member States no information was available, as shown in Fig. 3.2-3.

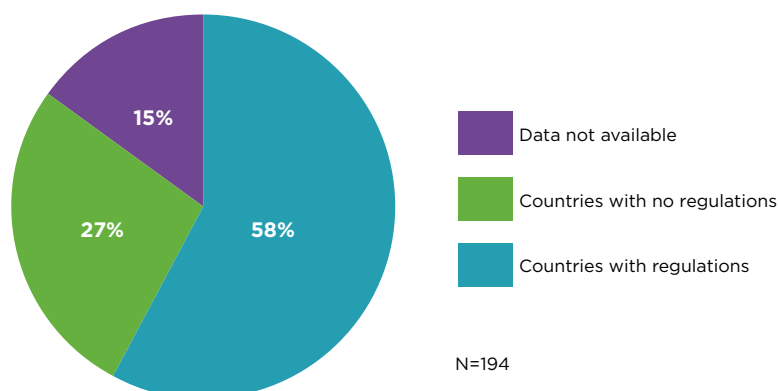


Fig. 3.2-3. Countries with a legal framework for medical devices (no matter how limited)

Based on the available data, the proportion of countries with a legal framework for medical devices is highest in the European region (91%) and lowest in the African region (32%), as shown in Fig. 3.2-4.

Of the low-income countries with data available, 45% have a legal framework for medical devices in place; from the high income countries 84% have such provisions (Fig. 3.2-5).

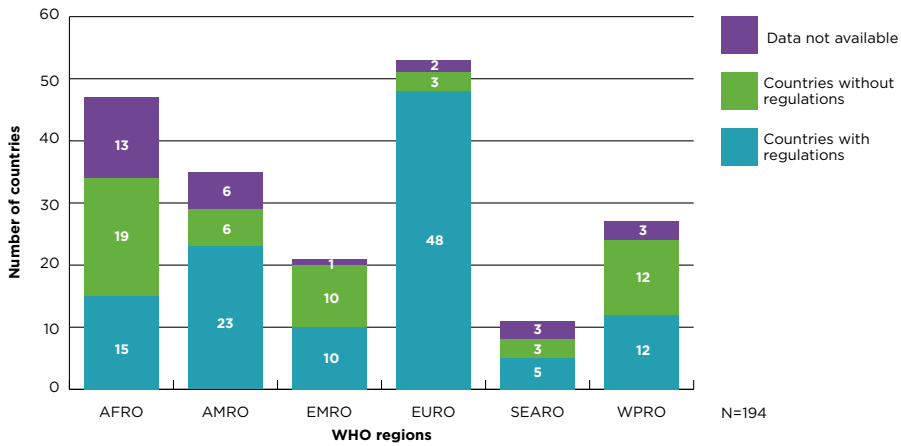


Fig. 3.2-4. Number of countries with a legal framework for medical devices by WHO region

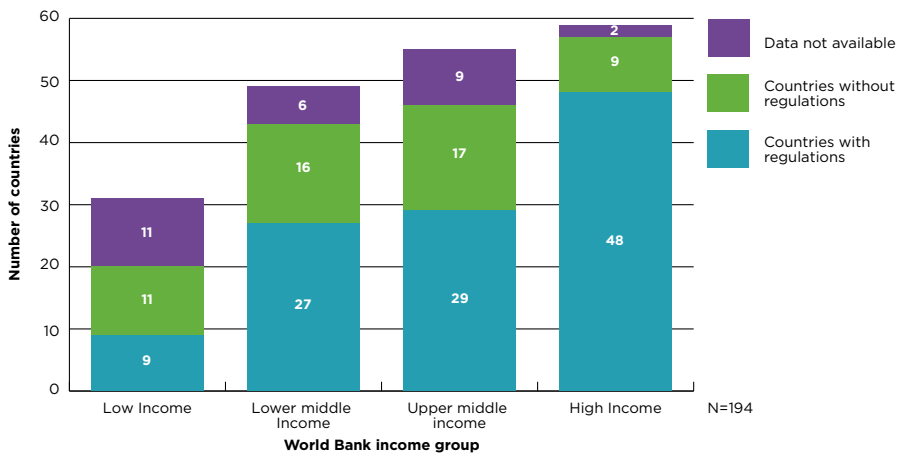


Fig. 3.2-5. Number of countries with a legal framework for medical devices by income group

As of 2015, at least 121 Member States have a national regulatory authority (NRA) responsible for implementing and enforcing product regulations specific to medical devices (Fig. 3.2-6). The ratios of countries with and without NRAs represented by region can be seen in Fig. 3.2-7.

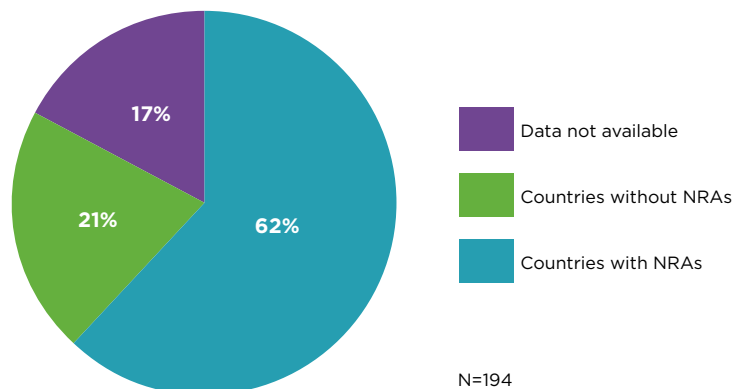


Fig. 3.2-6. Existence of national regulatory authorities responsible for medical devices

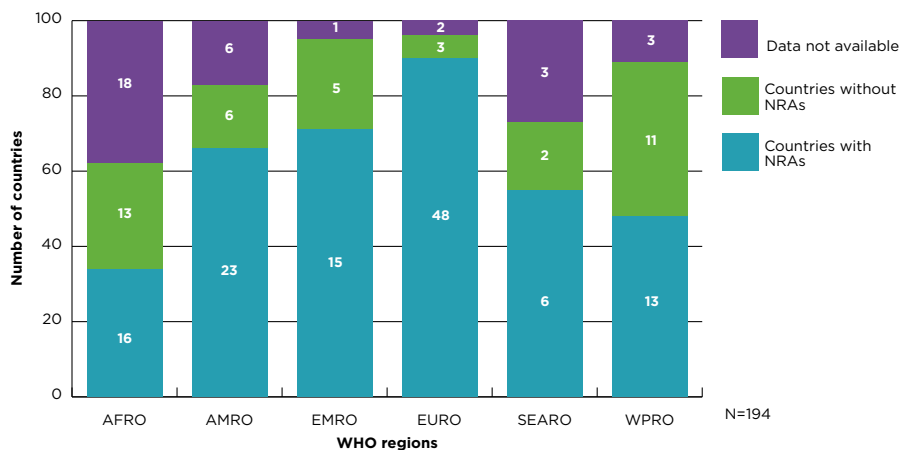


Fig. 3.2-7. Existence of national regulatory authorities responsible for medical devices by WHO region

Regulatory measures should be implemented in all phases of a medical device life span. In this survey, the following key elements of regulation were analyzed:

- a) **“Pre-market” regulation** including:
 - » Definition of a medical device
 - » Risk classification
 - » Essential principles of safety and performance.
- b) **“Placing on the market” regulation** including:
 - » Registration of establishments
 - » Listing of medical devices
 - » Import controls.
- c) **“Post-market” regulation:**
 - » Adverse event reporting.

The results of the survey are presented in Fig. 3.2-8. The percentages pertain to the 113 countries that have a legal framework for medical devices. More detailed descriptions of the basic elements are given below.

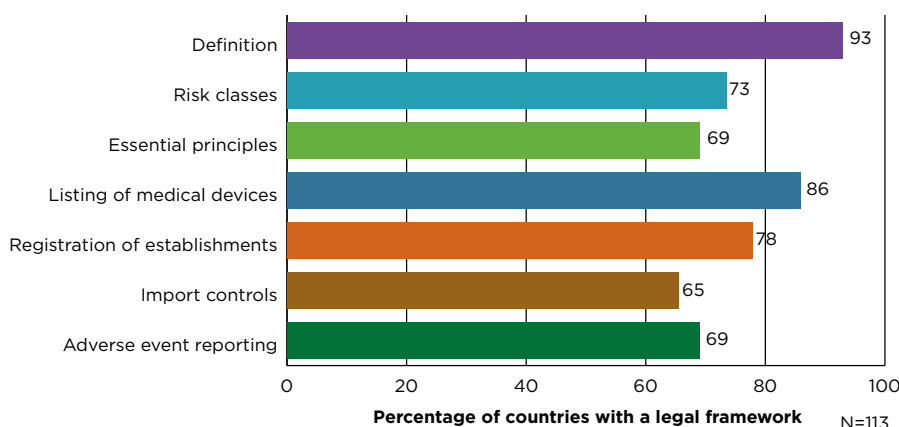


Fig. 3.2-8. Basic elements regulated in countries that have a legal framework for medical devices as found by the desk survey

(a) Pre-market regulation

Basic legal provisions of pre-market regulation would include *definition of a medical device, risk classification of medical devices and the essential principles of safety and performance*. These provide guidance to manufacturers, importers, authorized representatives and health care professionals regarding the scope of the regulated products.

Definition of medical devices:

As found in the desk survey, at least 113 countries have a legal framework for the regulation of medical devices. Of these, 93% have a medical device definition in law or regulation¹¹ (see Fig. 3.2-8). For in vitro diagnostic (IVD) medical devices the numbers are lower: only 48% of countries that regulate medical devices include an IVD definition in their legislation.

The global distribution of medical device definition in law or regulation is shown in Fig. 3.2-9. Fig. 3.2-10 shows the ratio of medical device definitions in law or regulation by World Bank income group.

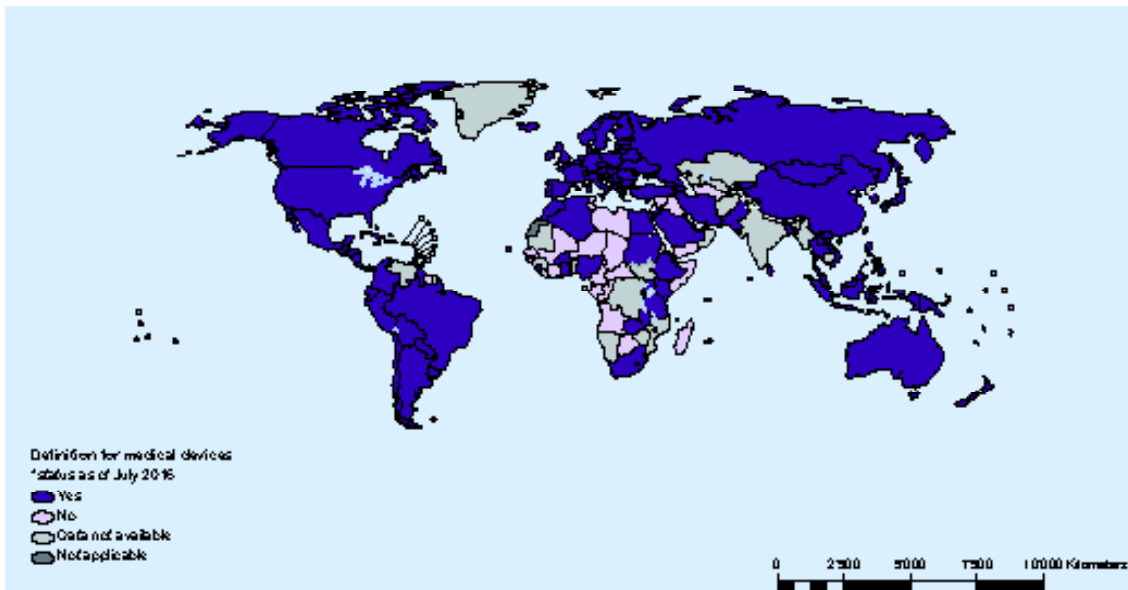


Fig. 3.2.9: Existence of a medical device definition in law or regulation

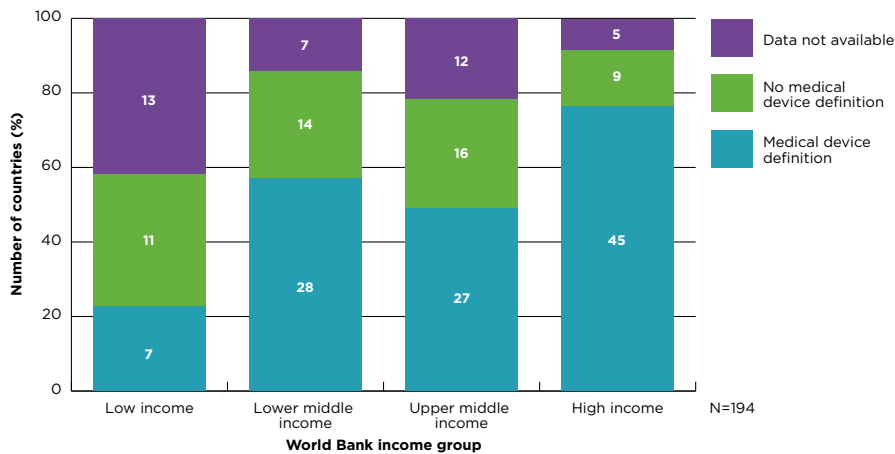


Fig. 3.2.10: Medical device definition in law or regulation in countries by World Bank Income group.

¹¹ One country does have a definition for medical devices, without having a legal framework.



Risk classes:

The universe of medical devices is very diverse with varying potential for harm to the patient or user. It is widely accepted that different types of medical devices are classified in groups or risk classes. Fig. 3.2-11 shows the global picture of risk classes for medical devices in countries' legal frameworks.

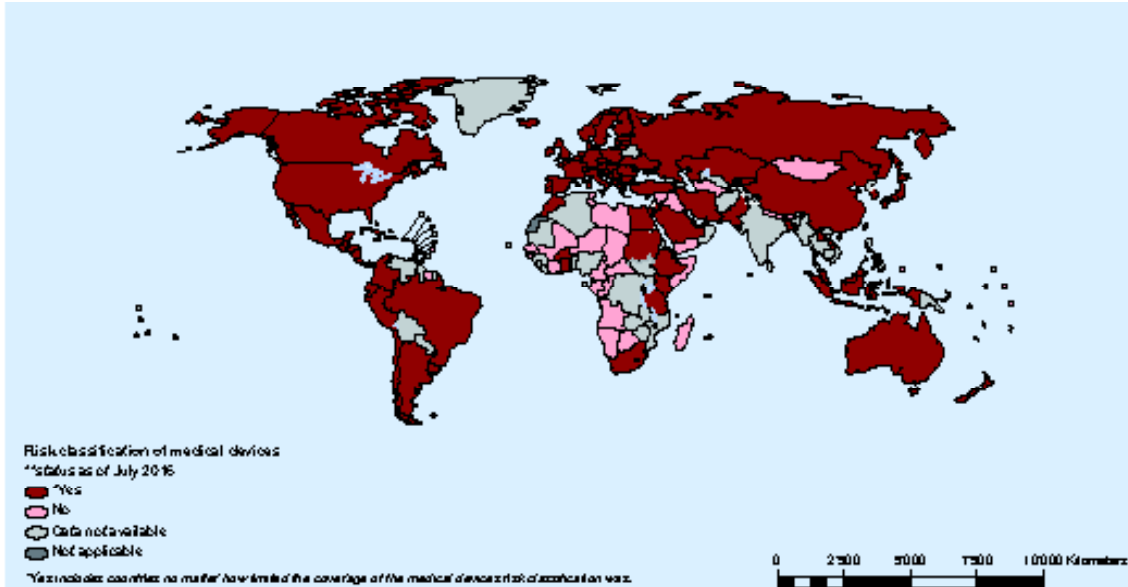


Fig. 3.2-11: Existence of a medical devices risk classes in legal framework

Of the 113 countries that have a regulatory framework for medical devices in place as found by the desk survey, 73% do have a risk classes stated in their legal framework (Fig. 3.2-8). The data was further analyzed by income group (Fig. 3.2-12).

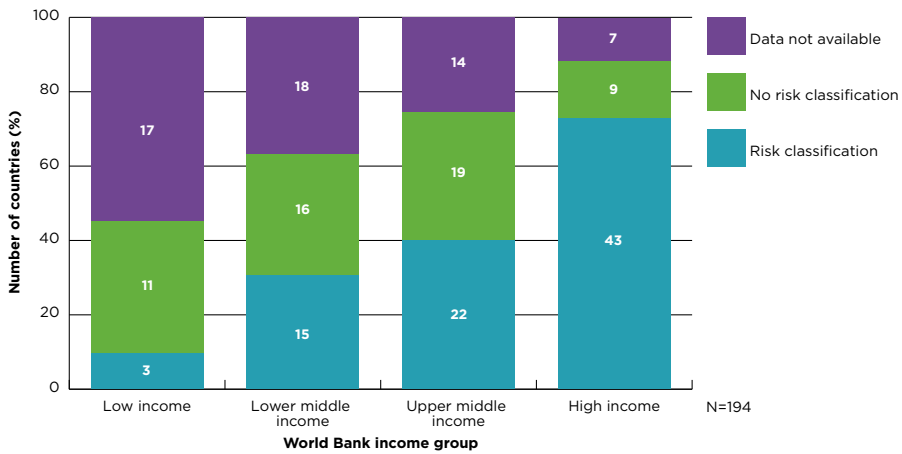


Fig. 3.2-12: Risk classes in legal framework for medical devices by World Bank income group

Essential principles of safety and performance:

Regulations should specify that a medical device be safe and effective when placed on the market. Those requirements, known as essential principles of safety and performance, have been widely adopted.

In total, 68% (78 countries of 113) of countries that were found to regulate medical devices do include essential principles as part of their regulatory requirements (see Fig. 3.2-8 and Fig. 3.2-13). The analysis by World Bank income group is illustrated in Fig. 3.2-14.

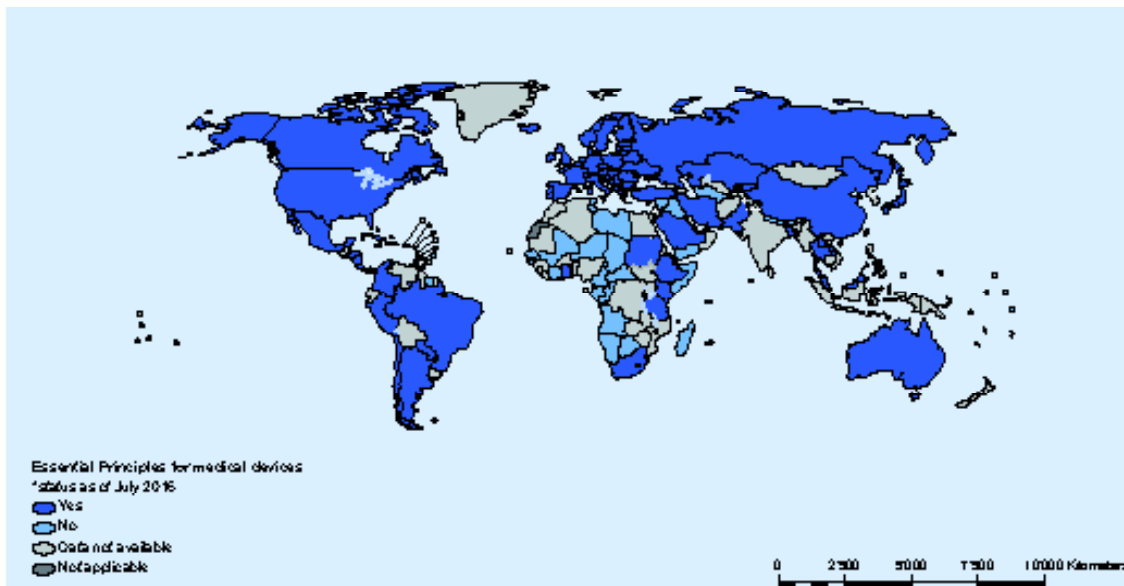


Fig. 3.2-13: Existence of essential principles for medical devices in the legal framework

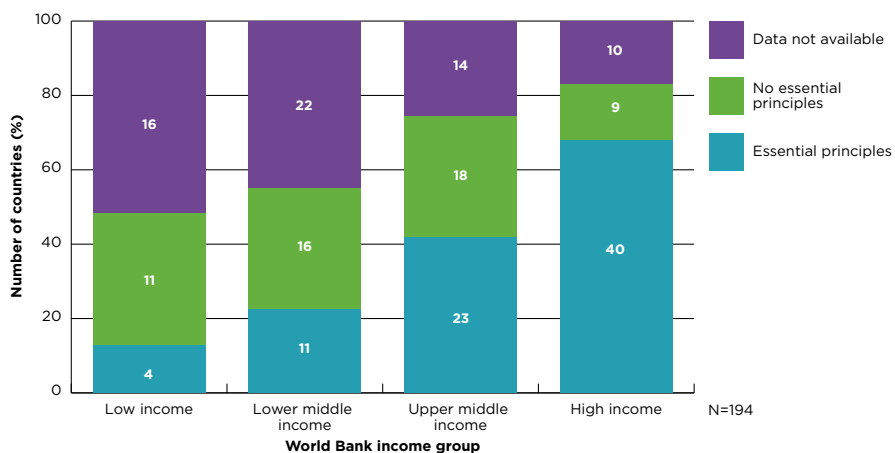


Fig. 3.2-14: Essential principles in countries according to World Bank income group



(b) “Placing on the market” regulation

Basic legal provisions of “placing on the market” regulation would include *registration of establishments*, *listing of medical devices* and *import controls*. These elements provide an overview of what is available on the domestic market and who are the responsible actors.

Registration of establishments:

Registration of establishments includes the registration of manufacturers, authorized representatives, importers and distributors. Such registration allows the regulatory authority of a country to determine who is responsible for a product’s conformity to the regulatory requirements. When listing and registration information is publicly available, it allows medical device purchasers and users of medical devices to identify products available to them and identify the location of their manufacturers and/or distributors and/or importers.

78% of the 113 countries that have regulation of medical devices as found by the desk survey have a provision for registration of establishments (Fig. 3.2-8). The analysis by income group can be seen in Fig. 3.2-15.

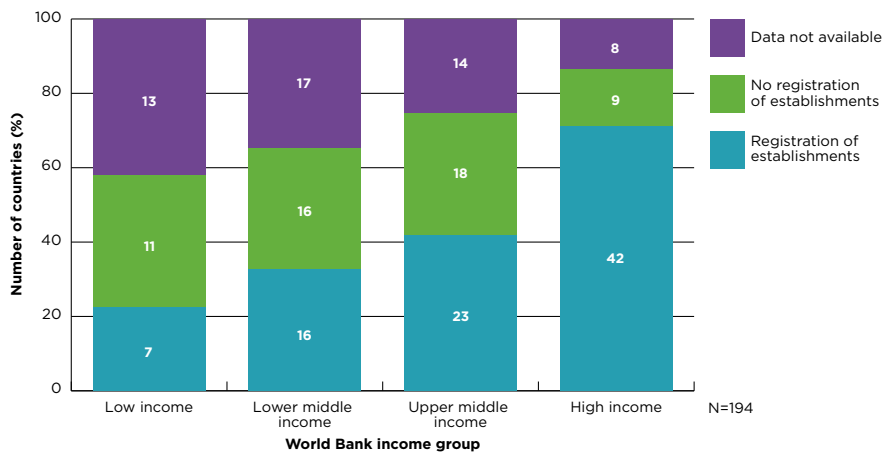


Fig. 3.2-15: Registration of establishments in countries by World Bank income group

Listing of medical devices:

Listing of medical devices allows a country to determine which medical devices are introduced and by whom. In the event of a suspected problem with a medical device, it allows the regulatory authority to contact the parties responsible for that product.

Of the countries that were found to regulate medical devices by the desk survey, 86% do have a provision in their legal framework that allows for listing of medical devices (see Fig. 3.2-8). A breakdown according to World Bank income group is shown in Fig. 3.2-16.

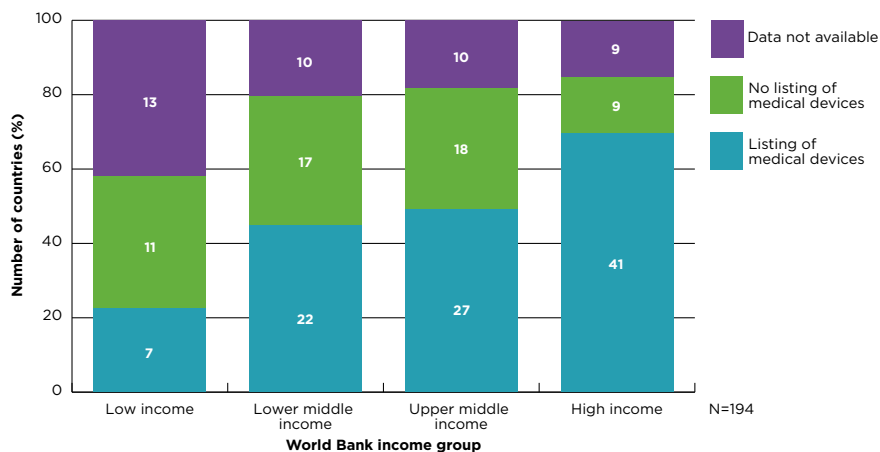


Fig. 3.2-16: Listing of medical devices in countries by World Bank income group

Import controls:

65% the basic controls of registration and listing, import controls may be appropriate.

Two thirds of the countries that regulate medical devices as found by the desk survey have a provision for import controls in their regulatory framework (Fig. 3.2-8). A breakdown according to World Bank income group is shown in Fig. 3.2-17.

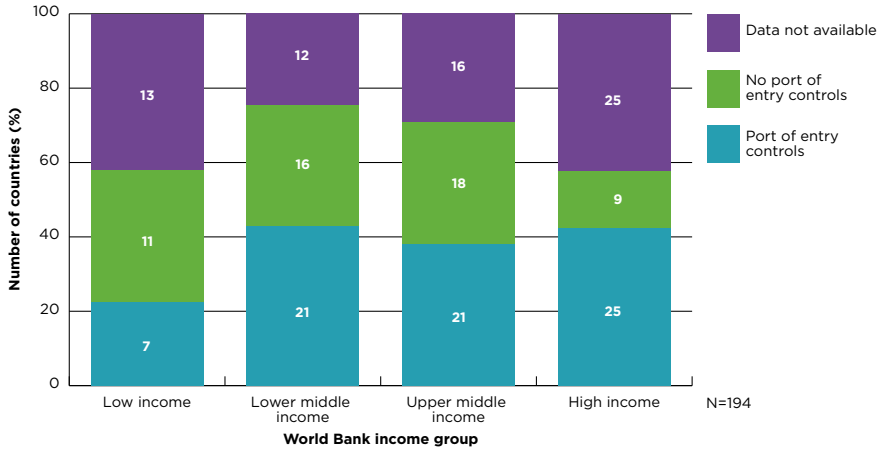


Fig. 3.2-17: Import controls in countries according to World Bank income group

(c) Post-market regulation

In clinical use, medical devices may not always perform as expected. Therefore it is important to analyze the medical devices after they are placed on the market. A system whereby users of medical devices may report problems, complaints or adverse events, especially when it concerns death or serious injury, may prompt the regulatory authority to take action.

Adverse event reporting:

Adverse event reporting allows the regulatory authority to take action when products do not perform as intended or when events happen that may endanger public health. Of the countries that regulate medical devices as found in the desk survey, 69% do have a provision in their legislation that enables adverse event reporting (Fig. 3.2-8). The analysis by income group can be seen in Fig. 3.2-18.

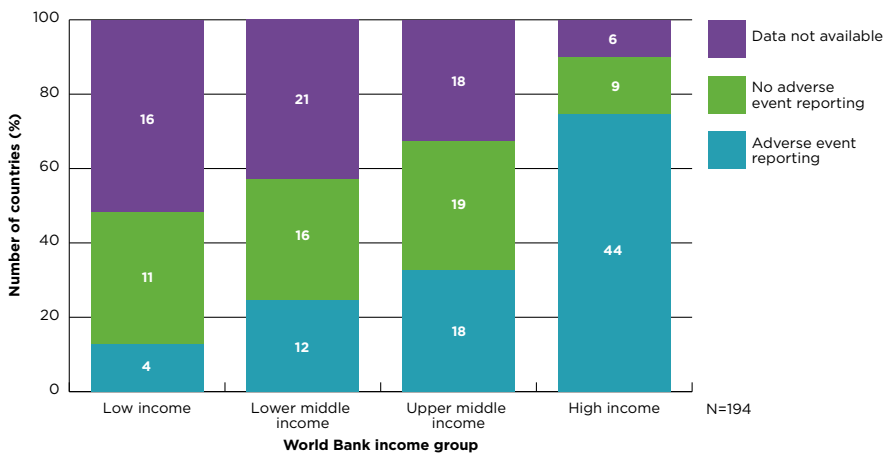


Fig. 3.2-18: Adverse event reporting in countries according to World Bank income group

The overall picture is that legal provisions and regulatory controls for all elements are regulated to a larger extent in high-income countries, whereas low-income countries include fewer basic elements in their legal framework for medical device regulation, as summarized in Table 3.2-1.



| Basic Elements | Low income | Lower middle income | Upper middle income | High income | Total |
|--------------------------------|------------|---------------------|---------------------|-------------|-------|
| Pre-market | | | | | |
| Definition | 7 | 26 | 27 | 45 | 105 |
| Risk classes | 3 | 15 | 22 | 43 | 83 |
| Essential principles | 4 | 11 | 23 | 40 | 78 |
| On the Market | | | | | |
| Listing of Medical Devices | 7 | 22 | 27 | 41 | 97 |
| Registration of Establishments | 7 | 16 | 23 | 42 | 88 |
| Import Controls | 7 | 21 | 21 | 25 | 74 |
| Post-market | | | | | |
| Adverse Event Reporting | 4 | 12 | 18 | 44 | 78 |

Table 3.2-1: Number of countries with established basic regulatory elements based on the 113 countries that have a legal framework for medical devices, analyzed by World Bank income group

3.2.3 Further Readings

For more information about the regulation of medical devices, please refer to the following:

Documents:

- WHO Global Model Regulatory Framework for medical devices including IVDs, World Health Organization, Geneva (Under public consultation). http://www.who.int/medicines/areas/quality_safety/quality_assurance/ModelregulatoryFramework-MedDev-QAS16-664.pdf
- Regulation of medical devices. A step-by-step guide. WHO Regional Publications, Eastern Mediterranean Series 38, 2016 http://applications.emro.who.int/dsaf/emropub_2016_EN_18962.pdf?ua=1
- Medical Device Regulations: Global overview and guiding principles, World Health Organization, Geneva, 2003. <http://apps.who.int/iris/bitstream/10665/42744/1/9241546182.pdf>
- The GHTF Regulatory Model, GHTF/AHWG-GRM/N1R13:2011. <http://www.imdrf.org/ghtf/ghtf-archived-docs.asp>
- Asian Harmonization Working Party, Playbook for implementation of medical device regulatory frameworks, 2014. http://www.ahwp.info/sites/default/files/ahwp-files/4_Technical_Committee/AHWP%20Playbook%20for%20Implementation%20of%20MD%20Reg%20Framework.pdf
- The Sixty-seventh World Health Assembly, WHA67.20, Regulatory System Strengthening for Medical Products, 2014. http://apps.who.int/gb/ebwha/pdf_files/WHA67/A67_R20-en.pdf?ua=1

Websites:

- International Medical Devices Regulatory Forum (IMDRF) <http://www.imdrf.org/>
- Asian Harmonization Working Party (AHWP) <http://www.ahwp.info/>
- WHO medical devices: www.who.int/medical_devices/
- WHO quality and safety regulations: http://www.who.int/medical_devices/safety/en/

3.3 Assessment: National health technology assessment unit

3.3.1 Introduction

Health systems throughout the world are struggling with the challenge of how to manage health care delivery in resource-constrained conditions to achieve Universal Health Coverage. Healthcare policy, practice and decisions are needed to maximize the positive impact of health care interventions on population health, while optimizing the value from the cost of providing the interventions (see Fig. 3.3-1).

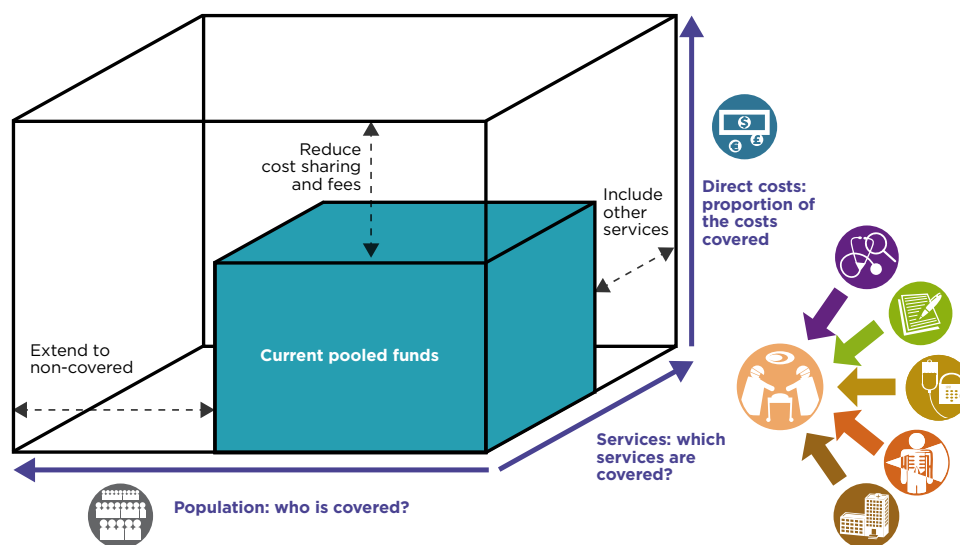


Fig. 3.3-1. Three dimensions to consider when moving towards Universal Health Coverage. (Modified from Health systems financing: the path to universal coverage. Executive Summary, World Health Report, WHO/IER//WHR/10.1, 2010)

In this context, alongside health technology regulation and health technology management, health technology assessment (HTA) is a key component in supporting evidence based decision-making by promoting technologies that increase the quality of the health system and by preventing the uptake of technologies that are of doubtful value at the same time. Health systems are strengthened when HTA is integrated into human and material resources, data, transparent decision- and policy-making, and linked to the overall vision of equity and accountability. Good governance can rely on HTA to provide a policy approach that is accountable to the population for its decisions.

In other words, alongside health technology regulation and health technology management, HTA is needed to ensure the appropriate, effective, and safe introduction and use of health technologies. During the 67th World Health Assembly in 2014, resolution WHA67.23 was approved, recognizing the importance of HTA in support of universal health coverage.ⁱ HTA can be defined as the “systematic evaluation of the properties and effects of a health technology, addressing the direct and intended effects of this technology, as well as its indirect and unintended consequences, and aimed mainly at informing decision making regarding health technologies.”ⁱⁱⁱ Here, “health technologies” refers to the application of organized knowledge and skills in the form of medicines, medical devices, vaccines, procedures and systems developed to solve a health problem and improve quality of life.⁴

HTA started out as a response to the technological breakthrough of computer-assisted tomography due to the very high costs per unit, and HTA processes nowadays are used to inform the decision-making process concerning the introduction of new technologies to a health system. In a well-defined scientific process, criteria such as the health technology’s medical efficacy, safety and cost are analysed in relation to social, economic, organizational and ethical aspects. Here, HTA relies on disciplines such as epidemiology, biomedical sciences, behavioural sciences, clinical effectiveness studies, health economics, implementation science, biomedical engineering, and health impact analysis and evaluation. The multidisciplinary and interdisciplinary nature of HTA is what gives it its strength commensurate with the call to action that the WHO research for health strategy has articulated.ⁱⁱⁱ In the case of medical devices,



Fig. 3.3-2 explains the domains of regulation, assessment and management, and illustrates the distinction of the regulatory and management aspects of health technologies for drugs and devices, and the position of HTA being independent of both. The complementary function of regulation and HTA is related to a set of questions that must be answered for the coherent introduction of technologies, especially medical devices, into health systems (Fig. 3.3-3).



Fig. 3.3-2. Domains of health technology regulation, assessment, and management for drugs and devices

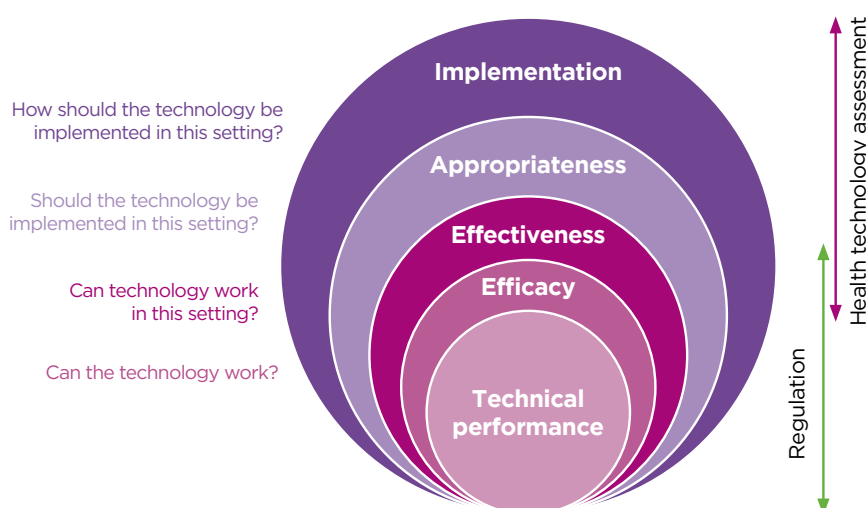


Fig. 3.3-3. From performance to use in health care: layers of questions

In response to the need for formal organization to structure and undertake reviews of the safety, efficacy and effectiveness of health technologies, various HTA agencies have emerged during the past years. The agencies are often established with a mission and provided with financial and human resources to undertake systematic assessment of public policy questions with a defined set of objectives. There are several international agencies supporting the advancement of HTA on the global stage, as shown by the following examples:

- The International Network of Agencies for Health Technology Assessment (INAHTA)^{iv} is a non-profit organization that has grown to 46 member agencies from 26 countries. All members are non-profit organizations producing HTAs, and are linked to regional or national governments.
- The Health Technology Assessment international society (HTAi)^v is a global scientific and professional society “for all those who produce, use, or encounter HTA, including researchers, agencies, policy-makers, industry, academia, health service providers, and patients/consumers”. It acts as a neutral forum for collaboration and the sharing of information and expertise. HTAi has over 1200 members from 59 countries.
- The International Information Network on New and Emerging Health Technologies (EuroScan International Network) “is a collaborative network of agencies for the sharing of information and development of methods for the early identification and assessment of key new and emerging health-related technologies”^{vi}.
- The European network for Health Technology Assessment (EUnetHTA)^{vii} is a European collaboration launched in November 2008 with 25 founding partners from 15 European countries. Its aim is to facilitate efficient use of resources available for HTA, create sustainable systems of HTA knowledge sharing, and promote good practices in HTA methods and processes.

HTA agencies are, however, not limited to government institutions; there are also HTA agencies that produce assessments in the academic sector. HTA can be used and introduced in countries based on their capability, capacity and need. Any country can access HTA knowledge through the international HTA database,^{viii} but networking is essential for finding ongoing HTA research. Furthermore, the development of the capacity to use HTA information often poses a challenge. Also, many HTA agencies and scientists from high-income countries seek to help HTA in developing countries by supporting local HTA activities and helping to build up local expertise.

3.3.2 Global facts

The Baseline Country Survey on Medical Devices collected information on the existence of a unit at national/federal level that is responsible for health technology assessment for medical devices. Results are visualized in Fig. 3.3-4. However, as the degree of HTA done in the corresponding countries is very variable – ranging from committees or units not formally called HTA, to specialized HTA agencies – the numbers only give an approximate idea of global HTA implementation.

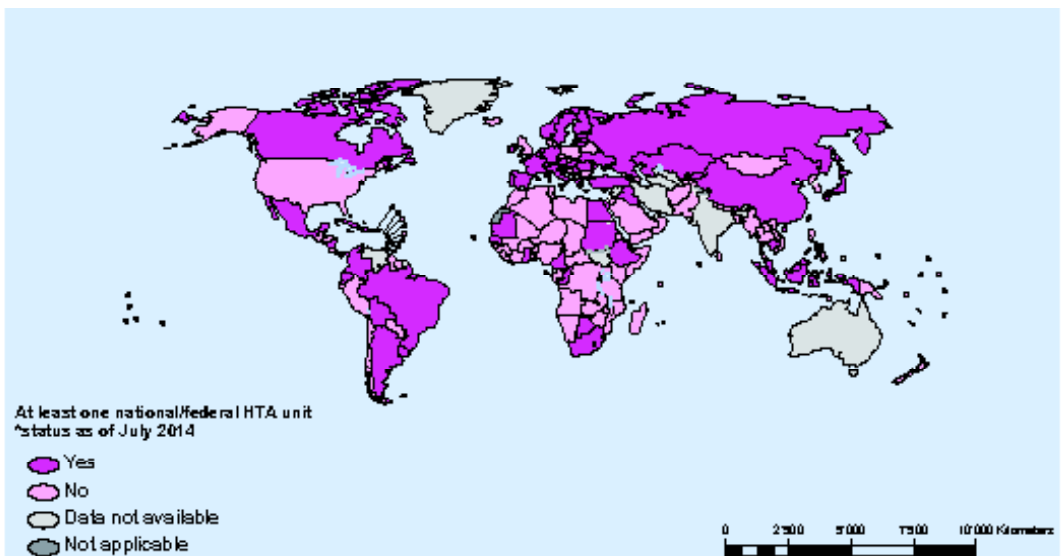


Fig. 3.3-4. Unit at national/federal level responsible for Health Technology Assessment (HTA)⁹

From the 177 country survey respondents, 174 provided information on HTA. In total, 68 Member States (39% of 174) have at least one HTA unit/committee/agency within the ministry of health and 106 Member States (61% of 174) do not have any formalized HTA units (Fig. 3.3-5).

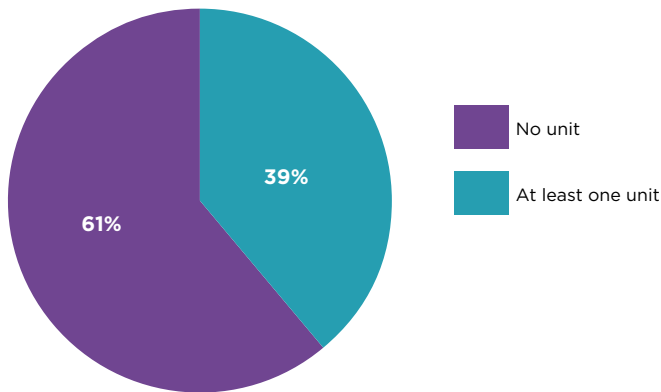


Fig. 3.3-5. Existence of an HTA unit within the country's MoH⁹

⁹ As the degree of HTA done in the corresponding countries is very variable – ranging from occasional HTA to HTA performed in specialized HTA units – the numbers only give an approximate idea of global HTA implementation.



Presenting the data with respect to WHO regions, all regions except the European region have less than 40% of countries with at least one HTA unit (from responding countries in each region). The EUR region has 69% of countries with at least one HTA unit. Furthermore, in Eastern Mediterranean, African and South-East Asia regions, three out of four countries do not have at least one HTA unit (see figure 3.3-6).⁹

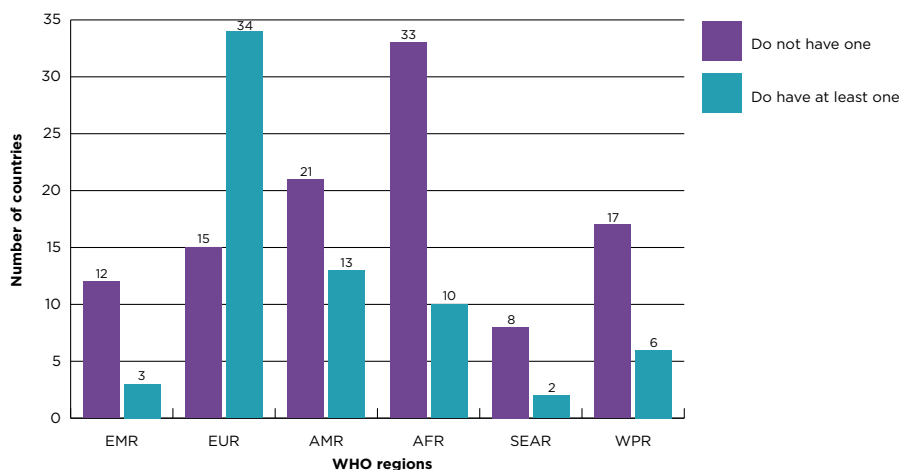


Fig. 3.3-6. Presence of an HTA unit within the country's MoH by WHO region⁹

As a response to the WHA67.23 resolution approved in May 2014 on Health Technology Assessment for Universal Health Coverageⁱ, in 2015, WHO did a global survey on health technology assessment as conducted by government or national institutions. Consistent with the WHA67.23 resolution, the survey included five sections that aimed to measure the utilization of HTA in public sector decision making, the scope of HTA and availability of guidelines, the institutional capacity and human resources supporting HTA, the governance of HTA processes, and the requirements for strengthening HTA capacity. The resulting report “2015 Global Atlas of Health Technology Assessment by National Authorities”^{ix} is available here:

http://www.who.int/health-technology-assessment/MD_HTA_oct2015_final_web2.pdf?ua=1.

The participation rate varied by region and country income, with higher response rates from EUR (79.2%), SEAR (72.7%), EMR (61.9%) and WPR (59.3%), than AMR (37.1%) and AFR (36.2%), with 111 respondent countries overall. Some of the most important findings are summarized in the following figures. Fig. 3.3-7 shows the distribution of the assessed types of technologies. Fig. 3.3-8 shows the considered frequency of ten pre-specified aspects of HTA regarding medical devices as estimated by the respondent countries.

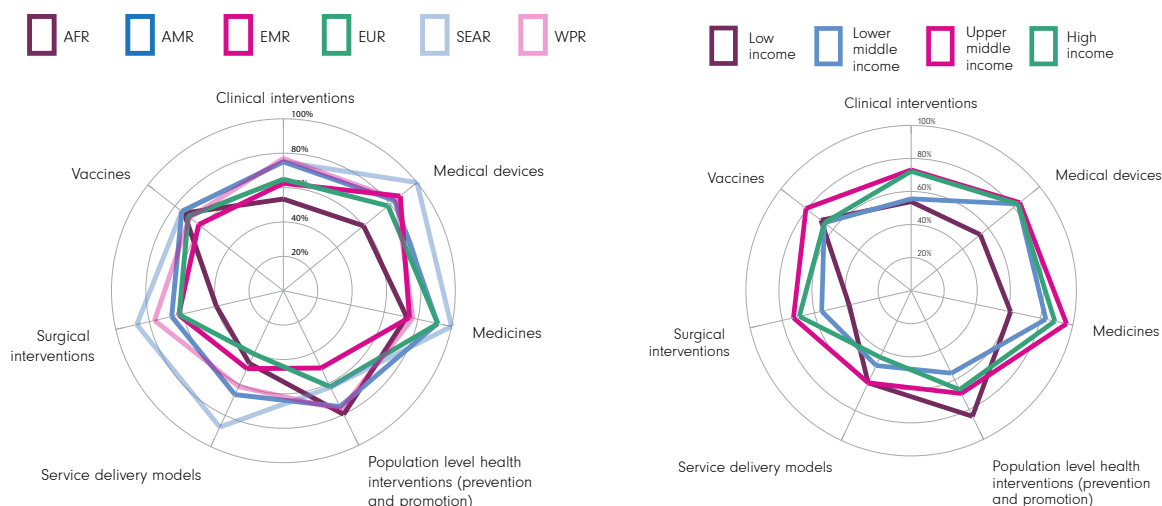


Fig. 3.3-7. Type of technologies or interventions assessed, proportion of countries by (a) region and (b) country income (graphic from “2015 Global Survey on HTA by National Authorities”^{ix}, page 9)

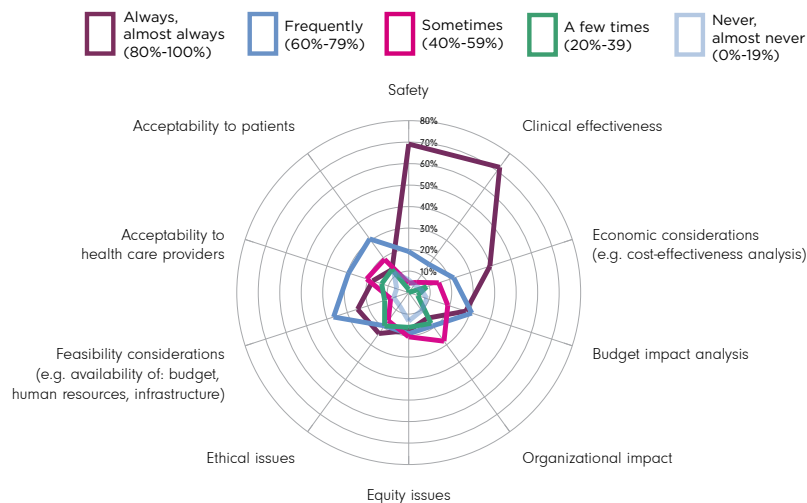


Fig. 3.3-8. Frequency of covering different aspects in HTA regarding medical devices (62 respondent countries), (graphic from “2015 Global Survey on HTA by National Authorities”^{ix} page 12)

As found in the survey, the preparation of HTA reports usually involves public health professionals as well as experts in clinical sciences. Fig. 3.3-9 shows the proportion of different professionals for HTA involved in the preparation of HTA reports for medical devices. Fig. 3.3-10 shows the proportion of different professionals for HTA involved in the decision-making process regarding medical devices.

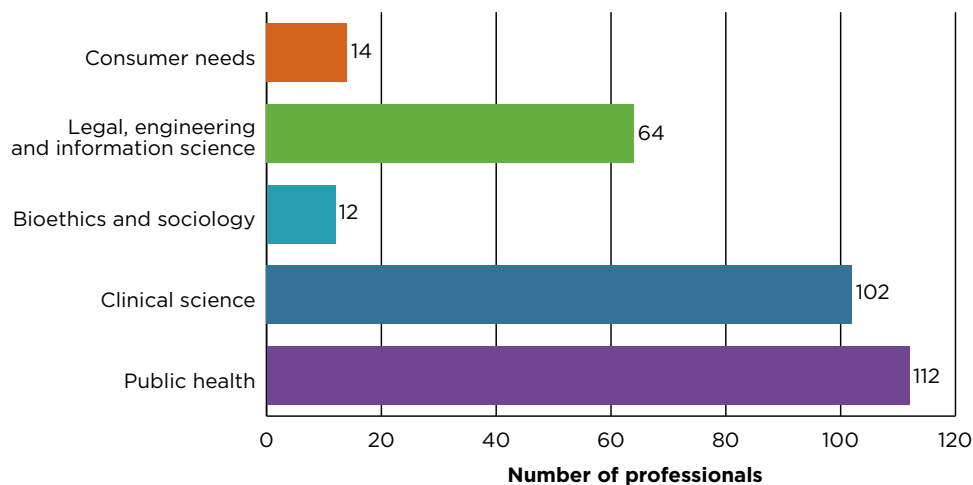


Fig. 3.3-9. Number of professionals from different backgrounds involved in preparation of HTA reports for medical devices (from “2015 Global Survey on HTA by National Authorities”^{ix}, page 19)

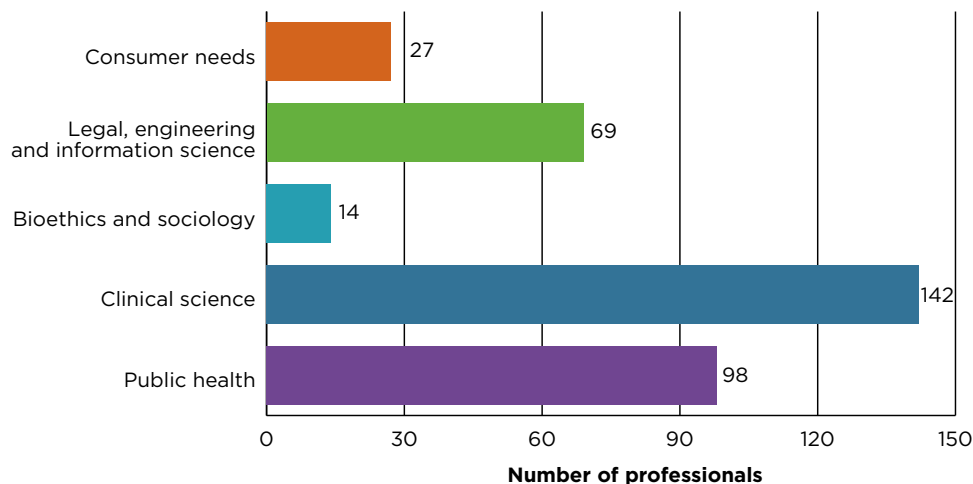


Fig. 3.3-10. Number of professionals from different backgrounds involved decision-making processes regarding medical devices (from “2015 Global Survey on HTA by National Authorities”^{ix}, page 19)



The health technology assessment of medical devices is an area under development. In high-income countries or where health systems are well developed, the HTA process is mainly to define which new sophisticated or costly technology to add to the packages of interventions or for public procurement. In low- and middle-income countries though, HTA is an important tool to consider which technologies should be included in the package of benefits of public insurance schemes, or to do prioritization when resources are limited (see Fig. 3.3-11).

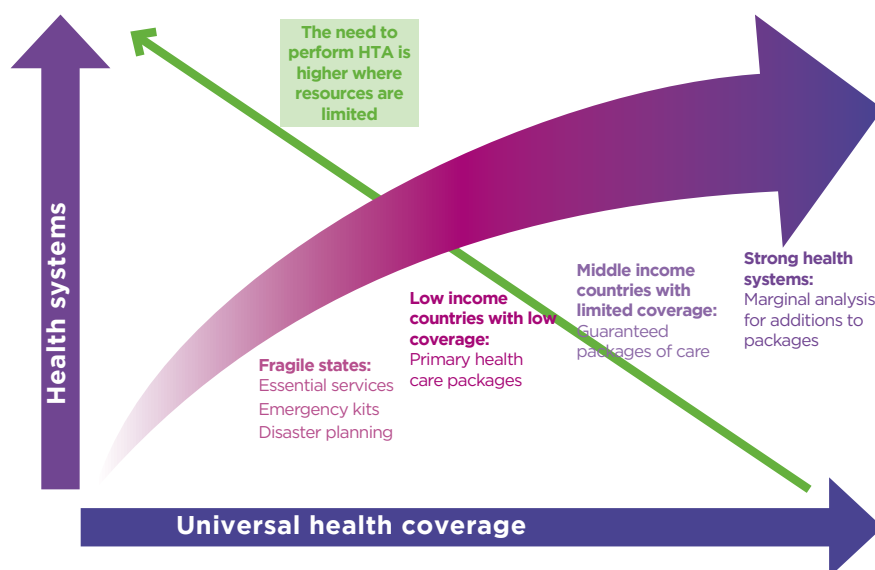


Fig. 3.3-11. The levels of application of an HTA process in the different Member States

3.3.3 Further readings

The following documents and websites contain further relevant information:

Documents:

- Health technology assessment of medical devices. WHO Medical Device Technical Series.^x
- Resources for health technology assessment. Health Technology Assessment international and the International Network of Agencies for Health Technology Assessment, 2005.^{xi}
- Health Technology Assessment resolution WHA67.23 on health intervention and technology assessment in support of Universal Health Coverage.ⁱ

Websites:

- <http://www.who.int/health-technology-assessment/en/>
- http://www.who.int/medical_devices/assessment/en/
- The International Network of Agencies for Health Technology Assessment (INAHTA).^{iv}
- Health Technology Assessment international (HTAi).^v
- Health technology assessment (HTA) database.^{vii}

Endnotes

- World Health Assembly resolution WHA67.23, May 2014: Health intervention and technology assessment in support of universal health coverage. (http://apps.who.int/gb/ebwha/pdf_files/WHA67/A67_R23-en.pdf, accessed April 2015.)
- HTA glossary. International Network of Agencies for Health Technology Assessment and Health Technology Assessment international (<http://www.htaglossary.net/>, accessed March 2015).
- WHO's role and responsibilities in health research: Draft WHO strategy on research for health. Report by the Secretariat to the Sixty-third World Health Assembly, Geneva, World Health Organization, 2010.
- The International Network of Agencies for Health Technology Assessment (INAHTA), <http://www.inahta.org>.
- Health Technology Assessment international (HTAi), <http://www.htai.org>.
- EuroScan International Network, <http://www.euroscan.org>
- European network for Health Technology Assessment (EUnetHTA), <http://www.eunetha.eu>.
- Health technology assessment (HTA) database [online database] National Institute for Health Research, Centres for Review and Dissemination (<http://www.crd.york.ac.uk/crdweb>, accessed April 2015).
- Global Survey on Health Technology Assessment by National Authorities – Main findings. World Health Organization 2015.
- Health technology assessment of medical devices. WHO Medical Device technical Series, 2011.
- Resources for health technology assessment. Health Technology Assessment international and the International Network of Agencies for Health Technology Assessment, 2005. (http://www.inahta.org/wp-content/themes/inahta/img/AboutHTA_Resources_for_HTA.pdf, accessed April 2015.)

3.4 Health technology management

3.4.1 Overview

Recognizing the important role of health technologies, the 60th World Health Assembly adopted resolution WHA60.29 in May 2007.ⁱ The resolution covers issues arising from the inappropriate deployment and use of health technologies, and the need to establish priorities in the selection and management of health technologies, specifically medical devices. The management of health technologies serves to make sure that medical assets are available, accessible, affordable, appropriate, and used safely. An operational and appropriate management leads to improved health outcomes through optimal use of the resources.

Health technology management, also called “clinical engineering” as an area of biomedical engineering, comprises the domains of planning, needs assessment, selection, procurement, donations, inventory, installation and maintenance of medical equipment, training for safe use and finally decommissioning. Each of these domains encompasses a wide range of activities, including “providing technical advice, planning and costing work, monitoring contracts, supply chain, decommissioning and disposal, managing workshop facilities, managing staff, record-keeping, managing the inventory, stock control of parts, consumables, managing waste, and implementing safety protocols”ⁱⁱ. An overview is shown in Fig. 3.4-1.

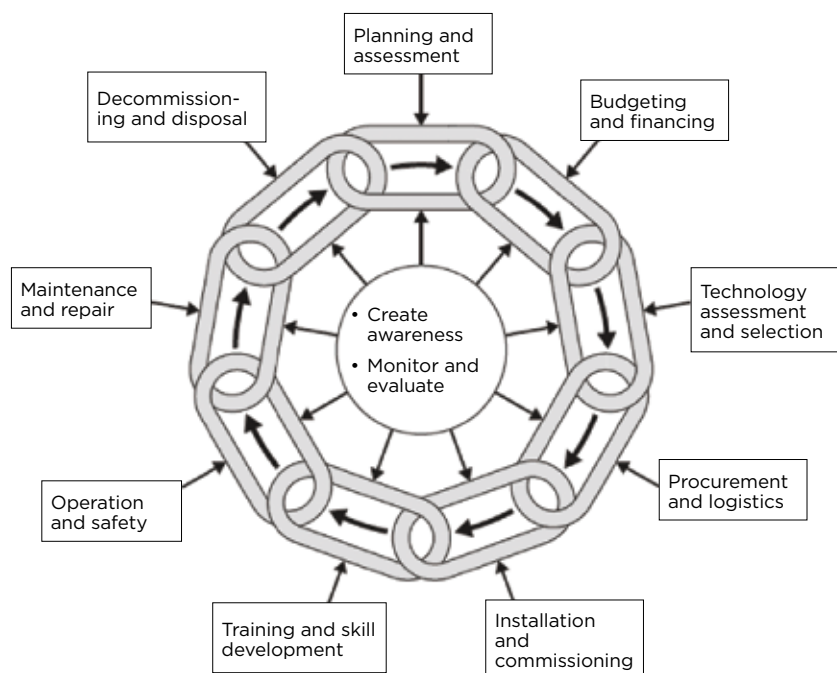


Fig. 3.4-1. Functions in the healthcare technology management cycleⁱⁱ

This chapter deals with the following main areas of health technology management:

- **health technology management units** (section 3.4.2 - 3.4.4);
- **health technology incorporation** (section 3.4.5 - 3.4.13), about integral elements in the acquisition of medical devices and the importance and challenges of:
 - » **procurement** (section 3.4.5 - 3.4.7)
 - » **donations** (section 3.4.8 - 3.4.10)
 - » **technical specifications** (section 3.4.11 - 3.4.13);
- **health technology inventory management** (section 3.4.14 - 3.4.16); and
- **health technology maintenance** (section 3.4.17 - 3.4.19).



3.4.2 Health technology management units – Introduction

Organization and execution of all activities of health technology management (HTM) require skilled staff on both a technical and a managerial level. In a clinical engineering department, the technical personnel usually consist of technicians and clinical or biomedical engineers. Biomedical or clinical engineers are educated in general engineering principles, the physical and biological sciences and their application to medical technology. Technicians, on the other hand, receive technical training with a primary focus on medical equipment maintenance. Alternatively, particularly in countries with fewer specialized training programmes, engineers and technicians may be trained in a related field (such as industrial engineering or electrical technology) and have taken certificate courses, received training or completed an apprenticeship enabling them to work in the area of medical equipment. The engineering management personnel provide leadership. They set department policies, provide budget recommendations, supervise technical staff, arrange for training, set priorities for the department activities and develop and administer the overall programmes. The background of those in this position would include a biomedical or clinical engineering degree or similar, and familiarity with the health care environment and health care technology or a combination of business and technical training.

Health technology management should be carried out on all levels of health care and ideally should be coordinated by a designated health technology management unit within the ministry of health that dictates policies on planning of medical equipment allocation, development of technical specifications for procurement purposes, application/user training or other related elements. It should relate to other government agencies like the regulatory agency or the health technology assessment or similar units in the ministry of health (see Fig. 3.3-2).

Governmental units for health technology management, or clinical engineering, can be located at the national, regional or local (hospital) level. In some countries, the national health technology management team is part of a national centre or governmental institution that issues national standards and guidelines for best practice in all areas of health technology management, as stated in WHA 60.29: “*The World Health Assembly urges Member States “to establish where necessary national institutions for health technologies[...].”*”ⁱⁱⁱ

Decision-makers can consult national centres for health technology for information on a host of issues including: medical equipment per facility, technical specifications, procurement best practices, maintenance procedures, content of user training courses, and steps required for certificate of need authorization. Health technology management teams on all facility and administrative levels need to work together to ensure coordination and supervision across the entire system.

It is also advisable to encourage continuous information exchange with the health technology assessment agency and regulatory authorities as well. Effective and efficient technical management of medical devices remains a concern in most low-income countries and middle-income countries despite the existence of dedicated responsible units at the national level.^{iii, iv}

3.4.3 Health technology management units – Global facts

The WHO Baseline Country Survey on Medical Devices collected information on the presence of national health technology management units globally. In this context, a health technology management unit is a designated unit within the ministry of health at federal/national level that technically manages medical devices through planning of medical equipment allocation, development of technical specifications for procurement purposes, and/or application/user training. Results are visualized in Fig. 3.4-2.

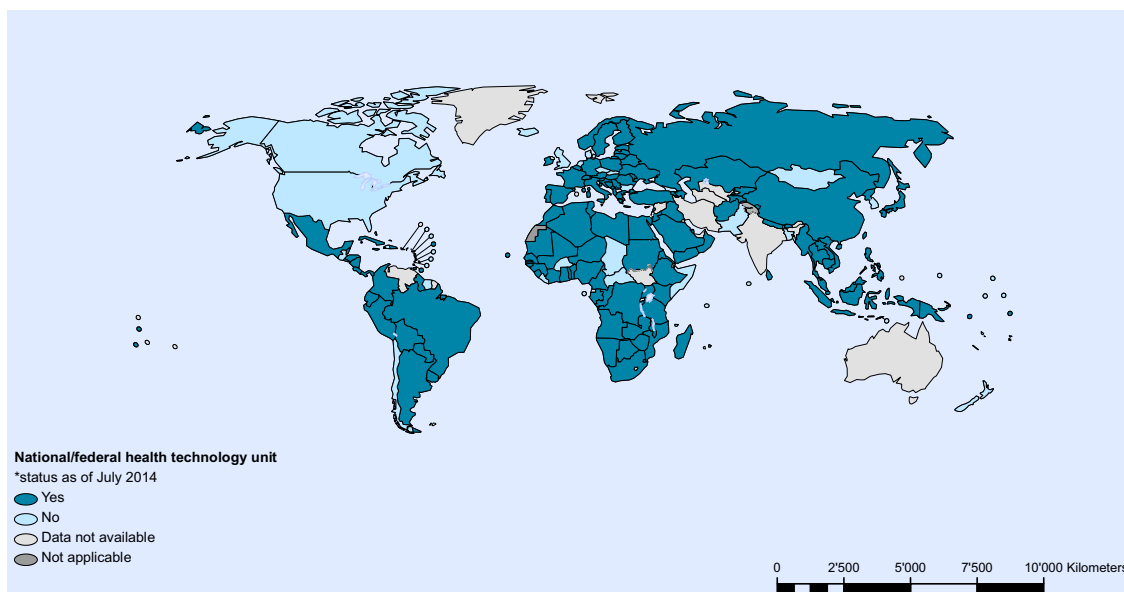


Fig. 3.4-2. Global map showing presence of management units of medical devices at national/federal level

Of the respondent 174 member states, 133 have a designated unit within the country's ministry of health that technically manages medical devices (76% of respondent countries, see Fig. 3.4-3).

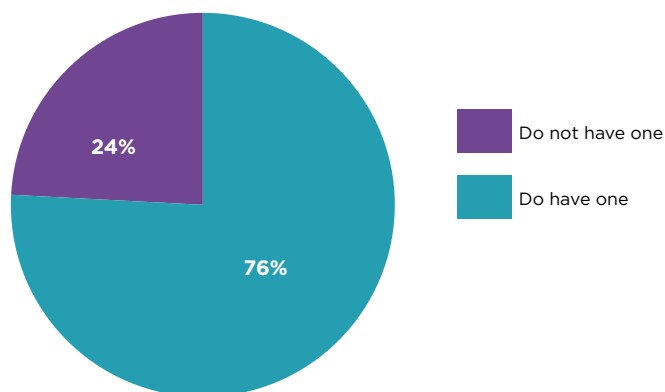


Fig. 3.4-3. Existence of a designated unit within the country's ministry of health that performs health technology management activities

Fig. 3.4-4 shows the proportions of the different HTM units or activities divided by income groups. In low-income countries, the proportion of national HTM units specifically responsible for procurement is higher than in upper-middle-income countries as most procurement is done for public institutions and is therefore centralized. On the other hand, low-income countries do little health technology assessment compared with health technology management in upper-middle-income countries (for the health technology assessment analysis please refer to section 3.3).

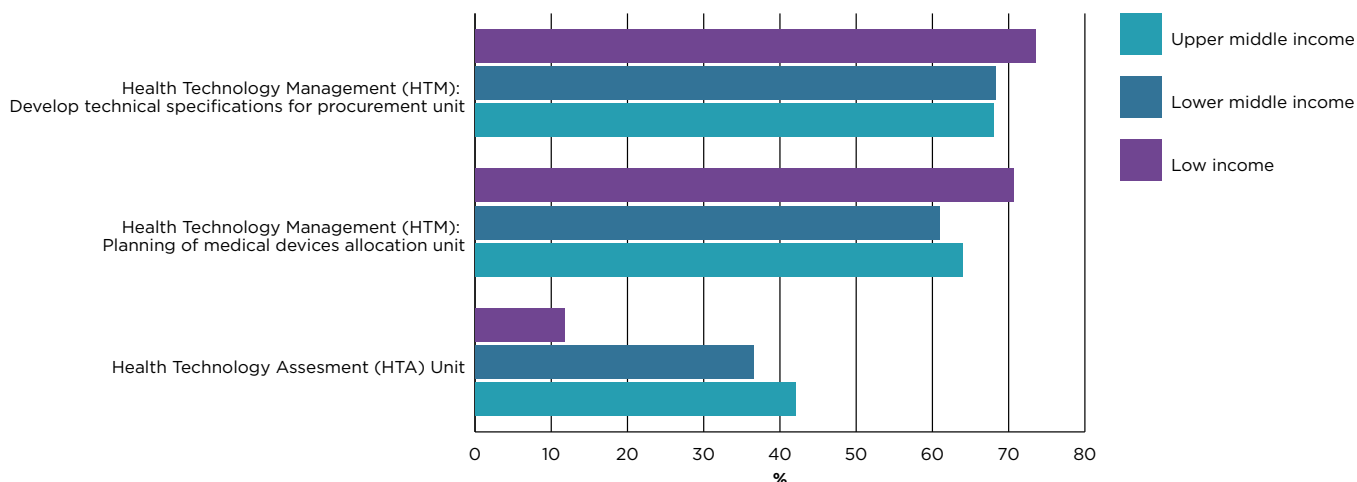


Fig. 3.4-4. Comparison of activities in national health technology management units versus health technology assessment units by income level. High income countries not included because of too few responses.

In Fig. 3.4-5, the HTM activities “planning of MD allocation” and “development of technical specifications” from the corresponding respondent countries that reported at least one health technology unit are analysed by regions. While in the South-East Asia region the presence of all types of units lies below 60%, in the American region it is higher than 59% for all types of units.

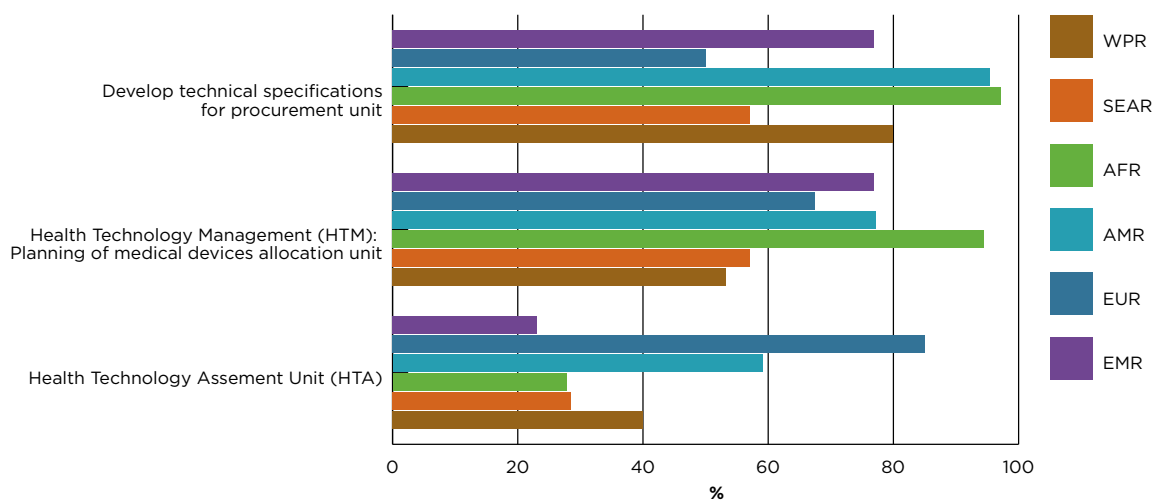


Fig. 3.4-5. Presence of health technology national units within the countries' ministry of health by WHO region. Comparison of HTM (planning of medical device allocation and development of technical specs) vs. HTA units.

3.4.4 Health technology management units – Further reading

For more information about health technology management units, please refer to the following documents and websites:

Documents:

- Development of medical device policies. WHO Medical Device Technical Series.ⁱⁱⁱ
- Medical equipment maintenance programme overview. WHO Medical Device Technical Series.^{iv}
- How to Organize a System of Healthcare Technology Management. ‘How to manage’ Series for Health Care Technology.ⁱⁱ

Websites:

- Health Partners International: How to manage, series of health care technology guides.^v
<http://resources.healthpartners-int.co.uk/resource/how-to-manage-series-for-healthcare-technology/>

3.4.5 Procurement of medical devices – Introduction

Procurement of health technologies is an indispensable element to ensure availability of products in health care service delivery. It can be defined as “the acquisition of property, plant and/or equipment, goods, works or services through purchase, hire, lease, rental or exchange”^{vi} and is taken to include “all actions from planning and forecasting, identification of needs, sourcing and solicitation of offers, evaluation of offers, review and award of contracts, contracting and all phases of contract administration until delivery of the goods, the end of a contract, or the useful life of an asset”^{vi}. In summary, standard procurement procedures comprise technology evaluation, planning and needs assessment, the actual procurement of the technology, installation, commissioning, and monitoring (Fig. 3.4-6).

Poor practices in procurement can lead to substandard provision or performance of health technology. Effective health technology procurement practice, on the other hand, can lead to safe, equitable and quality health care, and all parties involved can obtain the following benefits:

- procurement staff gain by carrying out clear and accountable work done to internationally accepted standards;
- funding agencies can trust that quality goods are being procured at the right price;
- health service professionals obtain safe quality materials and tools that comply with accepted standards; and
- most importantly, at the end of the process, patients can receive appropriate and effective health care treatment, if the medical devices purchased are handled effectively by the health care workers.

Good practices include transparency, good governance, the most economically advantageous terms for the equipment acquired – not necessarily the lowest price obtained through tender, but a good quality product that satisfies the need of the organization and of the final users; achieving timely delivery and handover; defining satisfactory and well-defined terms for delivery, installation, commissioning, training, payment and warranty; obtaining satisfactory after-sales service; and generating greater interest from the suppliers and manufacturers in submitting offers in the future.

National procurement regulations facilitate an efficient procurement process. A summary of currently available resources for achieving good practice in this area can be found in the procurement document “Procurement process resource guide” published in the WHO medical device technical series 2011^{vii}.

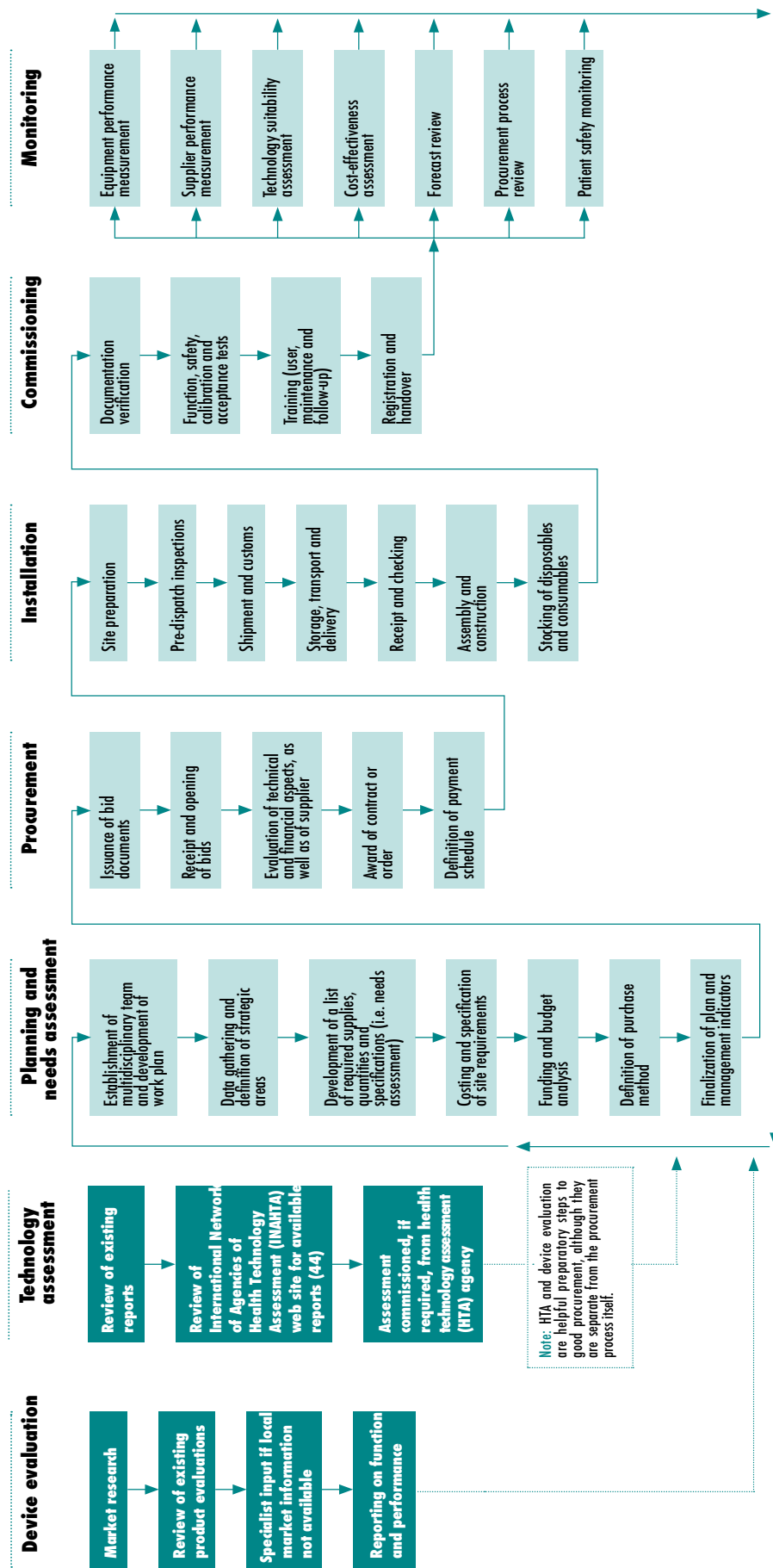


Fig. 3.4-6. Summary flow chart of standard procurement procedures (http://www.who.int/medical_devices/publications/procurement_guide/en/)

3.4.6 Procurement of medical devices – Global facts

The WHO Baseline Country Survey collected information about national recommendations and guidelines for procurement (Fig. 3.4-7).

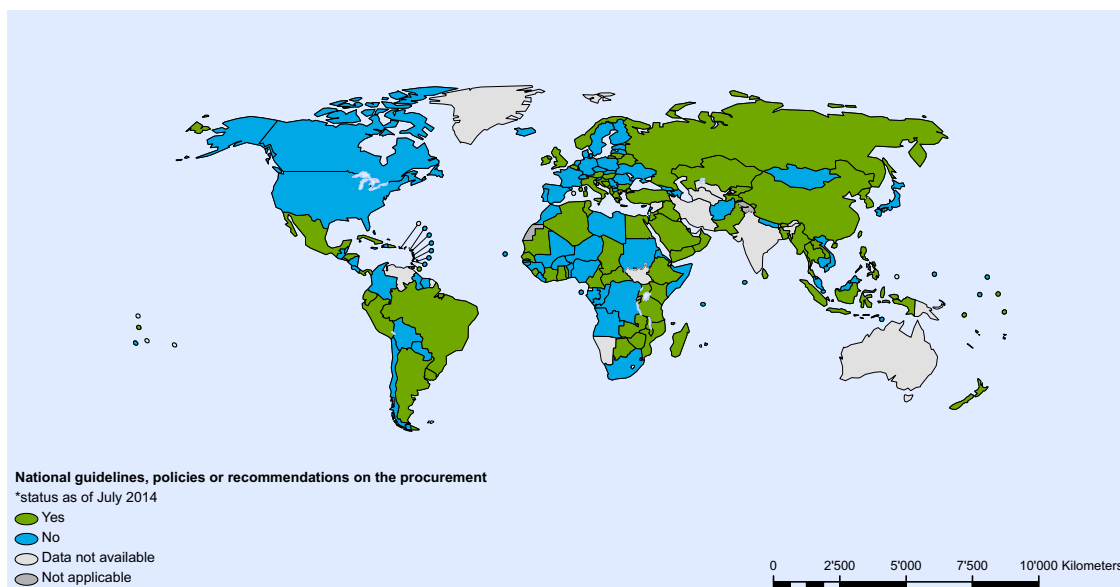


Fig. 3.4-7. National guidelines, policies or recommendations on the procurement of medical devices

The results of the survey on national recommendations and guidelines regarding procurement show that 91 member states do not have specific national guidelines, policies or recommendations on the procurement of medical devices. This comprises 53% of 172 respondent countries (Fig. 3.4-8). The availability of these guidelines depends on the need for nationally centralized procurement, which is mostly the case in lower-middle-income countries. The specific availability of institutional guidelines for procurement was not considered here.

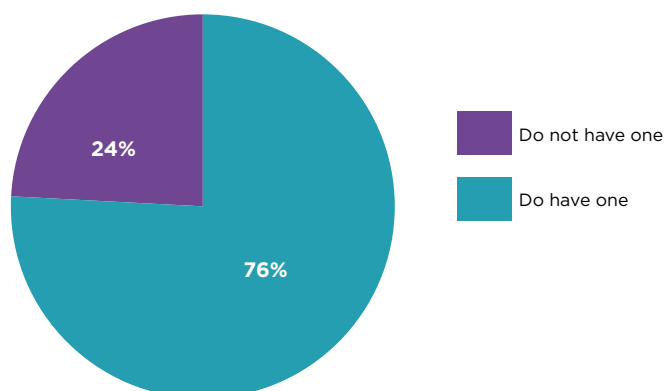


Fig. 3.4-8. Existence of national guidelines, policies, or recommendations on the procurement of medical devices as responded by 172 countries

3.4.7 Procurement of medical devices – Further readings

For more information about the procurement of medical devices, please refer to the following documents:

Documents:

- Procurement process resource guide, WHO medical device technical series^{vii}
- UN procurement practitioner's handbook^{viii}, New York, United Nations (UN) 2006



3.4.8 Donation of medical devices - Introduction

The provision of modern health care is heavily dependent on technology, which includes health care equipment. Because of economic constraints, the health sectors of many developing countries have to rely considerably on donations of equipment. In some countries, nearly 80% of health care equipment is donated or funded by international donors or foreign governments.^x

Although these donations are generally made with good intentions, the outcomes are not always positive if the donations are not properly planned and coordinated. The introduction, utilization and maintenance of health care equipment require considerable financial, organizational and human resources. Unfortunately, this is not always fully recognized. According to one estimate, only 10–30% of donated equipment becomes operational in developing countries.^x Reasons for unused equipment include mismanagement in the technology acquisition process, lack of user training and lack of effective technical support. In many cases, donations circumvent the regulatory authority, the selection and procurement systems of the recipient country and institution, where such systems exist. Consequently, little consideration is taken of actual local requirements, the burden of disease and level of care, the number of user-staff and their capability, and the available level of technical expertise to provide maintenance. Even local manufacturer representatives and equipment distributors, who may be expected to provide after-sales support, are bypassed. Further difficulties related to the purchase of consumables and availability of spare parts, among many others, could transform the donated equipment into a liability, rather than an asset, to the recipient.

Despite the many challenges associated with donations of medical equipment, the mutual benefit of both donors and recipients can be achieved with proper planning and communication between donors and donation solicitors, and the active involvement of donation solicitors in reviewing and approving donation offers. For an example of a good donation process based on a well-defined communication flow see Fig. 3.4-9. In order to establish a well-working donation system in a country that depends on donated technology, a certain set of recognized recommendations and guidelines that are adapted to the circumstances regarding national health care and medical technology needs to be followed.

An overview of the issues and challenges surrounding medical device donations and considerations and best practices that may be useful for making and soliciting donations can be found in the document “Medical device donations: considerations for solicitation and provision”^{xi} published in the WHO medical device technical series.

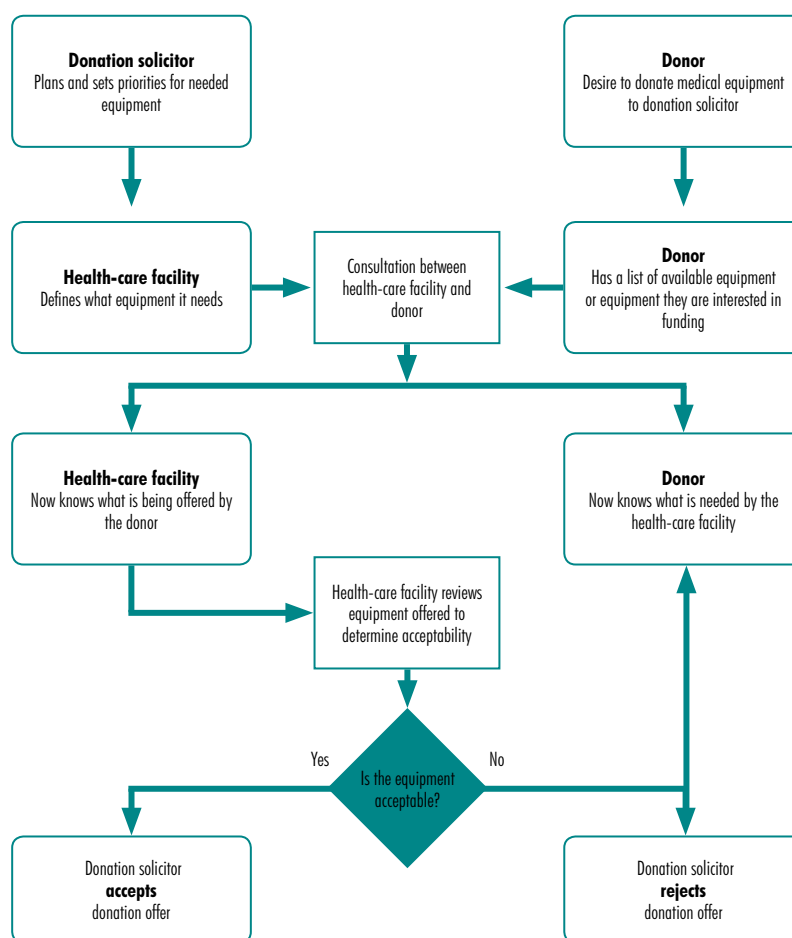


Fig. 3.4-9. Process for soliciting and offering donations of medical equipment (http://www.who.int/medical_devices/publications/med_dev_donations/en/)

3.4.9 Donations of medical devices – Global facts

The WHO Baseline Country Survey collected information about national policies, guidelines, and recommendations on donation of medical devices. Fig. 3.4-10 shows which countries use which type of guidelines (nationally developed, WHO recommended, not specified, or none).

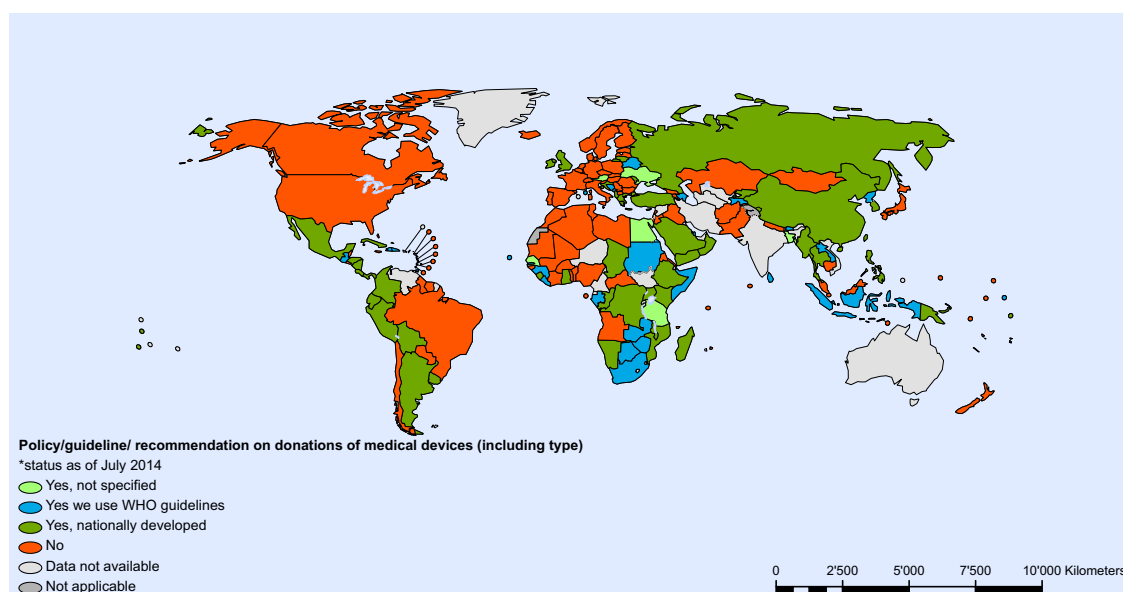


Fig. 3.4-10. Policies, guidelines, or recommendations on donations of medical devices



Of 174 respondent countries, 90 Member States do not have any national policies, guidelines or recommendations on donations for medical devices, which amounts to 52%. Countries using policies, guidelines, or recommendations either employ WHO guidelines (17% of 174) or nationally developed guidelines (28% of 174), or other (3% of 174); see Fig. 3.4-11.

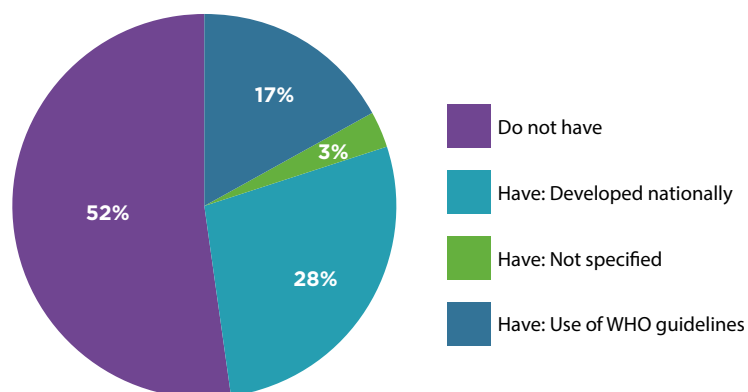


Fig. 3.4-11. Existence of policy, guideline or recommendation on donations for medical devices as responded by 174 countries

3.4.10 Donations of medical devices – Further readings

For more information about donations of medical devices, please refer to the following documents and websites:

Documents:

- Medical device donations: considerations for solicitation and provision, WHO medical device technical series^{xi}
- Donation of medical device technologies: Clinical engineering handbook.^{ix}
- THET Making it work: A toolkit for medical equipment donations to low resource settings^{xii}

Websites:

- HUMATEM (in French)^{xiii} <http://www.humatem.org>

3.4.11 Technical specifications – Introduction

The cost-effective acquisition of medical devices that are safe, good quality and can be used efficiently in the intended environment is a challenging task. As explained in the sections on procurement and donation before, good communication between all parties involved increases the likelihood of acquiring appropriate medical devices. A multitude of factors need to be taken into account in order to purchase or donate the best medical device in a given health care context. To facilitate communication during the acquisition process (e.g. for the bidding procedure or donation negotiations), a clear-cut and complete set of technical specifications is essential. Beside the purpose of use and technical characteristics of the medical device, other aspects that must be considered include: the characteristics of the accessories, consumables, safety, life time maintenance requirements, installation and training efforts, disposal information, sanitary regulations and warranty.

Technical specifications for procurement, donation or lease, define precisely the profile that the medical device needs to comply with and give information about the needed performance and standards by taking into account the infrastructure of the specific health care facility. Thus, a good set of technical specifications allows improved access to medical devices of high quality, safety and efficacy. Technical specifications also contribute to adequate planning for the financial, infrastructure, and human resources that need to be taken into account in the implementation, functioning and decommissioning of the devices. They help a successful acquisition by reducing probability of inadequate purchases as well as misguided favors; therefore, cost-effectiveness is easier to achieve, decrease risks for patients and end- users, maintenance problems including flow of consumables and spare parts become less likely, and the life time of the medical device becomes longer.

Technical specifications therefore aid technical health workers in a hospital such as biomedical engineers, hospital managers, planning officers, procurement officers, and other health related stakeholders such as employees in the ministry of health, regulators, manufacturers, NGOs, and UN agencies. However, the development of high quality technical specifications is a challenging task. The different requirements for good technical specifications depending on the levels of health care are summarized in Fig. 3.4-12.

| User | Required from technical specifications | How to increase usability? |
|-------------------------------|---|--|
| Planner | Guide on options available | Fit well with intervention Simplicity of access Different levels of technology |
| Medical staff | Understandable Guide as to what is appropriate | Simple language Local names Searchable Linked with intervention Different levels of technology |
| Biomedical engineer | Reference for internal TS development | Simple to cross reference with other formats Clear, consistent format |
| Procurement department | Reference use for bids Adaptable for local use | Not too many options to choose Simple contents |
| Maintainer of database | Easy to keep up | Manageable quantity of devices Simple, relational database |
| Industry | Benchmarking of products Marketing | Open access Facility to comment and object |

Fig. 3.4-12. Requirements of technical specifications (TS) for different user profiles

Unfortunately, health literature – for example clinical practice guidelines – does not usually include the specific profile of medical devices required for care. Various countries have developed national technical specifications for public procurement, and some have these data available on public websites, which is good practice regarding transparency, accountability and good governance.

In cooperation with international experts in the field and experts from other UN organizations, WHO has developed a medical device technical specifications template (as seen in Fig. 3.4-13) that can be downloaded by interested parties and serve as a guideline in acquisition processes. The topics to be filled-out on the template are the following:

- Name, category, and coding
- Purpose of use
- Technical characteristics
- Physical/chemical characteristics
- Utility requirements
- Accessories, consumables, spare parts, other components
- Packaging
- Environmental requirements
- Training, installation, and utilization
- Warranty and maintenance
- Documentation
- Decommissioning
- Safety and standards.

Based on this template, technical specifications of 61 medical devices were compiled by WHO in collaboration with a working group of experts. They are publically available on the WHO medical devices website.^{xiv} WHO will continue to collaborate with UN organizations, WHO collaborating centers and ministries of health to update these specifications continuously as these are important to ensure good procurement processes for quality products.



| NAME, CATEGORY AND CODING | | INSTRUCTIONS AND EXAMPLES |
|---------------------------|--|--|
| 1 | WHO Category / Code | |
| 2 | Generic name | Name of the medical device as commonly used (e.g. anaesthesia machine). |
| 3 | Specific type or variation (optional) | Characteristics of the device that distinguish it from other similar devices or devices of the same generic name (e.g. handheld, bench-top, portable, digital, adult/paediatric/neonatal, consumable/disposable, single-use, etc.). |
| 4 | GMDN name | Name as produced and maintained by the Global Medical Devices Nomenclature (GMDN) Agency, e.g. Anaesthesia unit, mobile. (NB: Access to GMDN Agency nomenclature system may be restricted - see http://www.gmdnagency.com/ for further information). |
| 5 | GMDN code | Comments as for [9]; GMDN code for 'Anaesthesia unit, mobile' is 47769 (all GMDN device codes have 5 digits) |
| 6 | GMDN category | Comments as for [9]; GMDN category for 'Anaesthesia unit, mobile' is '02 Anaesthetic and respiratory devices'. |
| 7 | UMDNS name | Name as produced and maintained by the ECRI institute, e.g. Anaesthesia Units (NB: Access to ECRI nomenclature system may be restricted - see https://www.ecri.org/Products/Pages/UMDNS.aspx for further information). |
| 8 | UMDNS code | Comments as for [12]; ECRI code for 'Anaesthesia Units' is 10134 (all ECRI device codes have 5 digits). |
| 9 | UNSPS code | United Nations Standard Products and Services Code [see http://www.unspsc.org/]. This coding system uses a hierarchy of Family-Class-Commodity. For an anaesthesia unit, which comprises a number of functional modules, there are a number of corresponding Commodity codes and titles listed under more than Class; e.g. Commodities 42272501 'Gas anaesthesia apparatus' and 42272502 'Absorber units for gas anaesthesia apparatus' are included under Class 42272500 'Anaesthesia apparatus and accessories and supplies' in the Family 42270000 'Respiratory and anaesthesia and resuscitation products'. |
| 10 | Alternative name/s (optional) | Name/s set by a regional or national authority, local names (e.g. Boyle's machine) or synonyms of formal nomenclature (e.g. anaesthesia apparatus or system). |
| 11 | Alternative code/s (optional) | Corresponding code/s set by a regional or national authority. |
| 12 | Keywords (optional) | Specific area / disease related to the device (e.g. anaesthesia, intra-operative care, etc.). |
| 13 | GMDN/UMDNS definition (optional) | Definitions produced and maintained by the GMDN Agency and ECRI Institute, respectively. |
| PURPOSE OF USE | | |
| 14 | Clinical or other purpose | A description of the essential clinical or other objective/s associated with the device's utilisation, e.g. anaesthesia units (allow the anaesthetist to) dispense a mixture of gases and vapours and vary the proportions thereof to control a patient's level of consciousness and/or analgesia during surgical procedures. |
| 15 | Level of use (if relevant) | The level of healthcare service delivery at which the device is to be used, or is typically used. [NB: Since the level of skill/s required of the device user/s should also be considered, and the levels of service delivery are not globally standardised, this level may vary from country to country.] Home use should also be considered as a level of care. For our example, the anaesthesia unit would typically be used at district, regional and tertiary hospitals. |
| 16 | Clinical department/ ward(if relevant) | The usual service area / functional department in which the device would be used, e.g. Operating room, Intensive Care Unit, Paediatric ward, Outpatient department). Home use should also be considered as a level of care. |
| 17 | Overview of functional requirements | General description of the device's function, e.g. for anaesthesia unit this would include gas/vapour delivery platform; ventilator with patient breathing circuit; scavenging system to capture and exhaust waste gases; physiological and multi-gas monitors, etc. |
| TECHNICAL CHARACTERISTICS | | |
| 18 | Detailed requirements | The required characteristics and specific/critical functional requirements. e.g. modules, components, measured and/or delivered parameters and associated values and ranges, compatibility / inter-operability requirements, etc. |
| 19 | Displayed parameters | User interface information requirements (e.g. display of pressure, volume, flow, status indicators, inspiration and expiration times, etc.) and format (continuous waveform display, digital, trends, etc.). |
| 20 | User adjustable settings | Device functional parameters, alarms, language, etc. that should be adjustable at the discretion of the user/s. |

| PHYSICAL/CHEMICAL CHARACTERISTICS | | |
|---|---|--|
| 21 | Components(if relevant) | Dimensions, configuration of complex equipment, etc. |
| 22 | Mobility, portability(if relevant) | Requirements for non-fixed/installed devices, e.g. weight, handles, on castor wheels of specified diameter, etc. |
| 23 | Raw Materials(if relevant) | Applies mainly to surgical instruments and /or implants. e.g. stainless steel (linked to bio-compatibility/patient safety, corrosion resistance, etc.). |
| UTILITY REQUIREMENTS | | |
| 24 | Electrical, water and/or gas supply (if relevant) | Electrical supply: e.g. nominal mains voltage with frequency and permitted fluctuations, battery operation (if relevant); Water and gas supply: quality and flow rate requirements. |
| ACCESSORIES, CONSUMABLES, SPARE PARTS, OTHER COMPONENTS | | |
| 25 | Accessories (if relevant) | Accessories needed (type, number, functional requirements, etc.) for full and proper functioning of the device. |
| 26 | Sterilization process for accessories (if relevant) | Preferred method to be specified, if appropriate; otherwise to be clearly indicated by manufacturer/supplier. |
| 27 | Consumables / reagents (if relevant) | Consumables (renewables) and disposables (including single-use accessories) to be used with the medical device. Where appropriate, quantity required, shelf life, etc. should be specified. |
| 28 | Spare parts (if relevant) | It would be very useful to know what parts are likely to be needed in the first year of operation (based on average usage and experience elsewhere) and/or in the year after expiry of the warranty period. |
| 29 | Other components (if relevant) | Complementary equipment (e.g. printers, stands, wall mounts, etc.). |
| PACKAGING | | |
| 30 | Sterility status on delivery (if relevant) | To be specified - applies to implantables or single-use devices that are delivered sterile |
| 31 | Shelf life (if relevant) | Shelf life and number of uses of the device to be specified |
| 32 | Transportation and storage (if relevant) | Specific considerations for transportation and storage |
| 33 | Labelling (if relevant) | Specific labelling requirements |
| ENVIRONMENTAL REQUIREMENTS | | |
| 34 | Context-dependent requirements | Storage and operating temperatures (specify ranges), resistance to high humidity and/or dust levels (specify requirements) - in accordance with local/anticipated conditions. |
| TRAINING, INSTALLATION AND UTILISATION | | |
| 35 | Pre-installation requirements(if relevant) | Construction / structural changes, utility requirements, etc. |
| 36 | Requirements for commissioning (if relevant) | Manufacturer/supplier to perform installation, safety and operation checks before handover. Acceptance tests to be specified and local clinical and technical staff to verify proper and full functioning of device. |
| 37 | Training of user/s (if relevant) | Training of users in operation and basic maintenance shall be provided. Training of maintenance personnel (if relevant) also to be specified and provided. |
| 38 | User care(if relevant) | Information to be provided by manufacturer/supplier, e.g. cleaning, disinfection/sterilization method (for reusable devices). |
| WARRANTY AND MAINTENANCE | | |
| 39 | Warranty | Date of commencement, duration of warranty period, exclusions/inclusions and other conditions such as maintenance support during warranty must be specified. |
| 40 | Maintenance tasks | Specific equipment for needed for calibration or testing purposes must be specified. Advanced maintenance tasks required shall be documented, with details of maintenance support from manufacturer/supplier. |
| 41 | Type of service contract | Non Comprehensive or Comprehensive Contract |
| 42 | Spare parts availability post-warranty | Usually at least 5 years after device acquisition. |



| | | |
|-----------------------------|--|--|
| 43 | Software / Hardware upgrade availability | To be specified. |
| DOCUMENTATION | | |
| 44 | Documentation requirements | Operating and service manuals (language/s to be specified) including lists of important spares and accessories - with their part numbers and list of equipment and procedures required for calibration and routine maintenance. Documentation must also show recommended procedures for disposal and any probable hazards to the environment and/or community. |
| DECOMMISSIONING | | |
| 45 | Estimated Life Span | Predictable average life span, if it is assumed the average frequency of utilization, maintenance and failure. The device would be better to be assessed on the replacement concerning this span. (see 'How to Plan and Budget for your Healthcare Technology' http://www.who.int/management/plan_budget_healthcare.pdf) |
| SAFETY AND STANDARDS | | |
| 46 | Risk Classification | To be provided by manufacturer/supplier (typically verified by regional or national regulatory agencies). There is increasing international harmonisation, facilitated by the International Medical Device Regulators Forum (see http://www.imdrf.org/) with at least four systems in use: Class A to D (IMDRF/GHTF); Class I, IIa, IIb, III (EU, Australia); Class I, II, III (USA); Class I to IV (Japan, Canada), with low-risk devices in Classes A or I and high-risk devices in Classes D or III (or IV for Japan and Canada). |
| 47 | Regulatory Approval / Certification | e.g. FDA approval (USA), CE mark (EU) |
| 48 | International standards | Specified for compliance by manufacturers in global marketplace, notably ISO 13485: Quality Management System and ISO 14971: Risk Management System. Apply to categories of devices, e.g. for electromedical devices IEC 60601-1 (General requirements for basic safety and essential performance), IEC 60601-1-1 (Collateral standard: safety requirements for medical electrical systems) and IEC 60601-1-2 (Collateral standard: Electromagnetic compatibility - Requirements and tests). Apply to specific devices, e.g. IEC 60601-2-19 (Particular requirements for the basic safety and essential performance of infant incubators), ISO 10079-1 (Medical suction equipment), etc. |
| 49 | Regional / Local Standards | Related standards for device in relevant regulatory jurisdiction (region or country) |
| 50 | Regulations | Related regulations for device in relevant regulatory jurisdiction (region or country) |

Fig. 3.4-13. WHO medical device technical specification template (http://www.who.int/medical_devices/management_use/mde_tech_spec/en)

3.4.12 Technical specifications – Global facts

The WHO Baseline Country Survey (BCS) collected information about national recommended technical specifications to support procurement or donation (see Figs. 3.4-14 and 3.4-15).

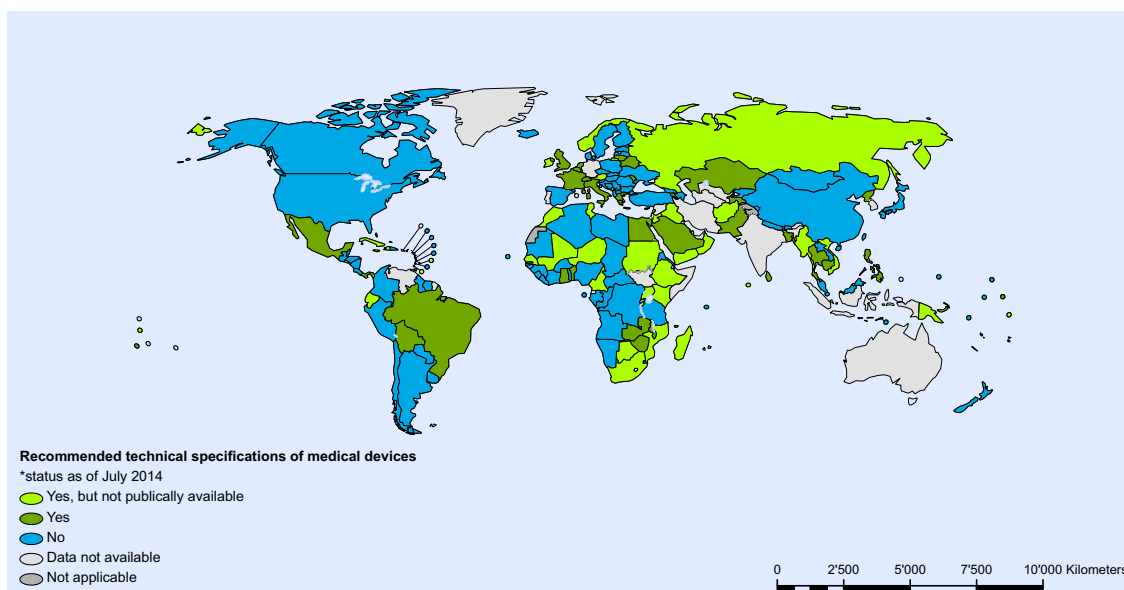


Fig. 3.4-14. Recommended publically available national technical specifications for procurement or donations of medical devices

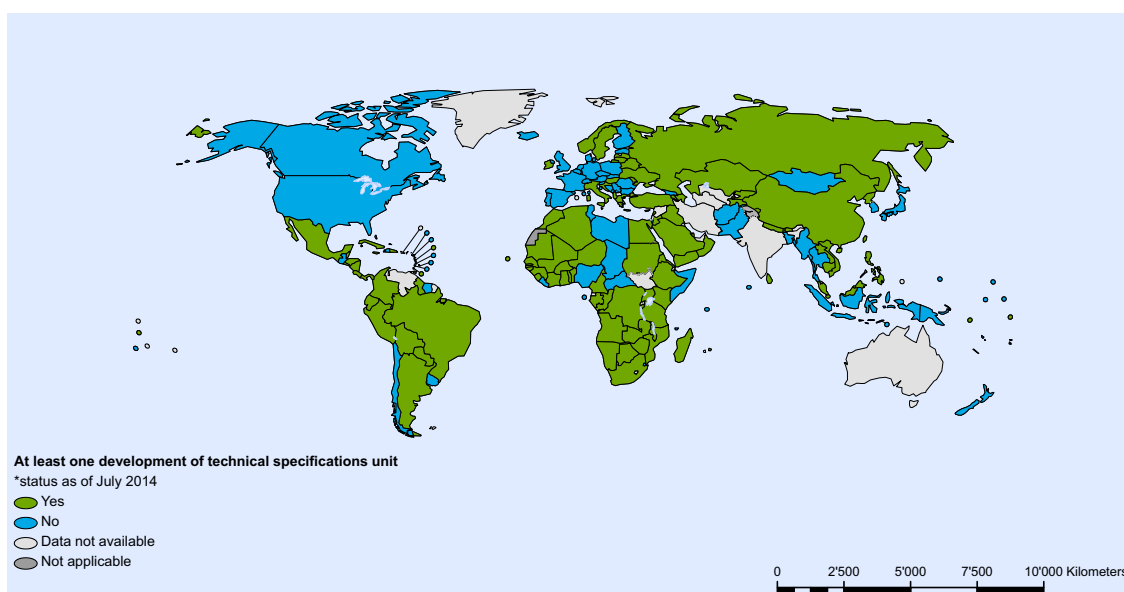


Fig. 3.4-15. Global map showing presence of units responsible for development of technical specifications for procurement purposes at national/federal level

Of 169 countries that responded to the survey, 91 stated that they do not have any national recommended technical specifications for procurement or donations of medical devices (54% of 169 respondent countries). Of the 78 countries that have recommended technical specifications for medical devices (46% of 169 respondent countries), 24% do not have publically available ones (see Fig. 3.4-16).

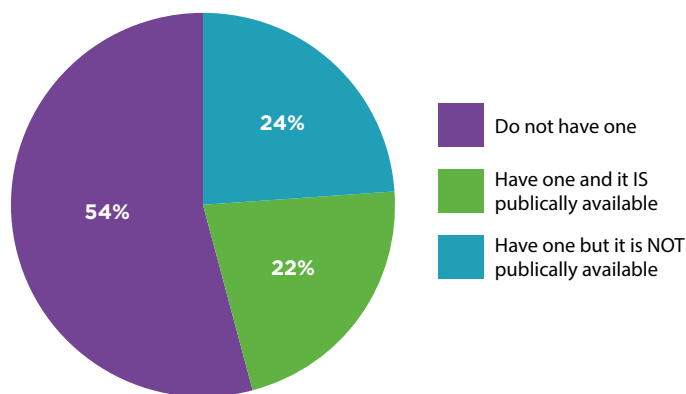


Fig. 3.4-16. Existence and availability of recommended technical specifications of medical devices to support procurement or donations as responded by 169 countries

3.4.13 Technical specifications – Further readings

For more information about technical specifications of medical devices, please refer to the following websites:

Websites:

- UN Agencies:
 - » WHO technical specifications on medical devices ^{xv}
http://www.who.int/medical_devices/management_use/userguide_dec2014.pdf?ua=1
 - » UNICEF Supply Catalogue, specifications for over 2,000 commodities that respond to the needs of children and their families ^{xvi}
<https://supply.unicef.org>
 - » UNFPA AccessRA, a procurement and information service for reproductive health commodities ^{xvii}
<http://www.myaccessrh.org/home>
- WHO Collaboration Centers:
 - » Centro Nacional de Excelencia Tecnológica en Salud - CENETEC (Mexico)^{xviii}
<http://www.gob.mx/salud/acciones-y-programas/centro-nacional-de-excelencia-tecnologica-en-salud-15655>
 - » India: National Health Systems Resource Center, Healthcare Technology and Innovation^{xix}
http://nhsrcindia.org/index.php?option=com_content&view=article&id=173&Itemid=642
- Example of country adoptions of technical specifications:
 - » Nepal: Ministry of Health & Population, Technical Specifications Bank^{xx}
<http://spec.dohslmd.gov.np>

3.4.14 Medical devices inventory management – Introduction

Health technologies and in particular medical devices are essential in the delivery of quality health care as they enable health care providers to diagnose, treat, monitor and provide therapy to patients within an appropriate environment of care. Quality management of medical devices helps ensure that these services are provided in a safe and effective way. Here, the medical devices inventory plays a vital role. Inventory management's main tasks are to record the purchase, receipt, retirement and discarding of equipment. Moreover, once properly established, a medical device inventory is a powerful tool in the clinical engineering department and the health care facility as a whole, as it is used as input for various areas in the health care management cycle (see Fig. 3.4-1). It serves as the foundation for moving forward within the health technology management system and for ensuring safe and effective medical equipment on many levels. It helps to develop budgets for capital purchases, maintenance and running costs; it helps to build and support an effective clinical engineering department by allowing for workshop planning, hiring and training of technical support staff and establishing and maintaining service contracts; it helps to support an effective medical equipment management programme, including planning preventive maintenance

activities and tracking work orders; and it helps to plan the necessary stock of spare parts and consumables. Furthermore, developing replacement and disposal policies, developing purchasing and donations goals, analyzing facility risk and mitigation, emergency and disaster planning, and equipment needs assessments are all supported by the existence of a medical devices inventory.^{xxi}

Inventory management can be classified into three stages: first, the inventory of all medical devices has to be compiled. Here, accessories, consumables and spare parts inventories should be directly correlated with the main medical equipment inventory. Second, the inventory needs to be updated whenever there is any change. Third, an annual audit needs to be performed. The health care facility decides on the level of detail of data to be included in its inventory in order to satisfy its own requirements and according to its own capabilities. Fig. 3.4-17 shows a list of minimum information that should be included. Additional useful information that can be included is listed in Fig. 3.4-18.

| Item | Brief description/purpose | Type of inventory |
|---|---|--------------------------------------|
| Minimum data included in inventory records | | |
| Equipment identification number | Unique identifier for each piece of equipment | Medical equipment |
| Type of equipment/item | Identifies what the item is, using standard and uniform nomenclature, such as the Universal Medical Device Nomenclature System (UMDNS) or Global Medical Device Nomenclature (GMDN) | All |
| Brief description of equipment/item | Describes the item, including its function/purpose | All |
| Manufacturer | Identifies the company that makes the item, including the name, address and contact details of the manufacturer | All |
| Model/part | Unique identifier of the product line (assigned by the manufacturer) | All |
| Serial number | Unique identifier of the item (assigned by the manufacturer) | All |
| Physical location within health-care facility | Includes room number or department; allows medical equipment to be located when preventive maintenance is due; may include storeroom information for consumables and spare parts | All |
| Condition/operating status | Identifies equipment as "in service" or "out of service"; includes reason for being out of service, such as calibration due, preventive maintenance due, under repair, awaiting spare parts or damaged beyond repair | Medical equipment, testing equipment |
| Power requirements | Clarifies the required power to run the equipment, such as 110V, 220V, 380V or three-phase; may be useful for identifying equipment that requires transformers or other special attention | Medical equipment, testing equipment |
| Operation and service requirements | Identifies any special requirements needed in operation or service of equipment | Medical equipment |
| Date inventory performed/updated | Date the equipment was entered into the inventory and the last date the information was updated | All |
| Maintenance service provider | Lists details of provider including name, contact details and contract details when medical equipment is maintained by an outside service organization (including when under warranty by manufacturer) or peripheral workshop; information on maintenance performed | Medical equipment, testing equipment |
| Purchase supplier | Used as a point of contact regarding purchase, reorders, warranty replacements, etc. | All |

Fig. 3.4-17. Inventory data, minimum information that should be included (http://www.who.int/medical_devices/publications/med_dev_inventory/en/)



| Additional useful information | | |
|---|---|--------------------------------------|
| Lot number | May be assigned for consumables or reagents manufactured in the same batch; can assist in identifying defects; useful for stock-control systems for consumables | Consumables |
| Current software and firmware version numbers | Used for equipment run with computer software or electronics (firmware); can be used to identify software- or firmware-related problems | Medical equipment, testing equipment |
| Department ownership details | Identifies point of contact for notification in service delays, and to schedule preventive maintenance | Medical equipment |
| Purchase cost | Serves as an input to capital inventory values and for budgeting purposes | All |
| Purchase date | In the case of capital assets, used to calculate depreciation values or replacement/obsolescence determination. In the case of consumables or spare parts, may be used to determine usage rates, reorder requirements and expiration dates | All |
| Warranty expiration date | Useful in tracking warranty validity and expiration | All |
| Installation date and acceptance testing information and results | Serves as a foundation for the service history record and is used as a reference when troubleshooting | Medical equipment, testing equipment |
| Safety/risk assessment/classification | Includes the risk assessment performed (or other rationale, if needed) that determined inclusion of equipment in the inventory; may also be used to determine equipment testing and repair priority | Medical equipment |
| Preventive maintenance schedule and procedures | Outlines frequency of preventive maintenance intervals and procedures for maintenance | Medical equipment, testing equipment |
| Calibration dates performed and results, dates due and procedures | Serves as a reference when troubleshooting equipment and ensures equipment is within calibration dates | Medical equipment, testing equipment |
| Stock and reorder quantities | When used in stock-control systems, serves as a trigger point for reorder when stock numbers reach an identified level | Spare parts, consumables |
| Associated devices/systems/accessories/consumables/spare parts | Identifies important supportive equipment, including any apparatus or accessories required to run a piece of equipment; part numbers for accessories, spare parts and consumables are helpful | Medical equipment, testing equipment |
| Year of manufacture | Used to calculate the age of the equipment; used with expected equipment lifetime as an input to determine when an item needs to be replaced, retired or discarded | Medical equipment, testing equipment |
| Expected equipment lifetime | Lists the expected amount of time (typically in years) that a piece of equipment may be safely and effectively in service; may be used as an input to determine when an item needs to be replaced, retired or discarded | All |
| Operating and service history | May include user or maintenance logbooks (for operation or service), work order or service reports, preventive maintenance reports and other information regarding the operation and service of the equipment; can be used when troubleshooting failures, evaluating purchases of new, similar equipment, and determining when an item needs to be replaced, retired or discarded | Medical equipment, testing equipment |
| History of recalls and reported hazards | Used to identify and follow up on any potential hazards associated with machine use | Medical equipment, testing equipment |
| Any other desired information | An inventory is useful to a health-care facility only if it contains important information needed by the facility; therefore, any data fields can be added as deemed necessary | All |

Fig. 3.4-18. Inventory data, additional useful information

Inventory management is done through a paper-based or computer-based system, as determined by the resources available.

3.4.15 Medical devices inventory management – Global facts

The WHO Baseline Country Survey on Medical Devices collected information on the existence and type of national inventory. Results are visualized in Fig. 3.4-19. The questionnaire included three main inventory categories:

1. Inventory of only high cost technologies
2. Inventory of medical equipment
3. Functional inventory of medical equipment.

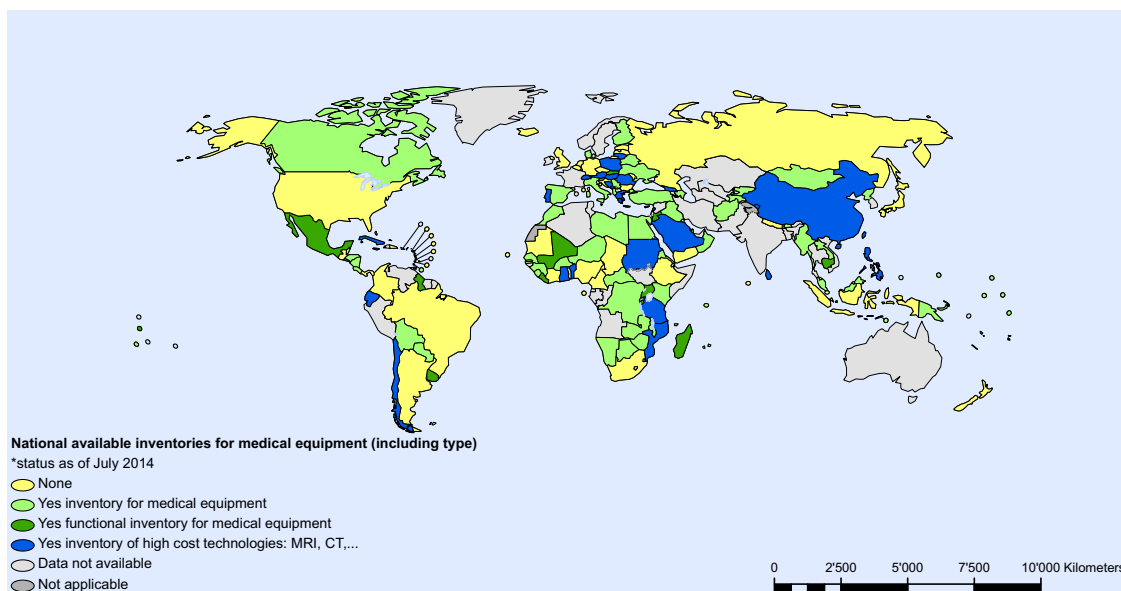


Fig. 3.4-19. National available inventories of medical equipment

From the 177 country survey respondents, 152 provided information on available national inventories for medical equipment. In total, 102 Member States (67% of 152) have available national inventories for medical equipment and 50 Member States (33% of 152) do not have any (Fig. 3.4-20).

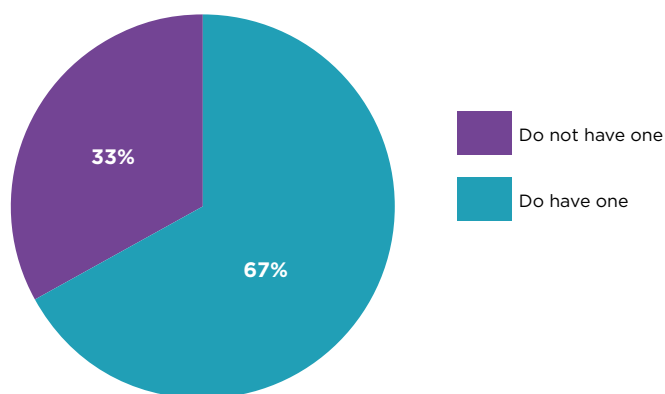


Fig. 3.4-20. Existence of country's available national inventory for medical equipment

This data on national inventories was also analyzed with respect to World Bank income groups (Fig. 3.4-21). The survey showed 25% of countries from the three income groups: low-income, lower-middle-income and upper-middle-income (28 out of 110 respondent countries across the three income groups), do not have available national inventories for medical equipment, compared to 52% of countries in the high-income group (22 out of the 43 respondent countries in this group).

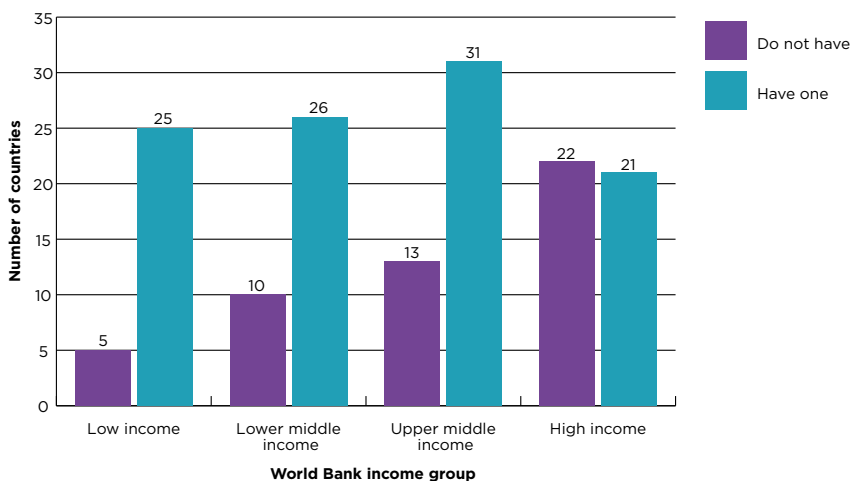


Fig. 3.4-21. Availability of national inventory for medical equipment by income group.

Taking a closer look at the respondents who reported having a specific type of national inventory for medical equipment (102 countries), this inventory was ‘national inventory for medical equipment’ in 73% to 84% of the countries from the three income groups: low-income, lower-middle-income and upper-middle-income, compared to 50% of the countries from the high-income group (Fig. 3.4-22).

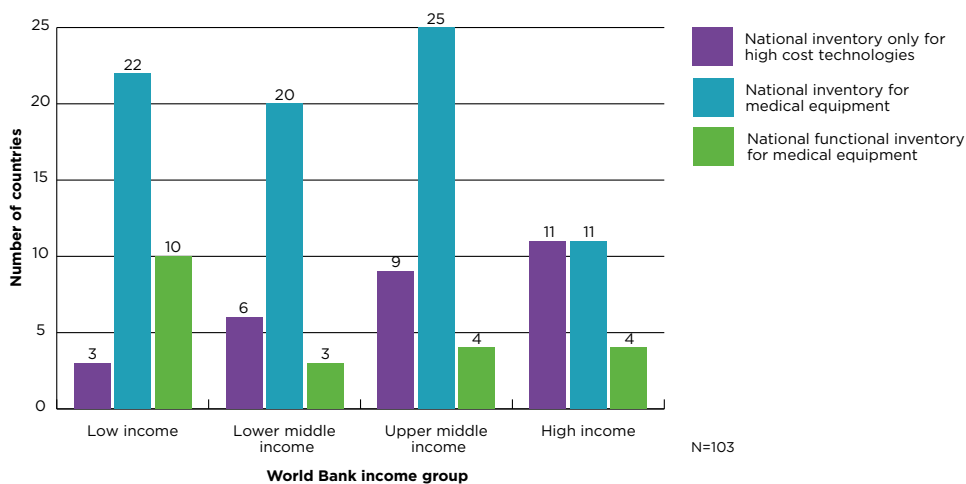


Fig. 3.4-22. Countries with available inventories of medical equipment by type of inventory and World Bank income group

Presenting this data with respect to WHO regions, across all regions more than 50% of the respondent countries have available national inventory for medical equipment (Fig. 3.4-23). Additionally, 80% or more of the respondent countries from the Eastern Mediterranean and Western Pacific regions have available national inventory for medical equipment. In South-East Asia, American and European regions, respondent countries have less often available national inventories for medical equipment (45%, 43%, and 63% respectively) as inventories are managed for example, on local levels instead of nationally.

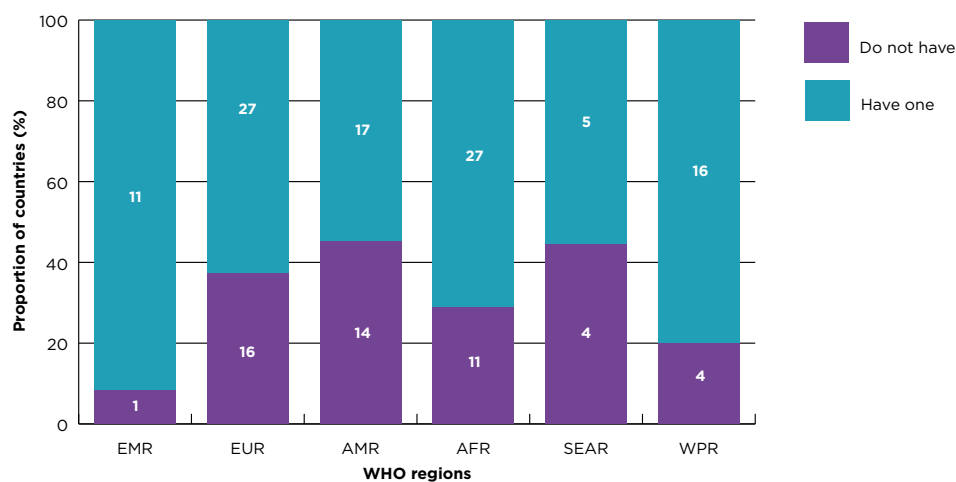


Fig. 3.4-23. Presence of country's medical equipment available inventory by WHO region

3.4.16 Medical device inventory - Further readings

For more information about medical device inventories, please refer to the following sources.

Documents:

- Introduction to medical equipment inventory management. WHO Medical Device Technical Series.^{xxi}
- Computerized maintenance management system. WHO Medical Device Technical Series.^{xxii}
- How to organize a system of healthcare technology management. 'How to Manage' series of health care technology guides no. 1. ^{xxiii}
- How to operate your healthcare technology effectively and safely. 'How to Manage' series of health care technology guides no. 4. ^{xxiv}



3.4.17 Medical device maintenance – Introduction

Medical devices are assets that directly affect human lives. Some of them are considerable investments for which not only the procurement costs have to be taken into account but also the costs for operation, maintenance and consumables, which are often much higher than the initial costs. The maintenance costs especially, are often underestimated (Fig. 3.4-24). In order to keep the medical equipment in a health care institution reliable, safe and available for use when it is needed for diagnostic procedures, therapy, treatments and monitoring of patients, it is essential for a health care facility – regardless of its size – to have a well-planned and well-managed maintenance programme. Such a programme also prolongs the useful life of the equipment and thereby minimizes the cost of equipment ownership.^{xxiv}



Fig. 3.4-24. Investments for the procurement of medical devices

A maintenance programme includes the following two types of procedures:

- Procedures for performance and safety inspection and preventive maintenance (IPM):
Performance inspections ensure that equipment is operating correctly, and safety inspections ensure the equipment is safe for both patients and operators. Preventive maintenance aims to extend the life of the equipment and reduce failure rates. Additionally, some hidden problems may be discovered during a scheduled inspection. However, performing inspections of equipment only ensures that the device is in good operating condition at the time of inspection and cannot eliminate the possibility of failure during future use; the nature of most electrical and mechanical components is that they can potentially fail at any time.
- Procedures for corrective maintenance (CM):
Corrective maintenance restores the function of a failed device and allows it to be put back into service. Identification of a device failure usually occurs when a device user has reported a problem with the device or when a technician finds that a device is not performing as expected during IPM. After completion of repair, it is essential to conduct a performance and safety inspection, and in some cases a re-calibration may be required.

To plan, manage, and implement an effective medical equipment maintenance programme is a complex task. It is important to have a well-functioning clinical engineering department in place, which needs competent staff such as experienced biomedical engineers and well-trained equipment technicians.

First, the clinical engineering department should identify and select the devices to be included in the medical device inventory (see section 3.4-14), and which of those to include in the maintenance programme. Next, the most efficient methods to maintain the various devices need to be chosen. Here, an analysis must be performed to decide which services should be delivered by which combination of internal and external service providers, based on the capacity of the facility and its staff. Finally, the clinical engineering department needs to consider the financial, physical and human resources needed to adequately implement the maintenance activities, which is challenging, as the actually-required resources are difficult to project. Even with certain resource constraints, a successful programme that suits the needs of a particular context can be designed and executed when the various financial, physical and human resource aspects are carefully assessed. For an overview of the critical factors in the planning process see Fig. 3.4-25. Furthermore, there are various safety aspects to consider, such as the safety of technical personnel while performing maintenance, safety of the user following maintenance, and general infection control.

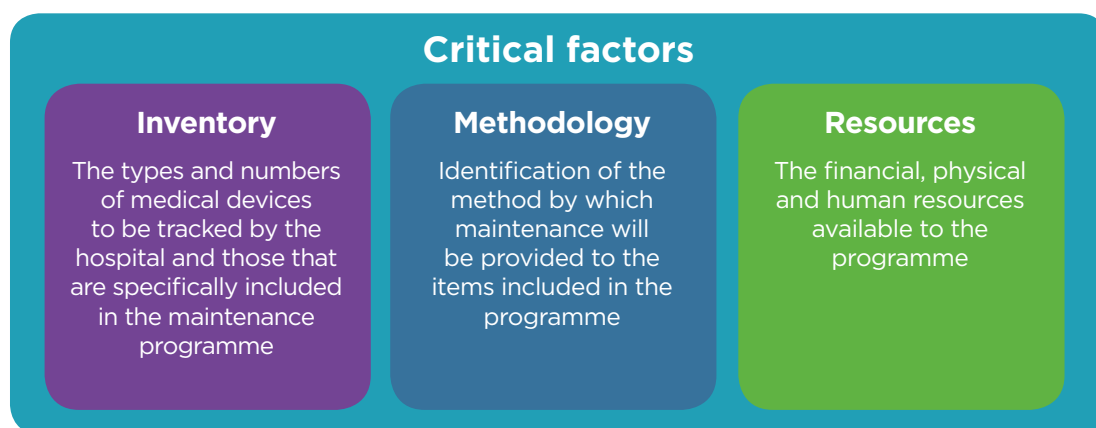


Fig. 3.4-25. Critical factors in planning a maintenance programme

Once the programme has been defined, financial, personnel and operational aspects need to continually be examined and managed to ensure the programme continues uninterrupted and improves as necessary. Ultimately, proper implementation of the programme is key to ensuring optimal equipment functionality.

The complexity of a medical equipment maintenance programme depends on the size and type of facility, its location and the resources required. However, the principles of a good maintenance programme will be the same if it is in an urban area in a high-income country or a rural setting in a low- to middle-income country.



3.4.18 Medical device maintenance - Global facts

The WHO Baseline Country Survey on Medical Devices collected information on the existence of management units with professionally trained biomedical/ clinical engineers or technicians and results are visualized in Fig. 3.4-26.

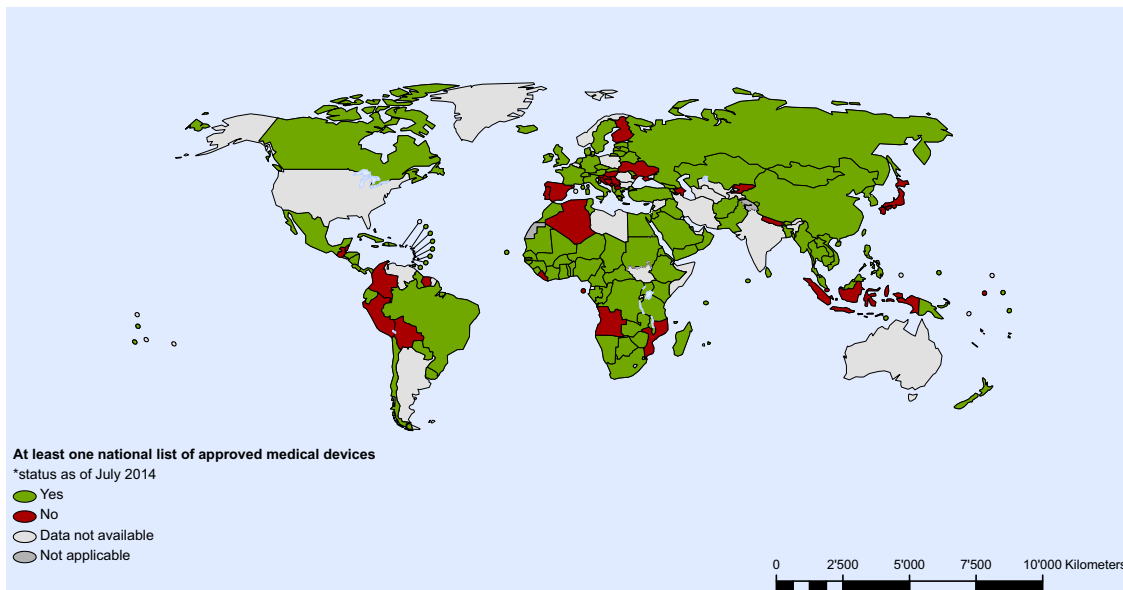


Fig. 3.4-26. Management units for medical equipment with professionally trained biomedical/clinical engineers or technicians

From the 177 country survey respondents, 163 provided information on available management units with professionally trained biomedical/clinical engineers or technicians. In total, 133 Member States (82% of 163) have medical equipment management units and 30 Member States (18% of 163) do not have any (Fig. 3.4-27).

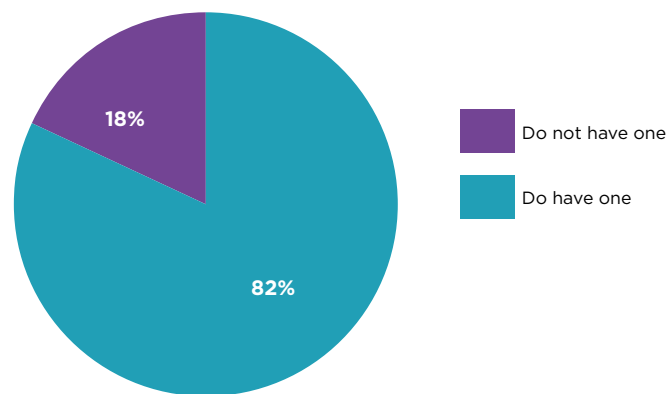


Fig. 3.4-27. Existence of a medical equipment management unit with professionally trained biomedical/clinical engineers or technicians

This data was also analyzed with respect to World Bank income groups (Fig. 3.4-28). Between 84% and 88% of countries from the three income groups: low-income, lower-middle-income and high-income (100 out of 117 respondent countries across the three income groups) have management units with professionally trained biomedical/clinical engineers or technicians. This number was lower for countries from the upper-middle-income group with 71% (33 out of the 46 respondent countries in this group).

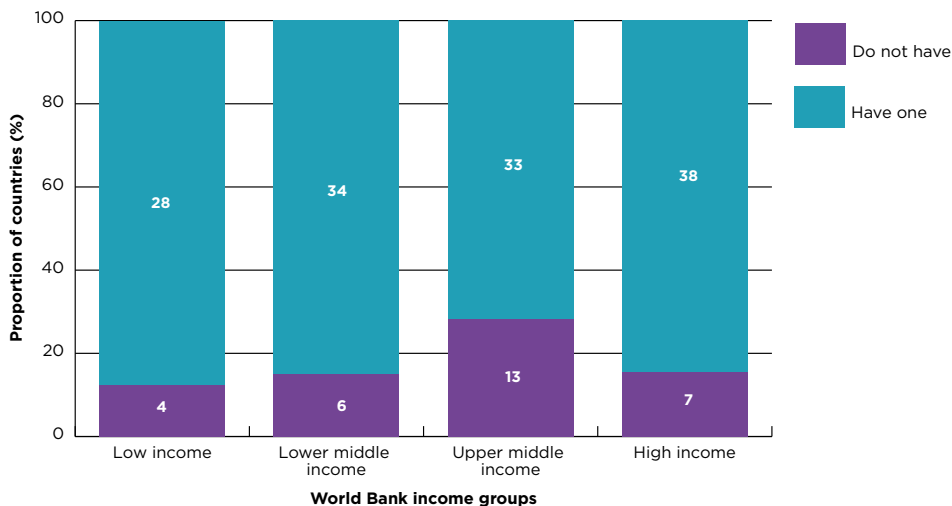


Fig. 3.4-28. Proportion of countries that reported a medical equipment management unit with professionally trained biomedical/clinical engineers or technicians by World Bank income group



3.4.19 Medical device maintenance – Further readings

For more information about medical device maintenance, please refer to the following sources.

Documents:

- Medical equipment maintenance programme overview. WHO Medical Device Technical Series.^{xxv}
- Computerized maintenance management system. WHO Medical Device Technical Series.^{xxii}

Endnotes

- i. World Health Assembly resolution WHA60.29, May 2007 (<http://apps.who.int/medicinedocs/documents/s17693en/s17693en.pdf>)
- ii. Kaur M et al.: 'How to Manage' Series for Healthcare Technology. Guide 1: How to Organize a System of Healthcare Technology Management. Ziken International (Health Partners International), 2005.
- iii. Development of medical device policies. WHO Medical Device Technical Series, 2011.
- iv. Medical equipment maintenance programme overview. WHO Medical Device Technical Series, 2011.
- v. Temple-Bird C et al. 'How to Manage' series of health care technology guides. St Alban's, Ziken International (Health Partners International), 2005, (<http://resources.healthpartners-int.co.uk/resource/how-to-manage-series-for-healthcare-technology/>)
- vi. UNOPS procurement manual, New York, UN Office for Project Services 2010, page 6.
- vii. Procurement process resource guide, WHO medical device technical series, World Health Organization 2011.
- viii. UN procurement practitioner's handbook, New York, United Nations (UN) 2006
- ix. Dyro J.: Donation of medical device technologies. In: Dyro J, ed. Clinical engineering handbook. Burlington, Elsevier Academic Press, 2004:155–158.
- x. Barriers to innovation in the field of medical devices. Background paper 6. Geneva, World Health Organization, 2010.
- xi. Medical device donations: considerations for solicitation and provision, WHO medical device technical series, World Health Organization 2011.
- xii. Mullally S.: THET Making it work, A toolkit for medical equipment donations to low resource settings, RAP Spiderweb Ltd (Manchester), 2014.
- xiii. Humatem (Association Loi 1901) (<http://www.humatem.org/>)
- xiv. WHO medical devices website on technical specifications: (http://www.who.int/medical_devices/management_use/mde_tech_spec/en/)
- xv. WHO user guide on technical specifications for medical devices: http://www.who.int/medical_devices/management_use/userguide_dec2014.pdf?ua=1
- xvi. <https://supply.unicef.org>
- xvii. <http://www.myaccessrh.org/home>
- xviii. <http://www.gob.mx/salud/acciones-y-programas/centro-nacional-de-excelencia-tecnologica-en-salud-15655>
- xix. http://nhsrcindia.org/index.php?option=com_content&view=article&id=173&Itemid=642
- xx. <http://spec.dohslmd.gov.np/>
- xxi. Introduction to medical equipment inventory management. WHO Medical Device Technical Series, 2011.
- xxii. Computerized maintenance management system. WHO Medical Device Technical Series, 2011.
- xxiii. Lenel A et al. How to organize a system of healthcare technology management. 'How to Manage' series of health care technology guides no. 1. St Albans, Ziken International (Health Partners International), 2005.
- xxiv. Temple-Bird C et al. How to operate your healthcare technology effectively and safely. 'How to Manage' series of health care technology guides no. 4. St Albans, Ziken International (Health Partners International), 2005a.
- xxv. Medical equipment maintenance programme overview. WHO Medical Device Technical Series, 2011.

3.5 Medical devices: Nomenclature system

3.5.1. Introduction

The nomenclature of medical devices is a coding system used to generically classify and identify all medical devices and related health products. Having a nomenclature system in place for medical devices facilitates their management and regulation by standardizing terms that enable communication despite linguistic and other barriers. Such standardization is currently used in some regulatory systems but is also a prerequisite for inventory management and databases for maintenance of equipment.

Several naming systems for medical devices exist and each is used by a different group of professionals depending on the needs of that particular group, needs such as maintenance, procurement, accounting, stock keeping, regulatory affairs, adverse medical device event reporting and customs operations. The number of systems in existence can make it difficult to communicate between individuals and organizations. Therefore, WHO is working towards a unified nomenclature system that can be used globally. Currently, several countries have their own nationally used nomenclature systems. However, the two nomenclature systems most widely used for medical devices are the Global Medical Devices Nomenclature System (GMDN)ⁱ and the Universal Medical Devices Nomenclature System (UMDNS)ⁱⁱ that are explained in more detail below.

The GMDN was developed by the European Committee for Standardization (CEN) and medical device experts from around the world (manufacturers, healthcare authorities and regulators) based on the international standard ISO 15225. It is managed and maintained by a not-for-profit company, the GMDN Agency, which reports to a Board of Trustees on which medical device regulators and industry are represented. To ensure continuing permanency of the GMDN, revenues are generated through the licensing and sale of GMDN Agency products, particularly the GMDN codes. The GMDN is a poly-hierarchical system. Product identification is done by unique numerical five-digit numbers that are associated with a term (medical device name), a definition that includes the intended use(s) and the device category (based on device application, technology, or other common characteristics). Identification of all specific medical devices having substantially similar generic features is possible through cross-referencing.

The UMDNS was developed by the Emergency Care Research Institute (ECRI). ECRI is a nongovernmental, not-for-profit organization, governed by an Executive Committee and a Board of Trustees. The UMDNS is poly-hierarchical and is developed as an interrelated vocabulary based on terms naming the medical devices. Terms are assigned a 5 digit code using consecutive numbering with no intrinsic meaning. The code is associated with a definition and a description of the intended use. Associated properties provide additional attributes for classification. Maintenance is done by a core group of ECRI nomenclature specialists, both for the ECRI's internal use and to provide support to external clients and licensees.

Further nomenclature systems of interest for medical device identification include, for example:

- The International Statistical Classification of Diseases and Related Health Problems (ICD)ⁱⁱⁱ. ICD-10 is the tenth revision of a WHO developed medical classification list for diseases, disorders, health symptoms, and injuries. It serves to accurately code medical diagnoses and is employed by all member states, in for example, epidemiology, health management and clinical settings.
- The Unique Device Identification (UDI)^{iv} system that is being developed by the U.S. Food and Drug Administration (FDA) to label medical devices through their distribution and use. The related Global UDI Database will be publically accessible for download and use.
- The United Nations Standard Products and Services Code (UNSPSC)^v that is an open, global, multi-sector classification system divided in five hierarchical levels. It was developed by the United Nations Development Programme (UNDP) and Dun & Bradstreet Corporation (D&B) in 1998 and is managed by GS1 US, a not-for-profit organization, since 2003.



3.5.2 Global facts

The Baseline Country Survey collected information about whether countries had nomenclature systems in place and if so, which type of system was used. In total, 174 countries responded. An overview of the results can be seen in Fig. 3.5-1.

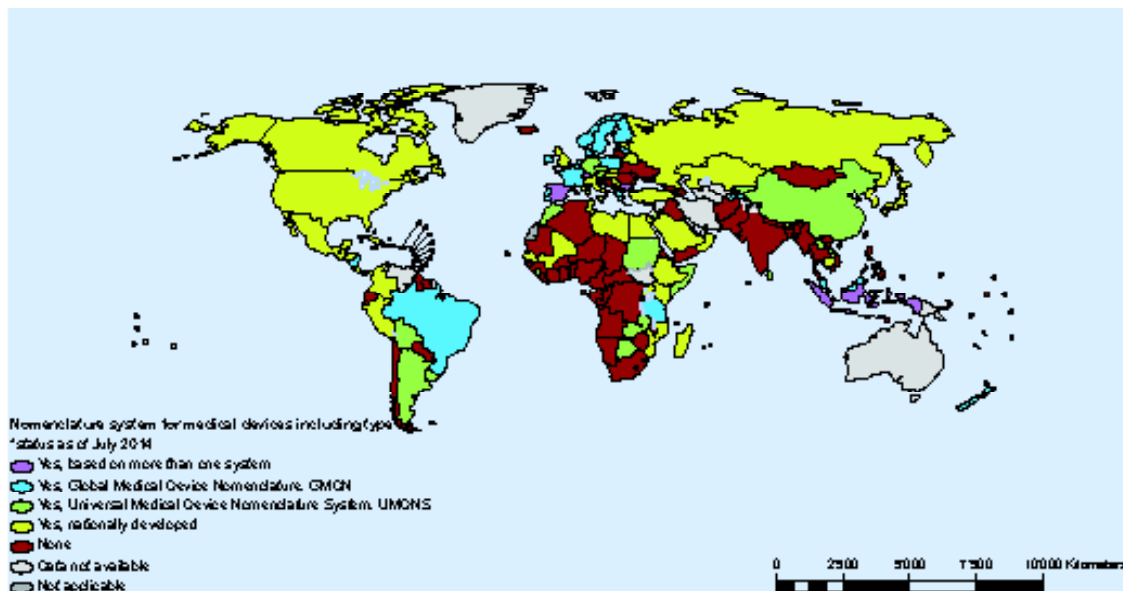


Fig. 3.5-1. Nomenclature systems for medical devices

About half of the responding member states, i.e. 90 countries (52%), use at least one official nomenclature system for medical devices. In contrast, 84 member states do not have any official national nomenclature (49%; see Fig. 3.5-2).

The 90 countries who have an official nomenclature system are using the following types: 26% have developed a system nationally, 12% use Universal Medical Device Nomenclature System (UMDNS) only, 10% use Global Medical Device Nomenclature (GMDN) only, and 3% more than one system.

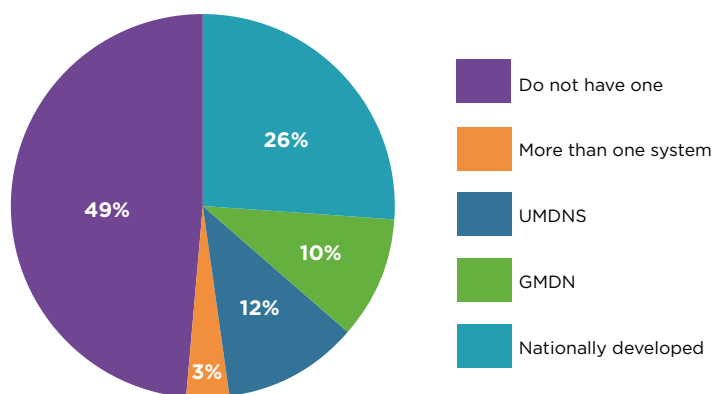


Fig. 3.5-2. Existence and type of the countries' official nomenclature system for medical devices.

More than 50% of the low- to middle-income countries do not have an official nomenclature system (71 countries from 126 responding low- and middle-income countries). In contrast, 74% of high-income countries have an official nomenclature system (36 from 49 responding high-income countries; see Fig. 3.5-3).

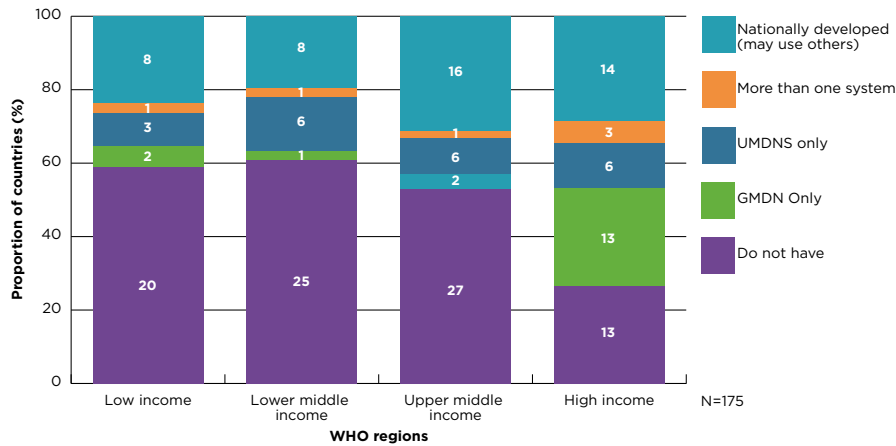


Fig. 3.5-3. Presence and type of the countries' official nomenclature system for medical devices by World Bank income group

More than 50% of the countries of WPR, SEAR, and AFR regions do not have an official nomenclature system. In contrast, more than 65% of the countries of EMR and EUR have an official nomenclature system (see Fig. 3.5-4).

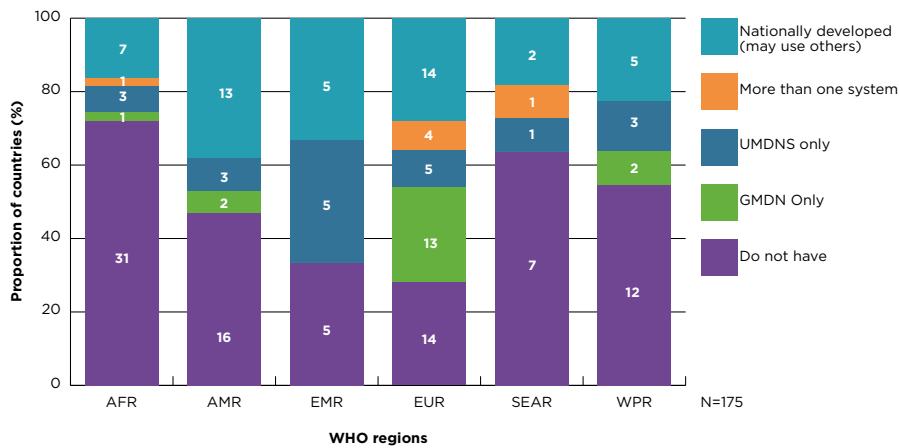


Fig. 3.5-4. Presence and type of the respondent countries' official nomenclature system for medical devices by WHO regions

It can be observed that in the European (34 of 50 respondent countries), Eastern Mediterranean (7 of 14 respondent countries), and American (17 of 34 respondent countries) regions at least 50% of the respondent countries have an official nomenclature system and a regulatory authority. In the case of African, South-East Asia, and Western Pacific regions more than half of the participant countries do not have any nomenclature system independent of the existence of a national regulatory authority for medical devices (Fig. 3.5-5).

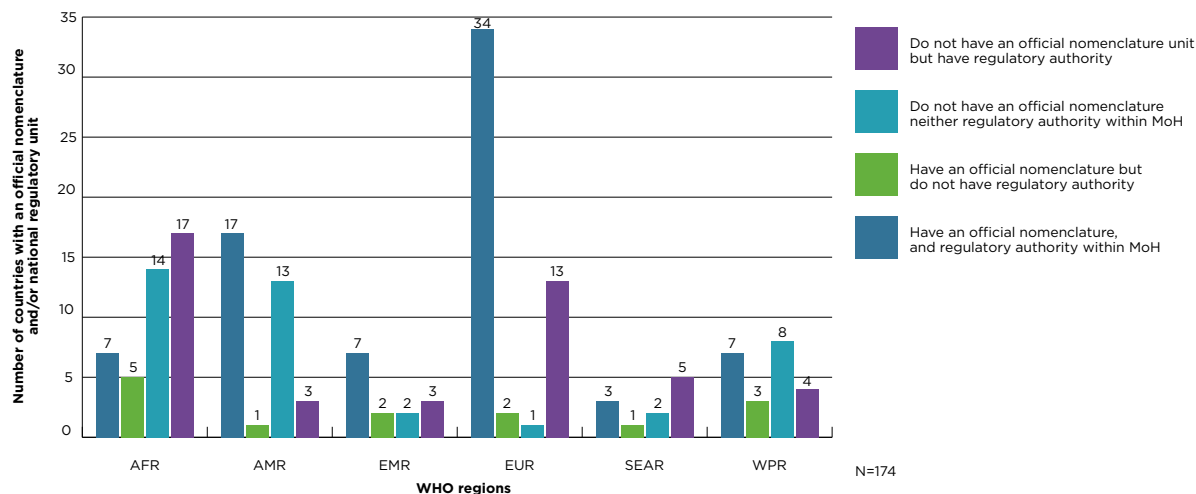


Fig. 3.5-5. Presence of an official nomenclature system and/or national regulatory authority for medical devices by WHO region

Fig. 3.5-6 shows that in none of the regions do more than 30% of countries have an official nomenclature system as well as lists recommending health technology within the ministry of health. However, in the European region 32 (71%) of 45 respondent countries, in the Eastern Mediterranean region 9 (64%) of 14 respondent countries and in the American region 18 (55%) of 33 countries have at least an official nomenclature system. Furthermore, for African, South-East Asia, and Western Pacific regions, more than half of the participant countries do not have any nomenclature system independent of the existence of any list recommending health technology within the ministry of health.

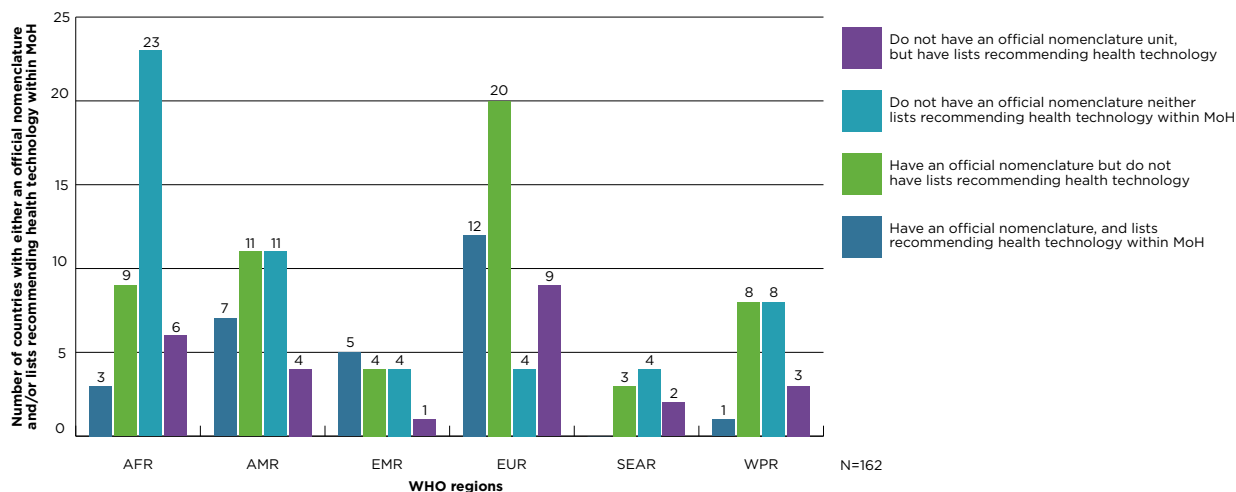


Fig. 3.5-6. Presence of an official nomenclature system and/or lists recommending health technology for medical devices by WHO regions

The nomenclature systems are used for different purposes such as for regulatory purposes, for procurement and/or inventory. An overview of the types of usages in the respondent countries can be seen in Figs. 3.5-7 and 3.5-8.

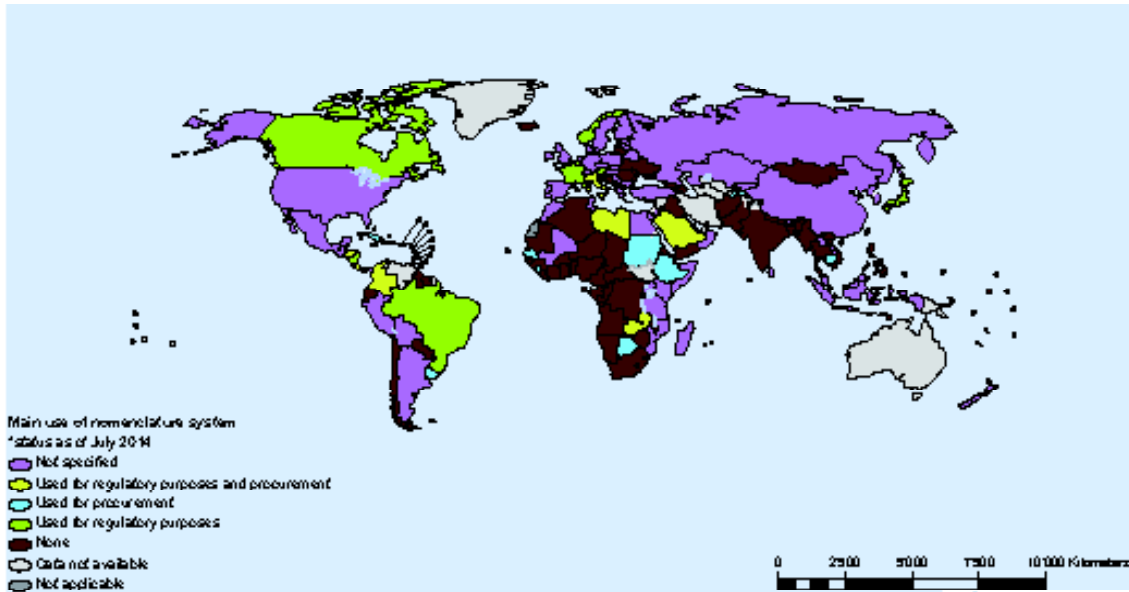


Fig. 3.5-7. Nomenclature system usage types for medical devices

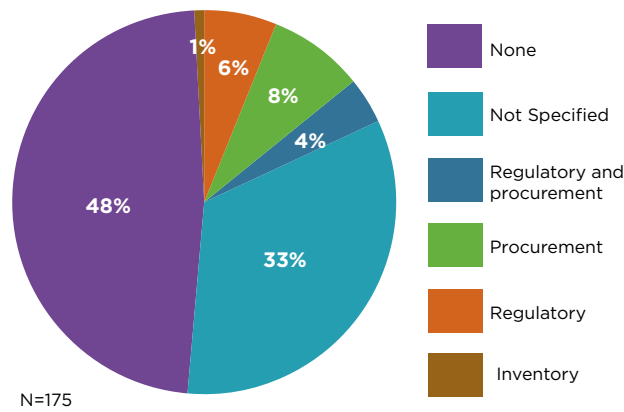


Fig. 3.5-8. Distribution of nomenclature system usage types: regulatory purposes, procurement, and inventory

In most regions, the nomenclature of medical devices is used for procurement and regulatory processes. However, in the African region, where regulatory processes of medical devices are very limited, the nomenclature systems – when available – are mainly used for procurement. The countries of the South-East Asia region did not specify any specific uses for the nomenclature systems (Fig. 3.5-9).

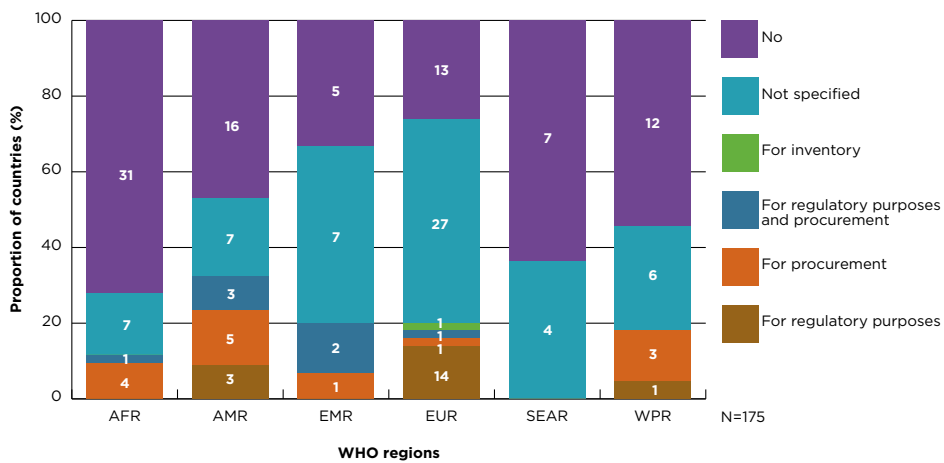


Fig. 3.5-9. Nomenclature system usage types for medical devices by WHO regions



Concurrently, analyzing the results by World Bank income groups shows that in high-income countries, the nomenclature is used to a greater extent for regulatory purposes than in the other countries. In contrary, the low- and lower-middle-income countries use the nomenclature more for procurement purposes, as regulatory processes are limited (Fig. 3.5-10).

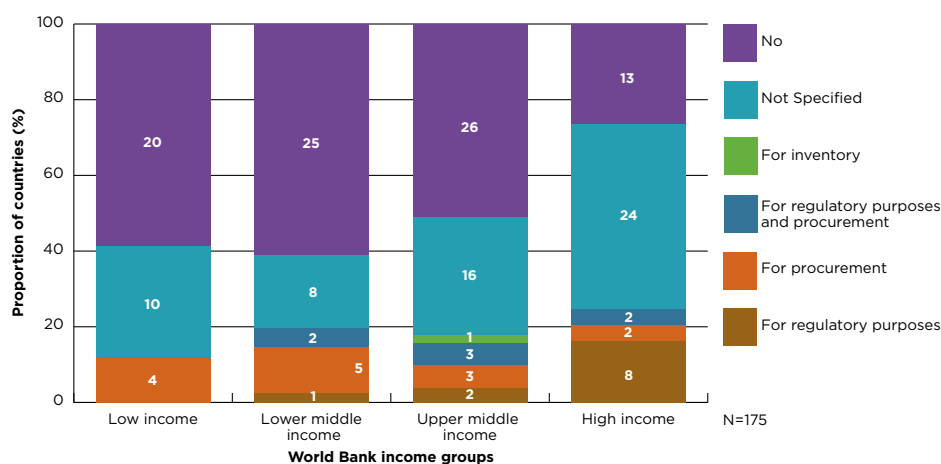


Fig. 3.5-10. Nomenclature system usage types for medical devices by World Bank income groups

3.5.3 Further reading

For more information about medical devices nomenclature systems, please refer to the following documents and websites:

Documents:

- International Medical Device Regulators Forum (IMDRF) Guidance document on the UDI

Websites:

- Global Medical Devices Nomenclature System (GMDN) Agency home pageⁱ <https://www.gmdnagency.org/>
- Universal Medical Devices Nomenclature System (UMDNS)ⁱⁱ by the Emergency Care Research Institute (ECRI) <http://www.ecri.org.uk/umdns/index.htm>
- Unique Device Identification (UDI) ^{iv} by the U.S. Food and Drug Administration (FDA) page <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/>
- United Nations Standard Products and Services Code (UNSPSC)^v page <http://www.unspsc.org/>

Endnotes

- <https://www.gmdnagency.org/>
- <http://www.ecri.org.uk/umdns/index.htm>
- <http://www.who.int/classifications/icd>
- <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/>
- <http://www.unspsc.org/>
- IMDRF Guidance document on the UDI of medical devices, IMDRF UDI Working Group, release 9 December 2013 (<http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-udi-guidance-140901.pdf>)

3.6 Medical devices: National lists

3.6.1 Introduction

Health care delivery is a complex endeavor that encompasses numerous specialized fields and entails a multitude of decisions based on the medical care needed on national and local levels. The health infrastructure and medical procedures offered in prevention, diagnosis, treatment, and rehabilitation must meet the medical situation in the country in order to gain optimal results. Medical devices are indispensable tools for quality health care delivery, but their selection and appropriate use pose a significant challenge. Here, agreed-upon lists of medical devices for specified purposes help improve access to suitable medical devices, increase safety, support quality of care and strengthen health care systems. These lists facilitate decision-making for health professionals in the areas of health policies, strategic planning, health technology assessment, resource allocation, procurement, biomedical engineering, regulation and facility assessment.

To allow for a consistent and appropriate selection of medical devices, different types of lists or catalogues exist, for example lists of medical devices that are needed to implement specific interventions; lists of medical devices that are needed for prevention, diagnosis and treatment of specific diseases; lists of medical devices that equip a specific type of health care facility or a specific room in a health care facility; or lists of medical devices that are recommended for procurement. The listed medical devices are usually categorized as basic/essential or priority medical devices through a national selection and approval process that normally involves quality, safety (regulatory approval) and then cost effectiveness studies, or national needs or feasibility studies, and in this way are approved for procurement or public reimbursement or to be included in the public insurance benefits package.

Some countries define medical devices for reimbursement, using a health technology assessment process and then consider the devices selected to be part of the “positive list”. Other countries have very established protocols and lists of medical devices for emergencies procedures like handling an H1N1 or Ebola outbreak. The choices of interventions and medical devices on the list are usually made by a national multidisciplinary committee. The process should be evidence-based, transparent, and according to general practices on health technology assessment, as recommended by the public agencies or units members of the International Network of Agencies for Health Technology Assessment (INAHTA)ⁱ, among other HTA networks.

In general, the classification of the medical devices should be well-structured to make consulting the list easy and straightforward; unfortunately WHO does not have a global nomenclature nor a classification of medical devices to support Member States in this matter. Due to the differences in nomenclature systems globally, some lists do include a reference to a national nomenclature and others to international ones, when used for procurement and hospital inventories where the most used nomenclature is the Universal Medical Device Nomenclature System (UMDNS)¹². Most countries have a website or catalogues or lists of approved medical devices to enter the national market. This approval is granted by the regulatory agency, and thus some of them use the Global Medical Device Nomenclature (GMDN)¹³. Some lists include links to technical specifications/characteristics of the selected item.

The Priority Medical Devices report from WHOⁱⁱ recommends the following methodology for development of useful lists of medical devices: (1) identify the disease burden of the target population, (2) select the associated WHO evidence-based clinical guidelines, (3) identify care pathways and protocols, (4) list medical devices according to the protocols and type of intervention (preventive, diagnostic, therapeutic or assistive), and (5) develop a list of medical devices needed to manage and treat the identified diseases.

Development of useful lists of medical devices for specific health care services is difficult as it demands expert knowledge on the use of the devices for different clinical interventions or health care facilities at various levels and

¹² <https://www.ecri.org/components/UMDNS/Pages/default.aspx>

¹³ <https://www.gmdnagency.org/>



settings. It is a very complex exercise and thus requires expertise, knowledge, time, and IT tools facilitating the task. To support low and middle income countries and help improve access to appropriate and safe medical devices, WHO and other non-governmental organizations publish lists of medical devices required for particular areas and interventions. Some examples are:

1. Lists organized by health care facilities:¹⁴

- Health Post: http://www.who.int/entity/medical_devices/innovation/health_post.xls?ua=1
- Health Centre: http://www.who.int/entity/medical_devices/innovation/health_centre.xls?ua=1
- District Hospital: http://www.who.int/entity/medical_devices/innovation/district_hospital.xls?ua=1
- Provincial Hospital: http://www.who.int/entity/medical_devices/innovation/provincial_hospital.xls?ua=1
- Specialized Hospital: http://www.who.int/entity/medical_devices/innovation/specialized_hospital.xls?ua=1

2. Lists featuring core medical equipment:

- http://www.who.int/medical_devices/publications/med_dev_core_equipt/en/

3. Lists organized by life course

- Medical devices for Essential interventions for Reproductive, Maternal, new born and Child Health: http://www.who.int/medical_devices/publications/interagency_med_dev_list/en/
- Ageing Population: http://www.who.int/medical_devices/publications/system_review_ageing/en/

4. Lists organized by disease

• Ebola:

- i. Interim list of medical devices:
http://www.who.int/entity/medical_devices/meddev_list_ebola_25nov_en.pdf
- ii. Personal protective equipment:
http://apps.who.int/iris/bitstream/10665/137410/1/WHO_EVD_Guidance_PPE_14.1_eng.pdf
- iii. Medical devices for Ebola organized by donation priority:
http://www.who.int/medical_devices/ppe_list_31mar2015EN.pdf

• Emergency kits:

- i. Interagency emergency kit:
<http://www.who.int/medicines/publications/emergencyhealthkit2011/en/>

5. Lists for health care in specialized units:

• Imaging:

- i. Imaging modalities:
http://www.who.int/diagnostic_imaging/imaging_modalities/en/
- ii. Manual of diagnostic ultrasound:
http://apps.who.int/iris/bitstream/10665/43881/1/9789241547451_eng.pdf

• Surgery

- i. WHO Generic Essential Emergency Equipment List:
<http://www.who.int/surgery/publications/s15982e.pdf>
- ii. Anaesthetic Infrastructure/Supplies:
<http://www.who.int/surgery/publications/s15983e.pdf>

• Laboratory:

- i. Laboratory Quality Management System:
http://apps.who.int/iris/bitstream/10665/44665/1/9789241548274_eng.pdf
- ii. Laboratory Biosafety Manual:
<http://www.who.int/csr/resources/publications/biosafety/Biosafety7.pdf>

¹⁴ Disclaimer: http://www.who.int/medical_devices/innovation/health_care_facility/en/index2.html

- **Blood transfusion**

- i. Essential items for blood transfusion in emergencies:

http://www.who.int/bloodsafety/transfusion_services/essential-items_bts.pdf

Further to the medical devices list for reproductive, maternal, and newborn health care, model lists of priority medical devices for non-communicable diseases are being developed by WHO. These lists will be available in the near future as it has been seen that they are required to target the needs of Universal Health Coverage in Member States.

3.6.2 Global facts

The Baseline Country Survey collected information about number and types of lists of medical devices that are officially used in the countries. The following four maps show the distribution of medical device lists for procurement or reimbursement (Fig. 3.6-1), for different types of health care facilities (Fig. 3.6-3), for specific procedures (Fig. 3.6-5), and for different diseases or situations (Fig. 3.6-6). Fig. 3.6-2 shows examples of lists of approved medical devices for procurement or reimbursement. Fig. 3.6-4 shows examples of national lists of medical devices for different types of health care facilities. An example of medical devices by health care facility in WHO working documents can be seen here:

http://www.who.int/medical_devices/innovation/health_care_facility/en/index1.html¹⁵

Fig. 3.6-7 shows examples of lists of health technologies for specific diseases or procedures.

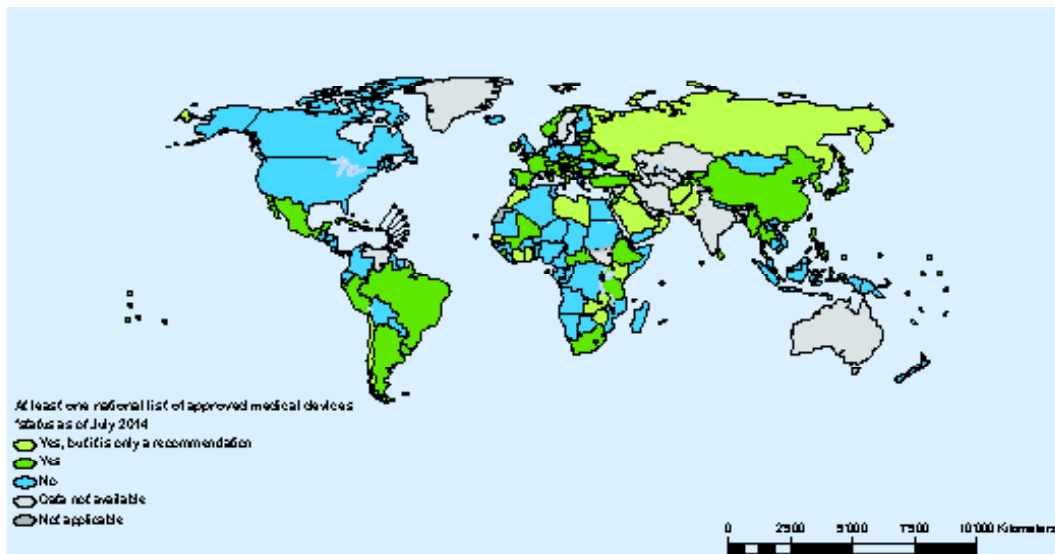


Fig. 3.6-1: Available national standards or recommended lists of medical devices for public procurement or reimbursement.

| Source | Name and link of list |
|--------|--|
| WHO | “Prequalified medical devices for immunization” http://apps.who.int/immunization_standards/vaccine_quality/pqs_catalogue/categorylist.aspx?cat_type=device |
| WHO | “Prequalified in vitro diagnostics products” http://www.who.int/diagnostics_laboratory/evaluations/PQ_list/en/ |
| Mexico | “List of basic surgical instruments and medical equipment” http://www.cenetec.salud.gob.mx/contenidos/biomedica/gequipamiento.html |

Fig. 3.6-2: Examples of lists of medical devices for procurement or reimbursement

¹⁵ The information here has not been reviewed by a committee of clinical experts and is work in progress. It must be adapted to the specific conditions or settings where they will be applied.

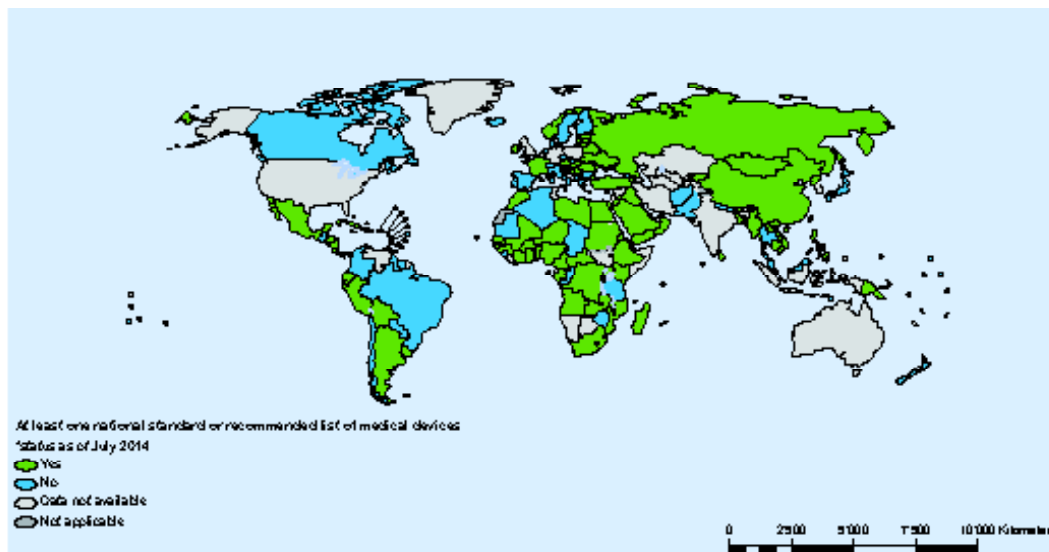


Fig. 3.6-3: Available national standards or recommended lists of medical devices for different types of health care facilities.

| Country | Link to list |
|-------------|--|
| Argentina | „Grillas de habilitacion categorizante“ http://www.msal.gov.ar/pngcam/grillas.htm |
| Belize | „Licensing & Accreditation Standards for Inpatient Health Facilities“ http://health.gov.bz/www/publications/quality-assurance/373-licensing-a-accreditation-standards-for-inpatient-health-facilities |
| El Salvador | „Norma disenyo y equipamiento casas salud“ http://asp.salud.gob.sv/regulacion/pdf/norma/Norma_diseno_y equipamiento_casas_salud.pdf |
| Estonia | „Haigla liikide nõuded“ https://www.riigiteataja.ee/akt/13252715 |
| Kyrgyzstan | “Emergency room acc. WHO recommendation” http://www.who.int/medical_devices/survey_resources/medical_devices_by_facility_kyrgyzstan.pdf |
| Latvia | „Noteikumi par obligātajām prasībām ārstniecības iestādēm un to struktūrvienībām“ http://likumi.lv/doc.php?id=187621 |
| Mexico | “Modelos de equipamiento” http://www.cenetec.salud.gob.mx/interior/modelos Equip.html |

Fig. 3.6-4: Examples of national lists of medical devices for different types of health care facility

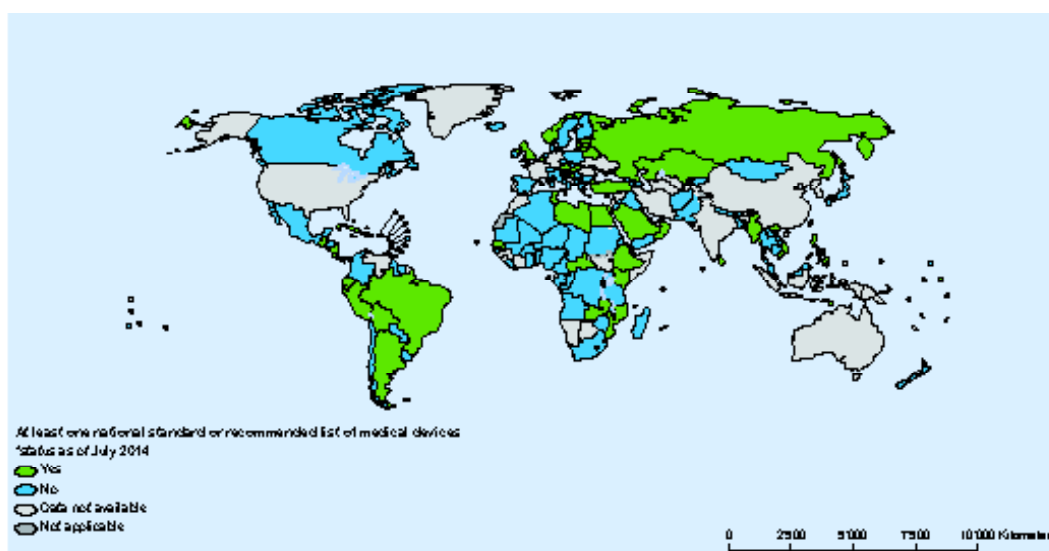


Fig. 3.6-5: Available national lists of medical devices for specific procedures.

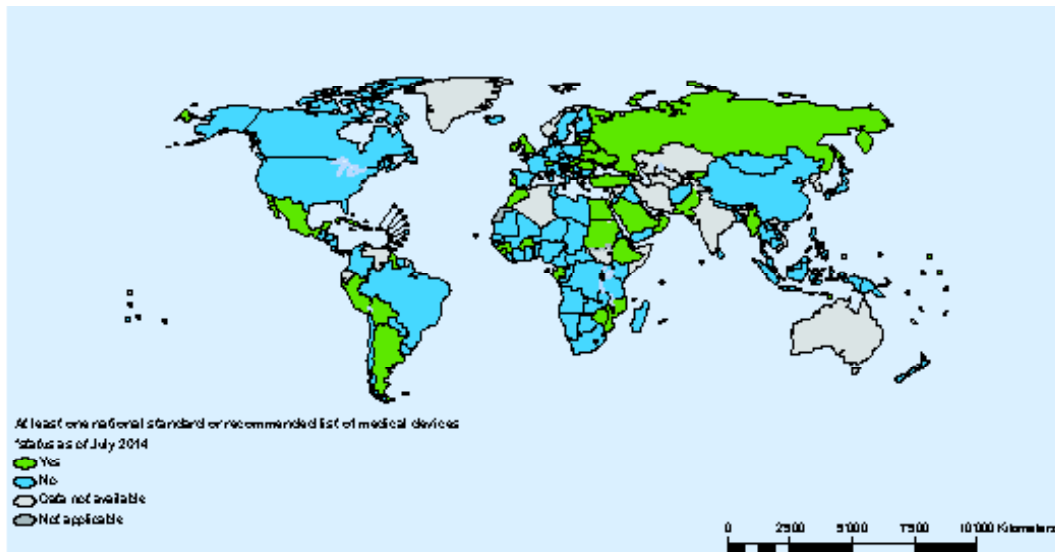


Fig. 3.6-6: Available national lists of medical devices for: communicable/non-communicable high burden diseases, injuries, or public health emergency situations.

| Source | Name and link to list |
|-------------|--|
| WHO | “Medical Devices for Ebola Outbreak” http://www.who.int/medical_devices/meddev_ebola/en/ |
| WHO | “Medical devices for life course: Interagency list of priority medical devices for essential interventions for reproductive, maternal, new born and child health” http://www.who.int/medical_devices/md_maternal_BOOK_May2016_D.pdf?ua=1 |
| El Salvador | „GUIA TECNICA PARA LA EVALUACION DE DAÑOS Y ANALISIS DE NECESIDADES DE SALUD EN SITUACIONES DE EMERGENCIAS Y DESASTRES“ http://asp.salud.gob.sv/regulacion/pdf/guia/Guia_edan_salud.pdf |
| Turkey | “Influenza Case Management Algorithm” http://www.grip.gov.tr/saglik-personeli-icin-bilgiler/282-influenza-vaka-yonetim-algoritmasi.html |

Fig. 3.6-7: Examples of lists of health technologies for specific diseases or procedures

In order to further illustrate the results for the different types of lists, selected facts and correlations are presented below.

List of approved medical devices for procurement or reimbursement:

The survey revealed that 98 countries do not have any national list of approved medical devices for procurement or reimbursement in the country (57% of 173 respondent countries). In addition, looking at the 75 countries that have a national list of approved medical devices for procurement or reimbursement, it shows that in 25% (20 countries) it is only a recommendation. Furthermore, 71% of lower-middle-income countries (29 out of 41 lower-middle-income respondents) do not have any national list of approved medical devices for procurement or reimbursement (see Fig. 3.6-8).

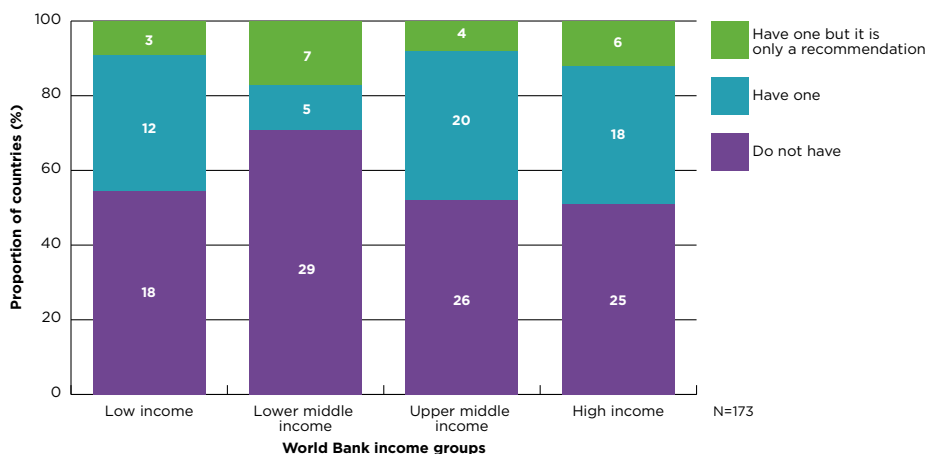


Fig. 3.6-8. Countries with national list of approved medical devices for procurement or reimbursement by World Bank income groups



Looking at the results by region, it can be observed that in the African Region around 62% do not have any national list of approved medical devices for procurement or reimbursement (27 out of 43 respondent countries; see Fig. 3.6-9). In the Region of the Americas more than 70% do not have any national list of approved medical devices for procurement or reimbursement (24 out of 34 respondent countries). On the other hand, 53% of the respondent countries in the European Region have national list of approved medical devices for procurement or reimbursement (26 out of 49 respondent countries).

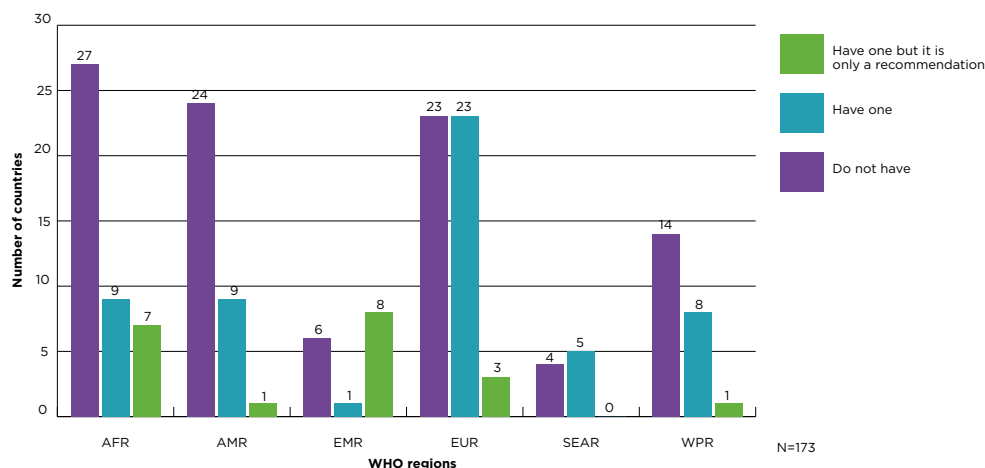


Fig. 3.6-9. Countries with national list of approved medical devices for procurement or reimbursement by WHO region

Lists of medical devices for different types of healthcare facilities:

In total, 93 Member States have recommended lists of medical devices for different types of health care facilities (59% of 158 respondent countries). In particular, it can be observed that in low- to upper-middle-income countries only one out of three does not have any list of medical devices for healthcare facilities (39 out of 115 respondent low- to upper-middle-income countries; see Fig. 3.6-10). However, in high-income countries 60% (26 of 43 respondent countries) do not have any list of medical devices for healthcare facilities. This difference is due to the different organization of national health systems with regard to the use of private, public, federal or state reimbursement policies.

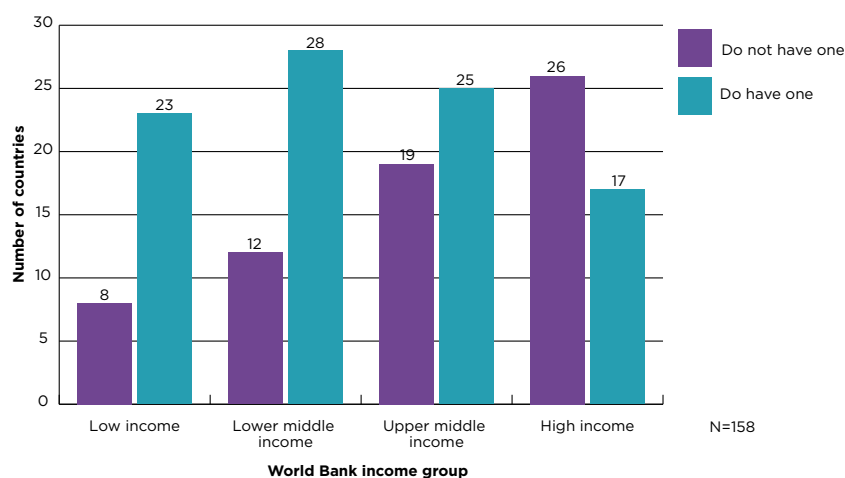


Fig. 3.6-10. Countries with lists of medical devices for different types of healthcare facilities for low- to middle-income WB groups

Looking into the statistics by WHO region, it can be observed that in the Eastern Mediterranean region, 85% of the countries have a recommended list of medical devices for different types of health care facilities (11 out of 13 respondent countries, see Fig. 3.6-11). In the African region, 70% of the countries have a recommended list of medical devices for different types of health care facilities (28 out of 40 respondent countries). On the other hand,

in the region of the Americas, only 42% of the countries have a recommended list of medical devices for different types of health care facilities (14 out of 33 respondent countries) while in the South-East Asia and Western Pacific regions, 56% (SEAR) and 57% (WPR) of countries have a recommended list of medical devices for different types of health care facilities.

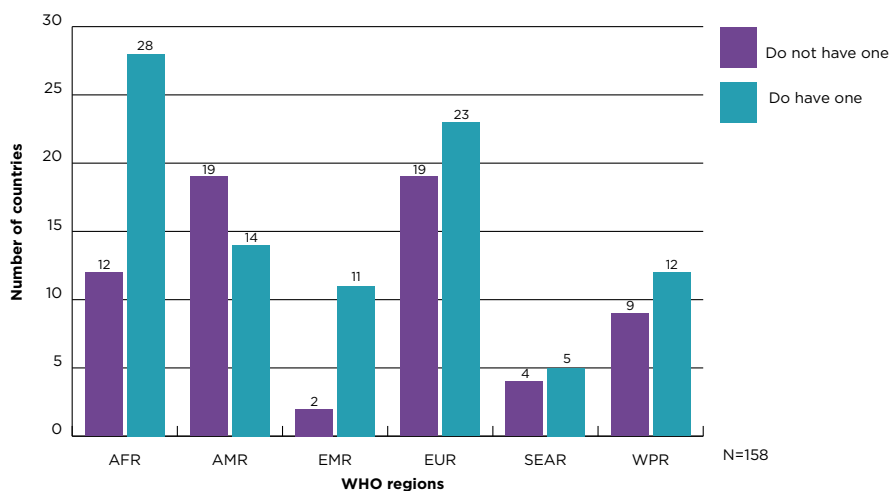


Fig. 3.6-11. Countries with lists of medical devices for different types of healthcare facilities by WHO region

Lists of medical devices for different procedures:

A total of 104 of the 154 respondent member states have recommended lists of medical devices for different procedures (67% of respondent countries). However, 42% of the lower middle income countries do not have any lists (15 out of 36 responding countries; see Fig. 3.6-12).

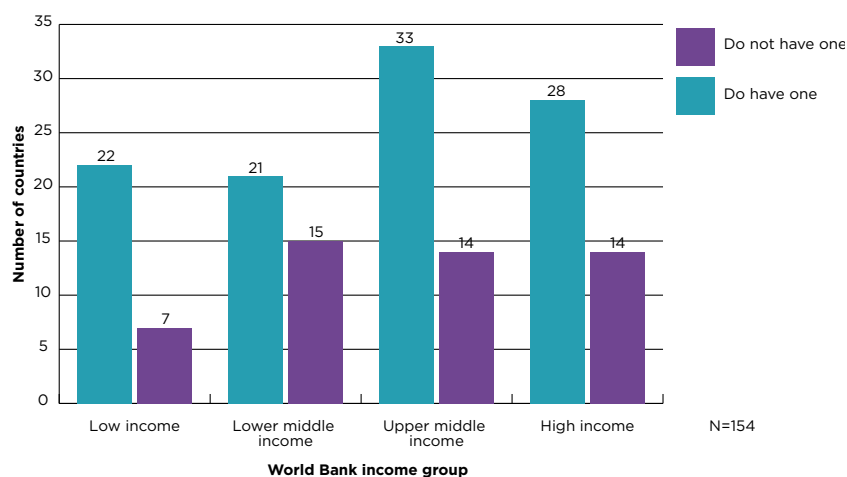


Fig. 3.6-12. Countries with recommended lists of medical devices for different procedures by WB income group



Lists of medical devices for different diseases or situations:

From 164 respondent countries, 53 have recommended lists of medical devices for high burden diseases (communicable or non-communicable), or injuries or health emergency situations. Of these, only 19% have one list of medical devices for each (see Fig. 3.6-13).

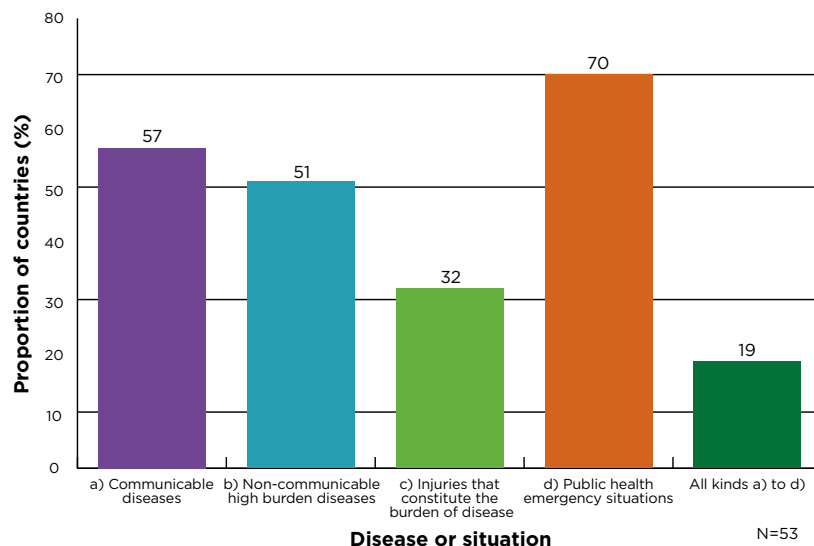


Fig. 3.6-13: Countries with recommended lists of medical devices for different diseases or situations

3.6.3 Further readings

For more information about national lists of medical devices, please refer to the following documents and websites:

Documents:

- Medical devices: managing the mismatch – an outcome of the Priority Medical Devices projectⁱⁱ.
- Development of Medical Device Policies, WHO medical device technical series .
- Interagency list of medical devices for essential interventions for reproductive, maternal, newborn and child healthⁱⁱⁱ.

Websites:

- The International Network of Agencies for Health Technology Assessmentⁱ (<http://www.inahta.org/>).

Endnotes:

- <http://www.inahta.org/>
- Medical devices: managing the mismatch – an outcome of the Priority Medical Devices project. Geneva: World Health Organization; 2010
- Development of Medical Device Policies, WHO medical device technical series, World Health Organization 2011.

3.7 Density of high-cost medical equipment

3.7.1 Introduction

Medical equipment is an integral part in the diagnosis and treatment of disease globally. In this chapter, the density of specific selected high-cost medical equipment was considered as an indicator of availability of specialized technologies. All of these technologies are costly, require special installation and infrastructure, and specialized human resources. Other organizations, like the International Atomic Energy Agency (IAEA) and the Organization for Economic Cooperation and Development (OECD), are doing studies based on similar indicators.ⁱ The data presented in the following sections and graphics was collected by WHO, provided by the health ministries of the countries, and in the cases of radiotherapy equipment and computed tomography (CT), was complemented based on the directory of radiotherapy centres (DIRAC) information from IAEA.ⁱⁱ Future studies will monitor availability of other high cost technologies.

In this section, the purpose and mode of operation of the selected established highly-specialized medical devices are summarized. They can be sorted into one of two groups:

1. *Medical imaging equipment* is used to reveal physical and physiological conditions inside the human body, mainly in the fields of screening, diagnostics, surgical planning, and image-guided surgery. Highly specialized medical imaging technology generates 3-D body images. Modern techniques allow for the manipulation of the resulting data to optimally visualize the desired details, for example, using different viewing angles, zoom levels, and colour highlighting.
2. *Radiotherapy equipment* makes use of ionizing radiation, mainly to control or destroy malignant cells in cancer treatment.

Medical imaging equipment:

- **Computed tomography (CT)**

CT is a three-dimensional imaging method using x-rays to scan body areas slice-by-slice. The technique is based on the fact that an x-ray travelling through the body is absorbed to a different degree by the different anatomical structures. The x-rays are created and sent out by an x-ray generator and captured by a detector on the other side of the body. A common radiograph produces two-dimensional images that represent a superposition of the internal structures. In contrast, CT produces images with minimal superposition. Here, the x-ray tube is moved around the body on a single axis of rotation, and mathematical algorithms are used to reconstruct a series of cross-sectional image slices out of the one-dimensional absorption profiles. In a second step, a 3-D image is generated. CT is well suited to depict anatomical details and is therefore employed for detection of tumours, haemorrhage and bone trauma. Furthermore, the use of contrast agents enables the visualization of blood vessels and the gastrointestinal tract. Common clinical applications are brain (with or without contrast and perfusion study)/cranial/head/neck CT, CT myelography, chest CT, abdominal CT, pelvic CT, CT urography, CT colonography, and cardiac CT.

The main disadvantage of CT imaging is the required radiation dose that is higher than for plain x-ray radiography. Therefore, especially for pregnant women and small children, CT imaging should not be performed without a careful consideration of risks and benefits.

- **Mammography**

“Breast cancer is the top cancer in women both in the developed and the developing world. Early detection to improve breast cancer outcome and survival remains the cornerstone of breast cancer control.”¹⁶ The detection can either be done by manual breast examination or by mammography, which is a two-dimensional x-ray imaging method used for breast cancer diagnostic, surveillance, and for the procedure of tumour marking. It employs low energy x-rays specifically for the imaging of the soft breast tissue. In order to improve the image

¹⁶ <http://www.who.int/cancer/detection/breastcancer>



quality and decrease the required radiation dose, the breast is carefully compressed between x-ray tube and detector of the mammography unit, which reduces the thickness of the tissue to be penetrated. The result is a 2-D image showing the superposed absorption profiles of the breast tissue. The five-year survival rate for breast cancer that is detected early (through either early diagnosis or screening¹⁷) is over 80%.

- **Gamma camera**

A gamma camera (also called Anger camera or scintillation camera) is used in nuclear medicine for the visualization of physiological or biochemical functions in the body. Here, radionuclides are injected, inhaled, or ingested, and the emitted gamma photons are captured by a crystal in the camera. In order to visualize different organ systems, radionuclides are attached to suitable molecules that are transported to the region of interest in the normal metabolism process. Using the localization and density of the captured photons, a 2-D image showing the radiation activity in the regions of the body where the radionuclides accumulated is computed.

- **Single Photon Emission Computed Tomography (SPECT)**

SPECT is an imaging method for functional diagnostics in nuclear medicine. The SPECT units consist of one or more gamma cameras rotating around the body to detect the photons emitted by ingested gamma emitting radionuclides. Based on the photons captured from different spatial directions, mathematical algorithms compute a series of cross-sectional body images. In a second step, a 3-D image is generated that shows the distribution of the radionuclides within the organs where they accumulated. SPECT is used to locate exact position of physiological abnormalities, commonly in cardiology and functional brain diagnostics.

- **Positron-Emission Tomography (PET)**

PET is an imaging method for functional diagnostics in nuclear medicine using positron-emitting radionuclides. The positron radiation provokes the emission of a pair of gamma photons moving in opposite directions. The photons are captured by a ring of stationary detectors placed around the body. Based on the time-gap in the arrival of two photons belonging to the same pair, the spatial localization of the radionuclides can be reconstructed. Similar to SPECT, mathematical algorithms use this information to compute a 3-D image that shows the distribution of the radionuclides in the organs. Compared to SPECT, PET produces images with greater resolution. PET is able to visualize functional biochemical processes and is commonly employed in clinical oncology and neuroimaging.

- **Magnetic resonance imaging (MRI)**

MRI is a 3-D imaging method well suited for soft tissue diagnostics. Other than CT-based methods, MRI units do not use ionizing radiation but produce strong magnetic fields that excite hydrogen atoms (present in water molecules) in the body. When the hydrogen atoms return to their equilibrium state, they emit a radio frequency signal that is captured by detectors of the MRI unit. The duration of that signal depends on the type of organ tissue; this is used to distinguish and represent different organs with good tissue contrasts. The localization of the source of the signals is realized through the superposition of additional gradient magnetic fields. Clinical applications include brain MRI with diffusion/perfusion studies, spinal MRI, abdominal MRI to assess liver, spleen, and kidneys, MR cholangiography, neck MRI, MR angiography, cardiac MRI, MRI for joints, muscles, and bone disorders, chest/mediastinal MRI as well as image-guided interventional procedures.¹⁷

MRI is the only imaging method presented here that does not use ionizing radiation and therefore does not pose an exposure risk to the patient. However, MRI is not suited for patients carrying magnetic implants or that are claustrophobic, as the patient needs to be placed in a narrow gantry in the middle of the magnetic fields.

¹⁷ http://www.who.int/diagnostic_imaging/imaging_modalities/dim_magresimaging/en/

Radiotherapy equipment:

Radiotherapy is a method used mainly in cancer treatment in which malignant cells are controlled or destroyed by applying ionizing radiation. This can be done either by direct contact of the radioactive substance with the malignant cells (called brachytherapy) or by irradiation of the cells through an external source (teletherapy).

For teletherapy, two different types of radiation generators are used: telecobalt units and linear accelerators.

- **Telecobalt unit**

A telecobalt unit is a container made of wolfram or lead filled with radioactive cobalt. The emitted x-rays leave the container through a set of holes that are arranged in a fan-shaped array. This leads to intersection of the different radiation beams on an external point outside the container. The patient is positioned next to the container in a way that the intersection of the beams lies inside the tumour in order to amplify irradiation to the malignant cells and prevent the surrounding tissue from damage at the same time.

- **Linear accelerator**

A medical linear accelerator generates high energy x-rays by accelerating electrons and then colliding them with a heavy metal target. In order to effectively kill cancer cells without damaging the healthy tissue around them, the tumour is irradiated by several x-ray sets coming from different spatial directions and superposing at the exact location of the tumour. This treatment demands a careful irradiation planning based on the results of various imaging modalities. In contrast to telecobalt units, linear accelerators can produce higher energy radiation, are more flexible and accurate and can be powered off when not in use. On the other hand, telecobalt units are simpler to maintain.

The regular employment of highly specialized medical equipment is demanding for several reasons: costs of acquisition, maintenance and disposal are comparatively high; safe and appropriate use requires a superior level of training; and the environment for effective installation and functionality has to meet clearly defined standards (further description is provided for example in the IAEA human health series^{iv}).

Moreover, medical equipment employing nuclear medicine such as the gamma camera, SPECT, PET, telecobalt units and linear accelerators as well as medical equipment employing x-rays need to be applied with the utmost care to prevent damage to the patient and healthcare worker from radiation exposure. Therefore, the equipment must be operated and handled by highly trained personnel only.

3.7.2 Global facts

The Baseline Country Survey collected information about the type and number of highly specialized equipment in the countries. It should be noted that many countries did not provide data. The following maps represent the data received from ministries of health including both the private and public sector, and the density was calculated considering total population.

In the case of the mammography units, the denominator comprises women between 50 to 69 years old, following the suggested screening age.ⁱⁱⁱ It should be noted that every country defines different screening ages, and thus the one used here is just a global reference.

The following five maps show the distribution and number of CT units (Fig. 3.7-1), mammography units (Fig. 3.7-2), gamma cameras (Fig. 3.7-3), PET units (Fig. 3.7-4), and MRI units (Fig. 3.7-5).

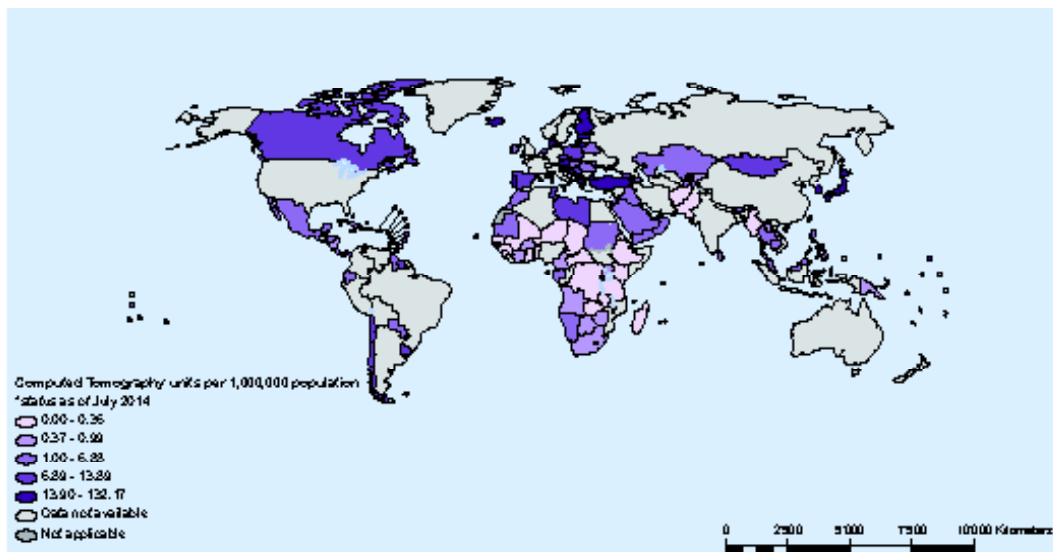


Fig. 3.7-1. CT units per million population

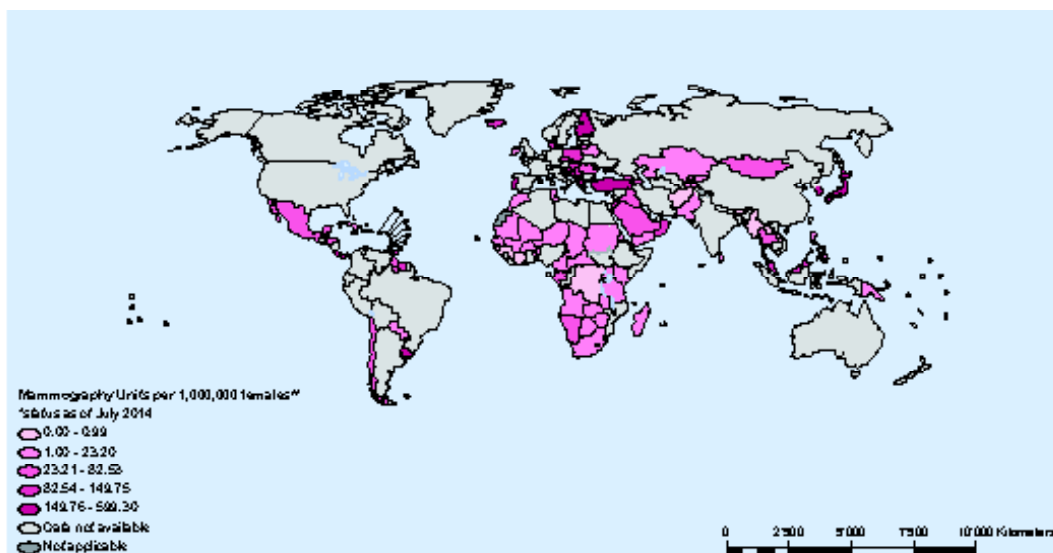


Fig. 3.7-2. Mammography units per million females between 50-69 years old

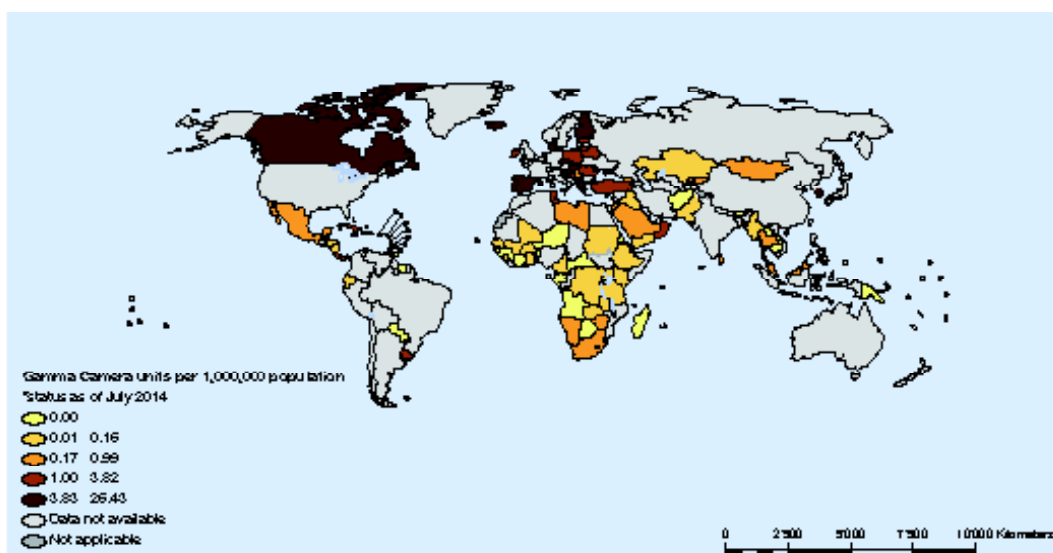


Fig. 3.7-3. Gamma cameras per million population

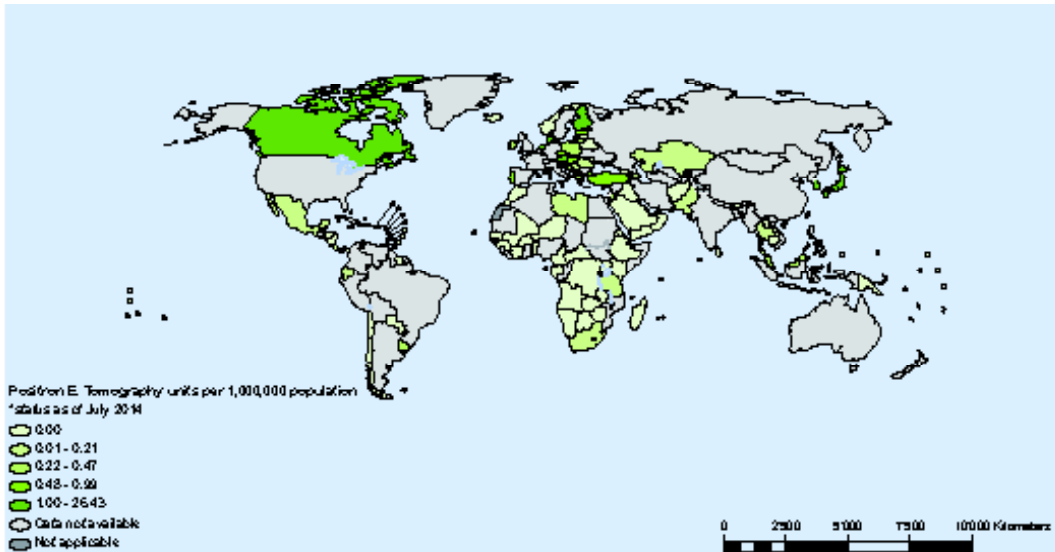


Fig. 3.7-4. PET units per million population

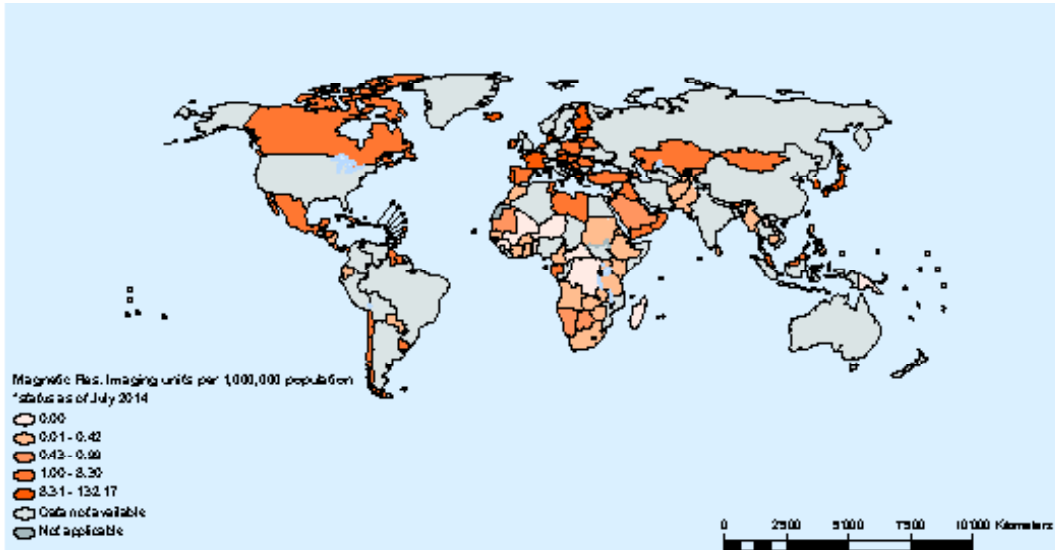


Fig. 3.7-5. MRI units per million population

In the following three maps, the information provided to WHO by the ministries of health was complemented by data from the DIRAC database from IAEA.ⁱⁱ The maps show the distribution and number of linear accelerator units (Fig. 3.7-6), telecobalt units (Fig. 3.7-7), and radiotherapy units (Fig. 3.7-8).

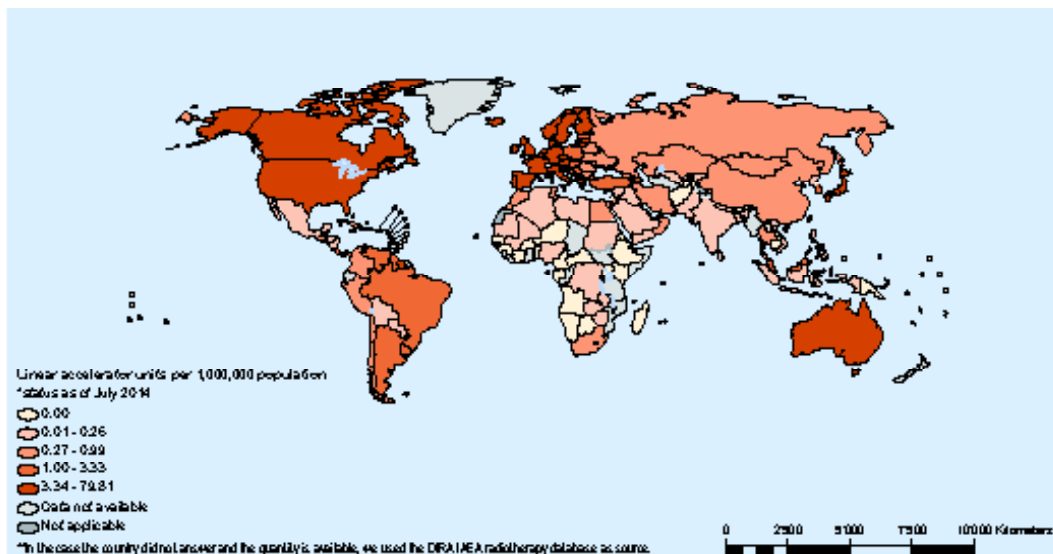


Fig. 3.7-6. Linear accelerator units per million population

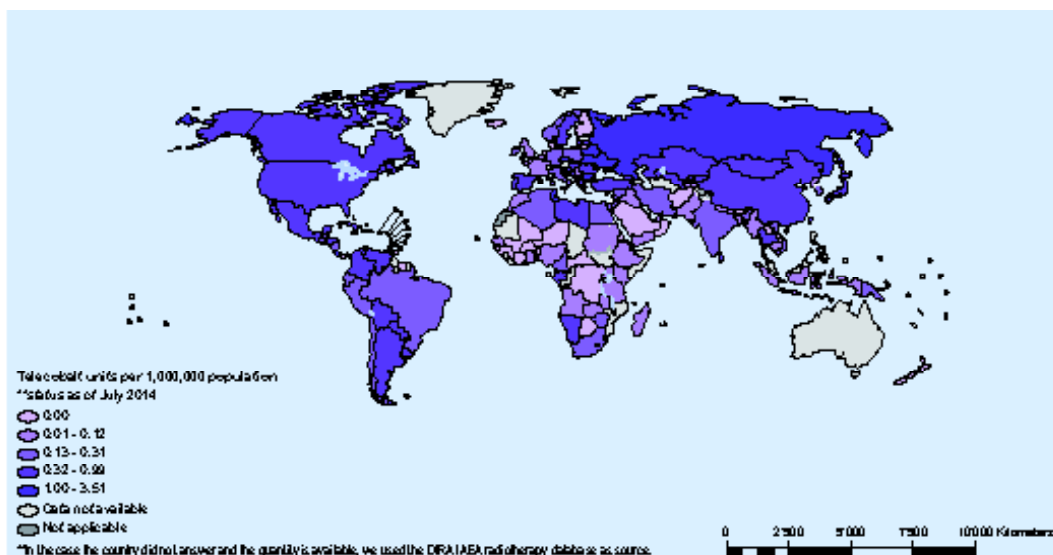


Fig. 3.7-7. Telecobalt units per million population

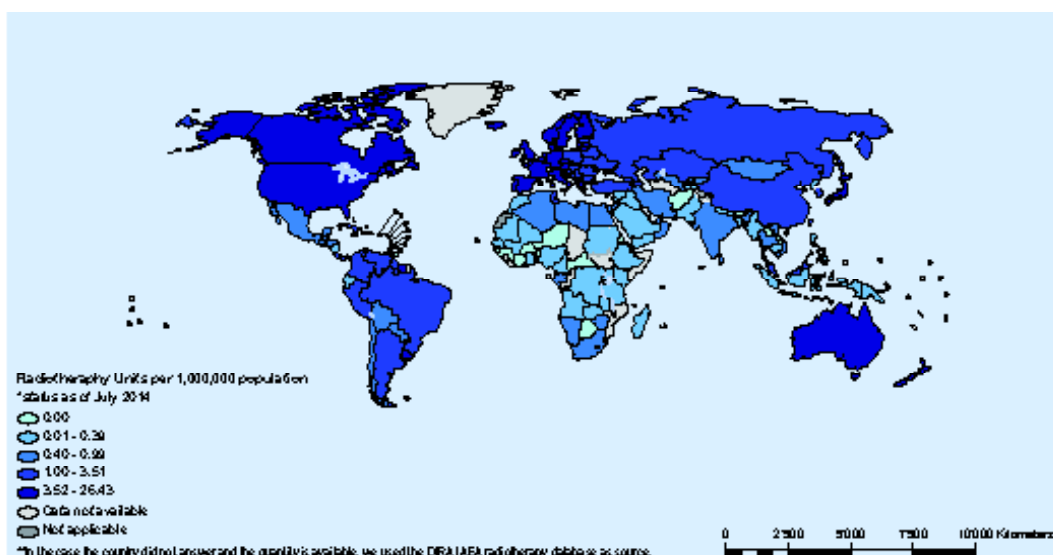


Fig. 3.7-8. Radiotherapy units per million population

Looking closer at the results yields the following facts:

On average, around 10% of countries have at least one PET scanner, 33% have at least one linear accelerator, 54% have at least one MRI unit, and 70% have at least one CT unit per million population (based on an average of 121 (116-135) responding countries for each equipment type, see Fig. 3.7-9). Sometimes the differences are huge: for example only 14% of the respondent low-income countries have at least one CT equipment per million inhabitants as opposed to 100% of responding high-income countries.

The higher the World Bank income group level, the higher is the proportion of countries with at least one specialized high technology medical equipment per million population for all seven selected medical equipment types. Looking at the WHO regions, American and European regions have the highest proportion of countries with at least one specialized high technology medical equipment per million population for all seven selected medical equipment types, and African and South-East Asia regions have the lowest corresponding proportion of countries (based on an average of 121 (116-135) responding countries for each equipment type).

| * | MRI | CT | PET | GC NM | MAM | LA | TU | RT |
|---|-----|------|-----|-------|------|-----|-----|-----|
| World Bank income classification | | | | | | | | |
| Low | 0% | 14% | 0% | 0% | 76% | 0% | 0% | 0% |
| Lower-middle | 30% | 60% | 4% | 8% | 79% | 7% | 7% | 17% |
| Upper-middle | 70% | 88% | 3% | 29% | 97% | 29% | 14% | 45% |
| High | 92% | 100% | 29% | 87% | 100% | 79% | 13% | 82% |
| Average | 54% | 70% | 10% | 33% | 89% | 33% | 9% | 40% |
| WHO region | | | | | | | | |
| EMR | 62% | 85% | 9% | 25% | 92% | 8% | 8% | 15% |
| EUR | 89% | 97% | 20% | 79% | 100% | 72% | 13% | 86% |
| AMR | 64% | 88% | 5% | 33% | 100% | 33% | 18% | 48% |
| AFR | 11% | 24% | 3% | 3% | 85% | 0% | 3% | 3% |
| SEAR | 50% | 80% | 0% | 0% | 60% | 25% | 20% | 20% |
| WPR | 41% | 65% | 15% | 8% | 69% | 25% | 0% | 25% |
| Average | 54% | 70% | 10% | 33% | 89% | 33% | 9% | 40% |
| Total respondent countries | 132 | 135 | 116 | 118 | 123 | 120 | 117 | 125 |

* Magnetic Resonance Imaging (MRI); Computed Tomography (CT Scanner); Positron Emission Tomography (PET Scanner); Gamma Camera or Nuclear Medicines (GC NM); Mammography Units (MAM); Linear Accelerator (LA); Telecobalt Unit (TU); and Radiotherapy (RT)=(LA+TU).

** All medical equipment densities are per million population except mammography units, which are per million females aged between 50-69 years old. Proportions are indicated from respondent countries only.

Fig. 3.7-9. Proportion of countries which have at least one unit of medical equipment per million population for selected specialized high technology equipment by World Bank income group and WHO region**

In Fig. 3.7-10, for each specialized equipment type, the proportion of respondent countries without any high-cost medical equipment is given, sorted by World Bank income group as well as by WHO region. For all specialized equipment, there is a clear trend: fewer countries from the upper-middle and high-income group do not have any unit at all than from the low- and lower-middle-income group. While in all income groups most countries seem to be equipped with at least one CT-unit per million inhabitants, low- and lower-middle-income countries have by far the highest proportion without any PET unit (95% and 92% respectively).

Looking at the matter by WHO regions shows that the proportion of countries having no PET unit is highest in the African region (90%) and lowest in the European region (31%). On the other hand, the proportion of countries without any CT unit is similarly low in all WHO regions (0%-8%) but the Western-Pacific region where it is at 24%.



| * | MRI | CT | PET | GC NM | MAM | LA | TU | RT |
|---|-----|-----|-----|-------|-----|-----|-----|-----|
| World Bank income classification | | | | | | | | |
| Low | 40% | 11% | 95% | 54% | 16% | 86% | 61% | 52% |
| Lower-middle | 27% | 10% | 92% | 42% | 21% | 43% | 33% | 31% |
| Upper-middle | 10% | 5% | 57% | 37% | 3% | 37% | 35% | 25% |
| High | 5% | 0% | 35% | 10% | 0% | 9% | 47% | 6% |
| Average | 18% | 6% | 65% | 35% | 9% | 39% | 43% | 26% |
| WHO region | | | | | | | | |
| EMR | 0% | 0% | 55% | 8% | 8% | 8% | 31% | 8% |
| EUR | 3% | 0% | 31% | 6% | 0% | 8% | 31% | 3% |
| AMR | 16% | 4% | 77% | 43% | 0% | 33% | 41% | 26% |
| AFR | 31% | 8% | 90% | 52% | 12% | 80% | 53% | 47% |
| SEAR | 0% | 0% | 75% | 40% | 20% | 50% | 40% | 40% |
| WPR | 47% | 24% | 77% | 77% | 31% | 63% | 62% | 50% |
| Average | 18% | 6% | 65% | 35% | 9% | 39% | 43% | 26% |
| Total respondent countries | 132 | 135 | 116 | 118 | 123 | 120 | 117 | 125 |

* Magnetic Resonance Imaging (MRI); Computed Tomography (CT Scanner); Positron Emission Tomography (PET Scanner); Gamma Camera or Nuclear Medicines (GC NM); Mammography Units (MAM); Linear Accelerator (LA); Telecobalt Unit (TU); and Radiotherapy (RT)=(LA+TU).

** All medical equipment densities are per million population except mammography units which are per million females aged between 50-69 years old. Proportions are indicated from respondent countries only.

Fig. 3.7-10. Proportion of countries without any unit of selected specialized high technology equipment by World Bank income group and WHO region**

To complement the findings of the Baseline Country Survey, the following section presents additional information collected by WHO on global distribution of medical equipment: in 2013, WHO did a survey called “Non-Communicable Diseases Country Capacity Survey”. It contained a set of questions regarding the existence of six essential procedures¹⁸ for the WHO Package of Essential Noncommunicable (PEN) disease interventions for primary health care.¹⁹ Five of these essential procedures rely on the availability of specific medical technologies. The survey results indicate that more than half of the low- and lower-middle-income countries have poor to medium availability of these technologies while for high-income countries the availability of at least 4 out of 5 technologies is 92% (see Fig. 3.7-12).

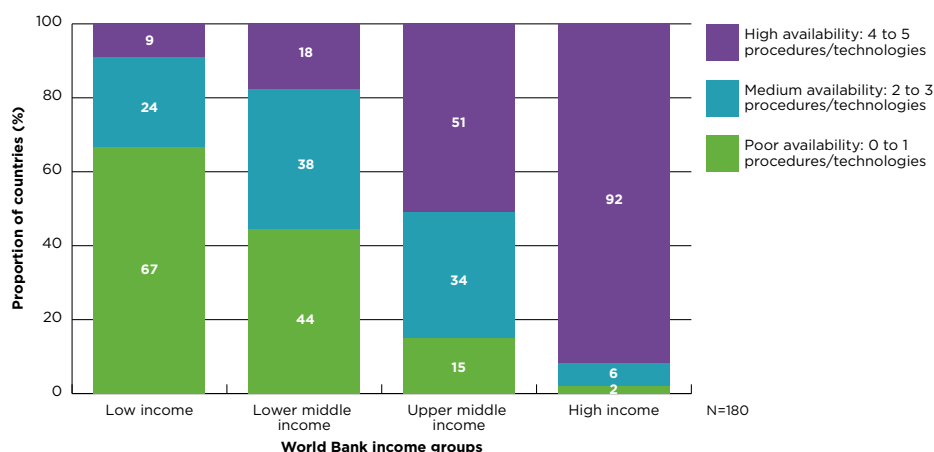


Fig. 3.7-12. Percentage of countries with availability of essential selected NCD procedures/tests relying on specific medical devices in the public health sector by World Bank income group based on 180 respondent countries (numbers from WHO Global Health Observatory²⁰)

18 Set of five selected NCDs essential procedures/tests related to the following technologies: radiotherapy, peak flow measurement, electrocardiogram, mammogram and colonoscopy.

19 http://www.who.int/nmh/publications/essential_ncd_interventions_lr_settings.pdf

20 www.who.int/gho

To give an example of the possible consequences, Fig. 3.7-13 links this information to cervical cancer mortality: cervical cancer age-standardized mortality per 100,000 females is higher when the HDI is lower.²¹ This seems to be due to the fact that the availability of essential NCDs-related procedures/tests including cervical cytology is higher when the HDI of the country is higher.

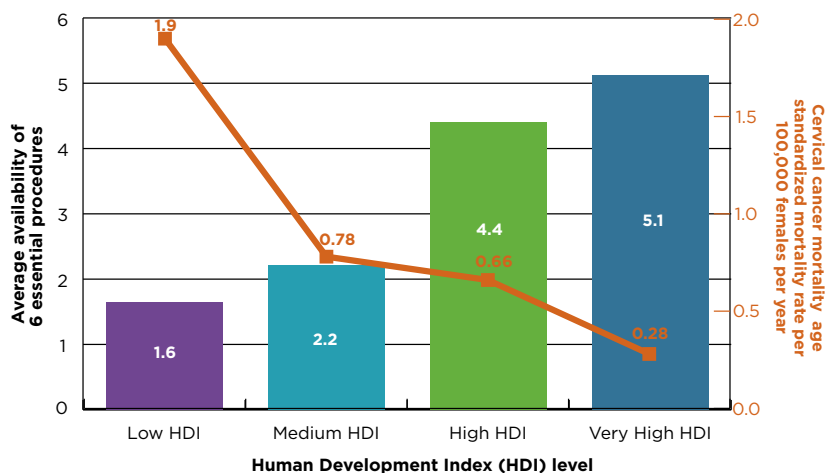


Fig. 3.7-13. Availability of five essential NCDs-related procedures/tests, and cervical cancer age-standardized mortality rates by Human Development Index (HDI) groups

3.7.3 Further reading

For more information about density of high-cost medical equipment, please refer to the following documents and websites:

Documents:

- WHO position paper on mammography screening, World Health Organization 2015ⁱⁱⁱ
- IAEA Human Health Series^{iv}

Websites:

- OECD data: Health equipment (<https://data.oecd.org/healtheqt/magnetic-resonance-imaging-mri-units.htm>)

Endnotes:

- <https://data.oecd.org/healtheqt/magnetic-resonance-imaging-mri-units.htm>
- <http://www.naweb.iaea.org/nahu/dirac/>
- WHO position paper on mammography screening. WHO Library Cataloguing-in-Publication Data. World Health Organization 2014.
- <http://www-pub.iaea.org/books/iaeabooks/series/140/human-health-series>

²¹ THE GLOBOCAN PROJECT, <http://globocan.iarc.fr>



4

Regional facts
and country
profiles

4.1 Introduction

As stated in previous chapters, after the World Health Assembly passed resolution WHA 60.29 (May 2007), WHO determined the key areas in which to support the development of health technology programme in regions and countries, and determined to share data, information, and knowledge among Member States facilitating decision making on a national, regional and global level.

This chapter is organized in six sections containing facts and country profiles for each of the official WHO regions: African, Americas, Eastern Mediterranean, South-East Asia and Western Pacific, as well as the 177 survey respondents' Member States (in alphabetical order)²².

Regional facts and Fig.s were obtained with the same sources and procedure as explained in section 3.0. However, country profiles were obtained from the extracted, cleaned data and information of the Baseline Country Survey of Medical Devices (see section 3.1.2) structured according to ten selected key topics (as explained in section 2.2), and representative country indicators extracted from selected databases (see Annex for indicators and sources). Participating countries are shown in Fig. 4.1.

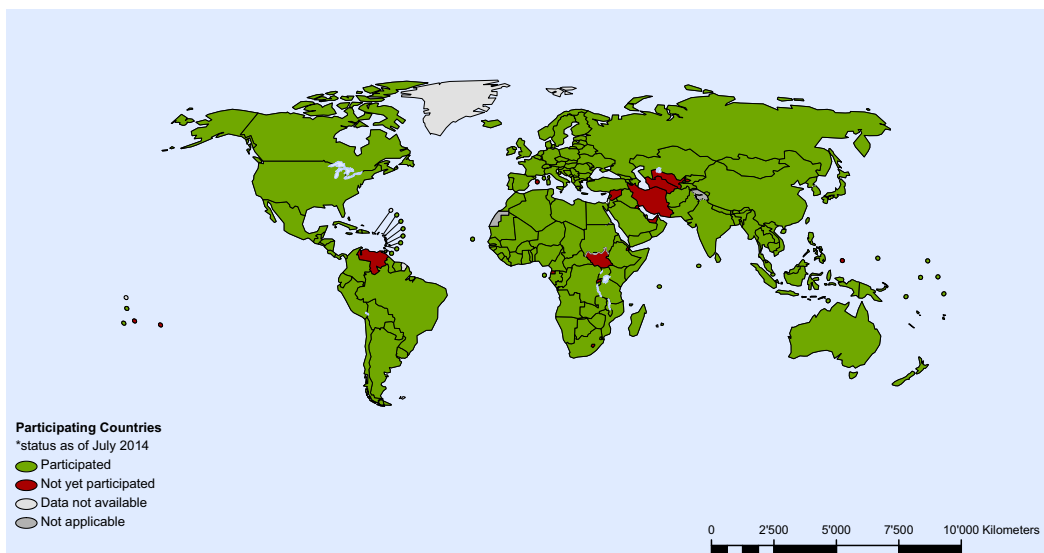


Fig. 4.1. Baseline Country Survey on Medical Devices, worldwide participation

²² See annex for lists of corresponding regions and countries.



4.2 African Region facts and country profiles

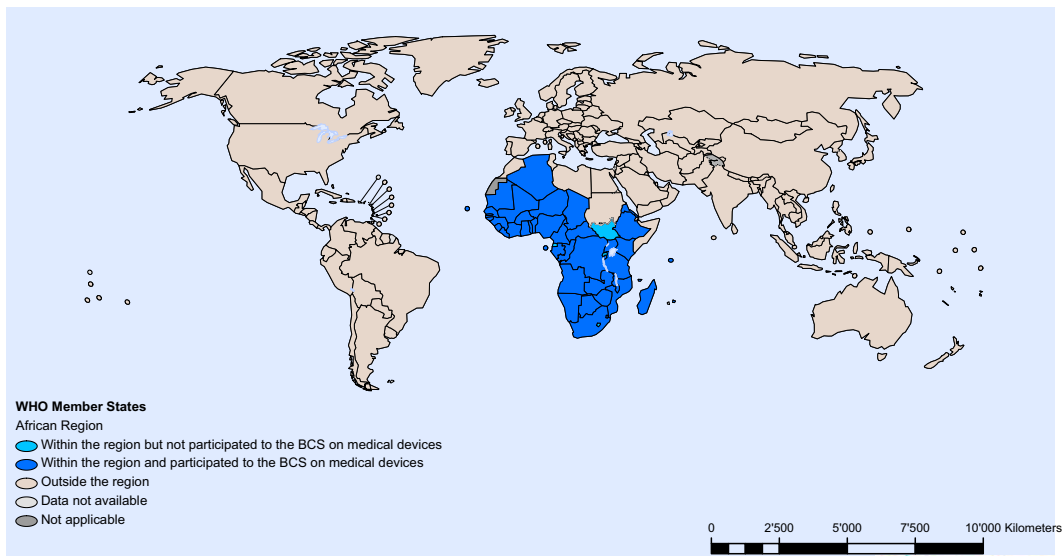


Fig. 4.2-1. Baseline Country Survey on Medical Devices African Region participation

Participation: The African Region’s survey participation was 91% (43/47). Participating countries are shown in Fig. 4.2-1.

National policy on health technology: Almost 2 of 3 respondent countries (62%: 26/43) do not have a Health Technology (HT) policy. However for more than the half of the countries which have a HT policy (13/17) it is part of the national health programme.

Regulatory agency:²³ 43% of the AFR Member States (20/47) have a regulatory authority responsible for medical devices.

National health technology assessment unit:²⁴ 33% of the respondent countries (5/15) have a national agency/unit/committee that produces Health Technology Assessment (HTA) reports for the Ministry of Health.

National health technology management units: 84% of the respondent AFR states (36/43) have a national unit which technically manages medical devices. Of these countries, 97% (35/36) have a national unit in charge of technical specifications development for procurement process, 94% (34/36) have a unit in charge of planning of medical devices allocation; and 75% (27/36) have a unit that supports user/training application of medical devices (Fig. 4.2-2).

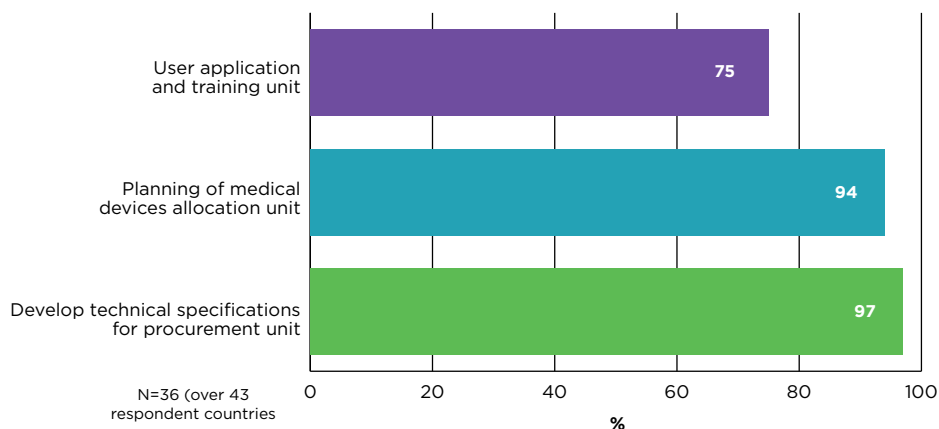


Fig. 4.2-2. Proportion of AFR countries having different types of health technology units (percentages taken from countries that have at least one health technology management national unit)

²³ Data obtained from the WHO Regulatory Status desk survey, May 2016.

²⁴ Data obtained from WHO 2015 Global Survey on HTA by National Authorities.

Medical device nomenclature system: Only 28% of the respondent AFR states (12/42) have an official nomenclature system for medical devices. The most used type of nomenclature is UMDNS only with 25% (3/12) of the countries having an official nomenclature (Fig. 4.2-3).

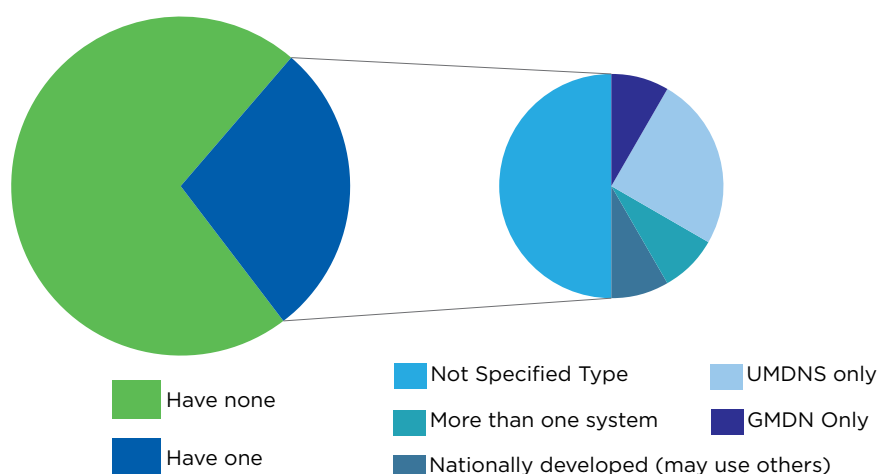


Fig. 4.2-3. Proportion of AFR countries with official nomenclature system for medical devices and their corresponding type (percentages taken from all respondent countries)

Medical device incorporation: 50% of the respondent AFR states (21/42) have national guidelines, policies or recommendations on the procurement of medical devices. In total, 72% of the respondent states (31/43) carry out the procurement of medical devices at national level; however 47% of the respondent states (20/43) do not have recommended technical specifications of medical devices to support procurement or donations.

Inventory and maintenance: 71% of the respondent AFR states (27/38) have an available inventory for medical devices. Of those countries, 85% (23/27) have a national inventory for medical equipment.

Lists of medical devices: 70% of the respondent AFR states (28/40) have some national standards or recommended lists of medical devices for different types of healthcare facilities. A total of 79% of the respondent states (30/38) have national list(s) of recommended medical devices for specific procedures, and 22% of the respondent states (9/41) have national lists of recommended medical devices for high burden diseases or injuries or health emergency situations.

Healthcare facilities: Only 17% of the respondent AFR countries have at least one district/rural hospital per 100 000 population, and 6% of the respondent countries have a least one specialized tertiary level hospital per 100 000 population. Therefore, the regional densities of district hospitals, provincial hospitals and regional/specialized/teaching and research hospitals per 100 000 population are among the lowest of the six WHO regions (Fig. 4.1).

| Healthcare facility | Have at least one per 100,000 pop. (%) | Number of responding countries | Regional Density per 100,000 pop. |
|--|--|--------------------------------|-----------------------------------|
| Health posts | 90% | 29 | 8.58 |
| Health centre | 74% | 35 | 3.77 |
| District/Rural hospitals | 18% | 34 | 0.59 |
| Regional/ Specialized/ Teaching and Research hospitals | 6% | 33 | 0.15 |

Fig. 4.2-4. Proportion of AFR countries and regional densities regarding existence of healthcare facility units (percentages taken from all respondent countries)



Medical equipment: More than 75% of the respondent countries do not have at least one CT unit per million population, but more than 85% of the respondent countries have a least one mammograph per million population. Regarding radiotherapy units, the density is 0.1 per million population. The regional density of medical high technology equipment per million population in this region is the lowest in the world for all seven surveyed high cost/high technology medical devices (see Fig 4.2.5).

| Medical equipment | Have at least one unit per 1,000,000 pop. (%) | Number of responding countries | Regional density per 1,000,000 pop. |
|--|---|--------------------------------|-------------------------------------|
| Magnetic Resonance Imaging (MRI) | 11% | 35 | 0.1 |
| Computed Tomography (CT Scanner) | 24% | 37 | 0.4 |
| Positron Emission Tomography (PET Scanner) | 3% | 31 | 0.01 |
| Gamma Camera or Nuclear Medicine | 3% | 33 | 0.09 |
| *Mammographs | 85% | 34 | 0.32 |
| Radiotherapy Unit: Linear Accelerator (LA) | 0% | 30 | 0.05 |
| Radiotherapy Unit:Telecobalt Unit (TU) | 3% | 32 | 0.05 |
| Radiotherapy Unit (LA+TU) | 3% | 32 | 0.10 |

* Mammographs density is per 100,000 females aged between 50 and 69 years old, and the regional density per million females of the same age

Fig. 4.2-5. Proportion of AFR countries and regional densities regarding high technology equipment (percentages taken from all respondent countries)

List of country profiles for WHO African Region

| | | | |
|----------------------------------|-----|------------------------------|-----|
| Algeria | 98 | Kenya | 140 |
| Angola | 100 | Liberia | 142 |
| Benin | 102 | Madagascar | 144 |
| Botswana | 104 | Malawi | 146 |
| Burkina Faso | 106 | Mali | 148 |
| Burundi | 108 | Mauritania | 150 |
| Cabo Verde | 110 | Mauritius | 152 |
| Cameroon | 112 | Mozambique | 154 |
| Central African Republic | 114 | Namibia | 156 |
| Chad | 116 | Niger | 158 |
| Comoros | 118 | Nigeria | 160 |
| Congo | 120 | Sao Tome and Principe | 162 |
| Côte d'Ivoire | 122 | Senegal | 164 |
| Democratic Republic of the Congo | 124 | Seychelles | 166 |
| Eritrea | 126 | Sierra Leone | 168 |
| Ethiopia | 128 | South Africa | 170 |
| Gabon | 130 | Swaziland | 172 |
| Gambia | 132 | Togo | 174 |
| Ghana | 134 | Uganda | 176 |
| Guinea | 136 | Tanzania, United Republic of | 178 |
| Guinea-Bissau | 138 | Zambia | 180 |
| | | Zimbabwe | 182 |

Algeria



Country indicators

| | | | | | |
|---------------------------------|--------|---|-----|--------------------------------------|--------------|
| Population (000s)* | 39'208 | Life expectancy at birth (years) ^a | 72 | World Bank income group ^β | Upper-middle |
| Internet users (%) ^γ | 16.5% | Per capita total health expenditure (PPP Int \$) ^δ | 439 | GNI per capita (US\$) ^ε | 5'330 |



National policy on health technology

Health technology (medical device) national policy: Yes, but is not part of the National Health Program

Web site: —

Language(s): Français

MOH responsible for health technology policy implementation: Direction Générale de la pharmacie



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Ministère de la santé, de la Population et de la Réforme Hospitalière

Web site: www.sante.dz



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: Cabinet of Minister, MoH.

Web site: —

OTHER: Autorisation d'importation par les opérateurs privés

Unit/department: Sous direction de l'enregistrement des produits pharmaceutiques

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: —

National level procurement: Yes

Web site: —

DONATIONS

Policy or guideline: No

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ: —



Inventory and maintenance

Type of inventories available: —

Comments: —

Medical equipment management unit: No

National level = —

Regional level = —

Hospital level = —

Management software: No

Software and comments^λ: —

Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:Lists comments^λ: —

Lists available: No

Unit: —

Web site: —

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES OR SPECIFIC PROCEDURES: Lists available: —

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: —

Web site: —

Types:

| | | | |
|-----------------------|---------------------------|----------|------------------------------------|
| Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|-----------------------|---------------------------|----------|------------------------------------|



Healthcare facility

| | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | n/a | n/a | n/a | n/a |
| Health centre | n/a | n/a | n/a | n/a |
| District hospital | n/a | n/a | n/a | n/a |
| Provincial hospital | n/a | n/a | n/a | n/a |
| Regional hospital | n/a | n/a | n/a | n/a |



Medical equipment

| | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | n/a | n/a | n/a | n/a |
| Computerized Tomography Scanner | n/a | n/a | n/a | n/a |
| Positron Emission Tomography Scanner | n/a | n/a | n/a | n/a |
| Nuclear medicine | n/a | n/a | n/a | n/a |
| Mammograph* | n/a | n/a | n/a | n/a |
| Linear accelerator | n/a | n/a | n/a | n/a |
| Telecobalt unit (Cobalt-60) | n/a | n/a | n/a | n/a |
| Radiotherapy | n/a | n/a | n/a | n/a |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ:

Le MoH fait spécial attention aux dispositifs médicaux, comme il peut s'apprécier dans les arrêtés du 30/10/2008 sur l'importation et leur correspondant conditions techniques des dispositifs médicaux

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|--------|---|-----|--------------------------------------|--------------|
| Population (000s)* | 21'472 | Life expectancy at birth (years) ^a | 51 | World Bank income group ^β | Upper-middle |
| Internet users (%) ^γ | 19.1% | Per capita total health expenditure (PPP Int \$) ^δ | 212 | GNI per capita (US\$) ^ε | 5'170 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Direcção Nacional de Medicamentos e Equipamentos

Web site: <http://dnme.co.ao/>



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: Gabinete de estudos e planeamento estatístico

Web site: —

OTHER: Regulation of equipment and medical devices

Unit/department: Equipamentos e dispositivos médicos

Web site: —

OTHER: Regulation of medical devices and in vitro diagnostics

Unit/department: Meios de Diagnósticos

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: Yes

Web site: —

DONATIONS

Policy or guideline: No

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ: —



Inventory and maintenance

Type of inventories available: —

Comments: —

Medical equipment management unit: No

National level = —

Regional level = —

Hospital level = —

Management software: No

Software and comments^λ: —

Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:Lists comments^λ: —

Lists available: No

Unit: —

Web site: —

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES OR SPECIFIC PROCEDURES: Lists available: For different healthcare facilities

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: —

Types:

| | | | |
|-----------------------|---------------------------|----------|------------------------------------|
| Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|-----------------------|---------------------------|----------|------------------------------------|



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | n/a | n/a | n/a | n/a |
| Health centre | n/a | n/a | n/a | n/a |
| District hospital | n/a | n/a | n/a | n/a |
| Provincial hospital | n/a | n/a | n/a | n/a |
| Regional hospital | n/a | n/a | n/a | n/a |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 1 | n/a | 1 | 0.047 |
| Computerized Tomography Scanner | 6 | 3 | 9 | 0.419 |
| Positron Emission Tomography Scanner | 0 | n/a | 0 | 0.000 |
| Nuclear medicine | 0 | n/a | 0 | 0.000 |
| Mammograph* | 5 | n/a | 5 | 6.325 |
| Linear accelerator | 0 | n/a | 0 | 0.000 |
| Telecobalt unit (Cobalt-60) | 1 | n/a | 1 | 0.047 |
| Radiotherapy | 1 | n/a | 1 | 0.047 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: —

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|--------|---|----|--------------------------------------|-----|
| Population (000s)* | 10'323 | Life expectancy at birth (years) ^a | 59 | World Bank income group ^β | Low |
| Internet users (%) ^γ | 4.9% | Per capita total health expenditure (PPP Int \$) ^δ | 70 | GNI per capita (US\$) ^ε | 790 |



National policy on health technology

Health technology (medical device) national policy: Yes, but is not part of the National Health Program

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Direction Des Etablissements Hospitaliers

Web site: —



National health technology assessment unit

Unit/department: Direction de la programmation et de la prospective (DPP) et Direction des hôpitaux

Web site: www.beninsante.bj



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: PROGRAMME DE CONSTRUCTION, D'EQUIPEMENT ET DE FONCTIONNALITE DES FORMATIONS SANITAIRES (PNCEFFS)

Web site: —

OTHER: Planning of medical equipment allocation/Application/user training

Unit/department: PROGRAMME DE CONSTRUCTION, D'EQUIPEMENT ET DE FONCTIONNALITE DES FORMATIONS SANITAIRES (PNCEFFS)

Web site: —

OTHER: Management of Medical Equipment/Application/user training

Unit/department: SERVICE GESTION DES EQUIPEMENTS

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: Yes

Web site: —

DONATIONS

Policy or guideline: No

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: Yes

Web site: —

Medical device incorporation comments^λ: —



Inventory and maintenance

Type of inventories available: National inventory only for high cost technologies (such as MRI, CT or PET scanners)

Comments: –

Medical equipment management unit: Yes

National level = 3

Regional level = 2

Hospital level = 3

Management software: Yes

Software and comments^λ: OPTIM and ITOJU (Logiciel conçu par un béninois)



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^δ:

Lists comments^λ: –

Lists available: No

Unit: –

Web site: –

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES OR SPECIFIC PROCEDURES^δ: Lists available: For different healthcare facilities

Web site - facilities: –

Web site - procedures: –

NATIONAL LIST FOR DISEASES AND SITUATIONS^δ:

Lists available: No list available

Web site: –

Types:

Communicable diseases

Non-communicable diseases

Injuries

Public health emergency situations



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | n/a | n/a | n/a | n/a |
| Health centre | 563 | n/a | 563 | 5.454 |
| District hospital | 26 | n/a | 26 | 0.252 |
| Provincial hospital | 5 | n/a | 5 | 0.048 |
| Regional hospital | 11 | n/a | 11 | 0.107 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 0 | 0 | 0 | 0.000 |
| Computerized Tomography Scanner | 2 | 1 | 3 | 0.291 |
| Positron Emission Tomography Scanner | 0 | 0 | 0 | 0.000 |
| Nuclear medicine | 0 | 0 | 0 | 0.000 |
| Mammograph* | 3 | 4 | 7 | 16.089 |
| Linear accelerator | 0 | 0 | 0 | 0.000 |
| Telecobalt unit (Cobalt-60) | 0 | 0 | 0 | 0.000 |
| Radiotherapy | 0 | 0 | 0 | 0.000 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: –

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|-------|---|-----|--------------------------------------|--------------|
| Population (000s)* | 2'021 | Life expectancy at birth (years) ^a | 62 | World Bank income group ^β | Upper-middle |
| Internet users (%) ^γ | 15.0% | Per capita total health expenditure (PPP Int \$) ^δ | 872 | GNI per capita (US\$) ^ε | 7'770 |



National policy on health technology

Health technology (medical device) national policy: Yes, but is not part of the National Health Program

Web site: —

Language(s): English

MOH responsible for health technology policy implementation: Biomedical Engineering Services



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: No

Name of principal institution: —

Web site: —



National health technology assessment unit

Unit/department: Clinical Services

Web site: —



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: Clinical Services

Web site: —

OTHER: Planning of medical equipment allocation/Application/user training

Unit/department: Clinical Services

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: Yes **Type:** Based on UMDNS (Universal Medical Device Nomenclature System) **Use:** For procurement

Nomenclature system name: — **Web site:** <http://www.ecri.org>



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: <http://www.ppadb.co.bw>

National level procurement: Yes

Web site: —

DONATIONS

Policy or guideline: Yes

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: Yes, but not publically available

Web site: —

Medical device incorporation comments^λ: —



Inventory and maintenance

Type of inventories available: National inventory for medical equipment

Comments: Medical Equipment Asset Register which was completed in December 2009

Medical equipment management unit: Yes

National level = 0

Regional level = 0

Hospital level = 0

Management software: —

Software and comments^λ: Custom Solution is being implemented, we signed a contract on 19/05/2010



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^δ:

Lists available: No

Unit: —

Web site: —

Lists comments^λ:

Still revising many lists and it will implemented soon.

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES OR SPECIFIC PROCEDURES: Lists available: —

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: —

| | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|--------|-----------------------|---------------------------|----------|------------------------------------|



Healthcare facility

| | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | n/a | n/a | n/a | n/a |
| Health centre | n/a | n/a | n/a | n/a |
| District hospital | 16 | n/a | 16 | 0.792 |
| Provincial hospital | 7 | n/a | 7 | 0.346 |
| Regional hospital | 3 | n/a | 3 | 0.148 |



Medical equipment

| | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 0 | 1 | 1 | 0.495 |
| Computerized Tomography Scanner | 2 | n/a | 2 | 0.990 |
| Positron Emission Tomography Scanner | 0 | n/a | 0 | 0.000 |
| Nuclear medicine | 0 | n/a | 0 | 0.000 |
| Mammograph* | 2 | n/a | 2 | 19.103 |
| Linear accelerator | 0 | n/a | 0 | 0.000 |
| Telecobalt unit (Cobalt-60) | 0 | n/a | 0 | 0.000 |
| Radiotherapy | 0 | n/a | 0 | 0.000 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ:

Concerning Section Infrastructure: We have 800 clinics, healthposts and mobile clinics.

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

Burkina Faso



Country indicators

| | | | | | |
|---------------------------------|--------|---|----|--------------------------------------|-----|
| Population (000s)* | 16'935 | Life expectancy at birth (years) ^a | 58 | World Bank income group ^β | Low |
| Internet users (%) ^γ | 4.4% | Per capita total health expenditure (PPP Int \$) ^δ | 90 | GNI per capita (US\$) ^ε | 670 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Direction générale de la pharmacie, du médicament et des laboratoires

Web site: <http://www.dgpml.sante.gov.bf/>



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): No

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: —

Web site: —

OTHER: Procédures d'achat

Unit/department: DMP

Web site: —

OTHER: achats groupés équipements et consommables

Unit/department: CAMEG

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: Yes

Web site: —

DONATIONS

Policy or guideline: No

Web site: —

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ:

les achats se font selon plusieurs procédures en fonction de la source de financement (les projets font des appels d'offres de façon indépendante, les hôpitaux exécutent en interne une partie du budget achat, les achats groupés au niveau national sont en train d'être expérimentés par la CAMEG (Centrale d'Achat des Médicaments Génériques). Aussi des appels d'offres internationaux sont quelque fois lancés par les projets



Inventory and maintenance

Type of inventories available: National inventory for medical equipment, National functional inventory for medical equipment

Comments: Inventaire technique au niveau national a été fait par la DGIEM en 2003 avec l'appui de la GTZ; un inventaire non technique a été fait par la DAF en 2007 suivant une procédure du Ministère de l'Economie et des Finances. la mise à jour de ces inventaires n'est pas effective.

Medical equipment management unit: Yes

National level = 1

Regional level = 13

Hospital level = 11

Management software: Yes

Software and comments^λ: PLAMAHS (Heart Consultancy)



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:

Lists available: No

Unit: —

Web site: —

Lists comments^λ:

Lists available for communicable and non communicable diseases.

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: For different healthcare facilities

Web site - facilities: <http://www.sante.gov.bf/SiteSante/documents/normes-infra.pdf>

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: One or more

Web site: <http://www.sante.gov.bf/SiteSante/documents/index.html>

| | | | | | | |
|--------|-----------------------|---|---------------------------|---|----------|------------------------------------|
| Types: | Communicable diseases | x | Non-communicable diseases | x | Injuries | Public health emergency situations |
|--------|-----------------------|---|---------------------------|---|----------|------------------------------------|



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | n/a | n/a | n/a | n/a |
| Health centre | 1'629 | 384 | 2013 | 11.887 |
| District hospital | 41 | 2 | 43 | 0.254 |
| Provincial hospital | n/a | n/a | 0 | 0.000 |
| Regional hospital | 9 | n/a | 9 | 0.053 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 1 | 0 | 1 | 0.059 |
| Computerized Tomography Scanner | 5 | 6 | 11 | 0.650 |
| Positron Emission Tomography Scanner | 0 | 0 | 0 | 0.000 |
| Nuclear medicine | 1 | 0 | 1 | 0.059 |
| Mammograph* | 4 | 5 | 9 | 13.591 |
| Linear accelerator | 0 | 0 | 0 | 0.000 |
| Telecobalt unit (Cobalt-60) | 0 | 0 | 0 | 0.000 |
| Radiotherapy | 0 | 0 | 0 | 0.000 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ:

Concerning HT national policy we provide the following doc.: Medical Equipment and Devices Policy 2010 March.doc.
Concerning Section Infrastructure: We have 3 CHU and 1 Hôpital national.

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

Burundi



Country indicators

| | | | | | |
|---------------------------------|--------|---|----|--------------------------------------|-----|
| Population (000s)* | 10'163 | Life expectancy at birth (years) ^a | 56 | World Bank income group ^β | Low |
| Internet users (%) ^γ | 1.3% | Per capita total health expenditure (PPP Int \$) ^δ | 45 | GNI per capita (US\$) ^ε | 260 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: No

Name of principal institution: —

Web site: —



National health technology assessment unit

Unit/department: DISE

Web site: —



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: DISE

Web site: —

OTHER: Planning of medical equipment allocation

Unit/department: DISE

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: —

National level procurement: Yes

Web site: —

DONATIONS

Policy or guideline: No

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: Yes, but not publically available

Web site: —

Medical device incorporation comments^λ:

Procédé aux achats/Système d'appel d'offres ouvert national/international. Il existe des entreprises nationales spécialisées dans la vente de ces produits.



Inventory and maintenance

Type of inventories available: National functional inventory for medical equipment

Comments: –

Medical equipment management unit: Yes

National level = 2

Regional level = 0

Hospital level = 1

Management software: No

Software and comments^λ: –



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^δ

Lists available: Yes

Unit: DISE

Web site: –

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: For different healthcare facilities and specific procedures

Web site - facilities: –

Web site - procedures: –

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: One or more

Web site: –

Types:

| | | | | | | | |
|-----------------------|---|---------------------------|---|----------|---|------------------------------------|---|
| Communicable diseases | x | Non-communicable diseases | x | Injuries | x | Public health emergency situations | x |
|-----------------------|---|---------------------------|---|----------|---|------------------------------------|---|

Lists comments^λ:

Nous avons des listes préétablies suivant le type de catégories conformément aux normes en vigueur au MoH. Lists available for communicable and non communicable diseases, injuries, and public health emergency situations. Also we have documentation over the normalisation des équipements par structures de soins



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | n/a | n/a | 0 | 0.000 |
| Health centre | 370 | 139 | 509 | 5.009 |
| District hospital | 33 | n/a | 33 | 0.325 |
| Provincial hospital | 15 | n/a | 15 | 0.148 |
| Regional hospital | 3 | n/a | 3 | 0.030 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 0 | 0 | 0 | 0.000 |
| Computerized Tomography Scanner | 1 | 1 | 2 | 0.197 |
| Positron Emission Tomography Scanner | 0 | 0 | 0 | 0.000 |
| Nuclear medicine | 0 | 0 | 0 | 0.000 |
| Mammograph* | 1 | 0 | 1 | 2.693 |
| Linear accelerator | 0 | 0 | 0 | 0.000 |
| Telecobalt unit (Cobalt-60) | 0 | 0 | 0 | 0.000 |
| Radiotherapy | 0 | 0 | 0 | 0.000 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: –

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|-------|---|-----|--------------------------------------|--------------|
| Population (000s)* | 499 | Life expectancy at birth (years) ^a | 74 | World Bank income group ^β | Lower-middle |
| Internet users (%) ^γ | 37.5% | Per capita total health expenditure (PPP Int \$) ^δ | 166 | GNI per capita (US\$) ^ε | 3'620 |



National policy on health technology

Health technology (medical device) national policy: Yes, and it is part of the National Health Program/Plan or Policy

Web site: <http://www.minsaude.gov.cv>

Language(s): Portuguese

MOH responsible for health technology policy implementation: Direction General of pharmacy



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: MINISTRY OF HEALTH

Web site: <http://www.minsaude.gov.cv>



National health technology assessment unit

Unit/department: Direction General of Pharmacy

Web site: —



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: DIRECTION GENERAL OF PHARMAY

Web site: —

OTHER: —

Unit/department: CABINET OF PLAN AND COOPERATION

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: Yes

Web site: <http://www.minsaude.gov.cv>

DONATIONS

Policy or guideline: Yes

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ: —



Inventory and maintenance

Type of inventories available: None

Comments: We don't have a national inventory of medical equipment. We are planning to do it soon.

Medical equipment management unit: Yes

National level = 0

Regional level = 0

Hospital level = 0

Management software: No

Software and comments^λ: —



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^δ:

Lists available: No

Unit: —

Web site: —

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES OR SPECIFIC PROCEDURES^δ: Lists available: For different healthcare facilities

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS^δ:

Lists available: No list available

Web site: —

| | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|--------|-----------------------|---------------------------|----------|------------------------------------|

Lists comments^λ:

Standards we have the: CARTA SANITÁRIA DE CABO VERDE (1999). Lists for procedures: No, it is done according to the needs and the procedures we want to implement. We don't have any available lists for communicable and non communicable diseases, injuries, and public health emergency situations.



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 167 | n/a | 167 | 33.474 |
| Health centre | 19 | n/a | 19 | 3.808 |
| District hospital | 3 | n/a | 3 | 0.601 |
| Provincial hospital | n/a | n/a | 0 | 0.000 |
| Regional hospital | 2 | n/a | 2 | 0.401 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 0 | 1 | 1 | 2.004 |
| Computerized Tomography Scanner | 0 | 1 | 1 | 2.004 |
| Positron Emission Tomography Scanner | 0 | 1 | 1 | 2.004 |
| Nuclear medicine | 0 | 0 | 0 | 0.000 |
| Mammograph* | 2 | 2 | 4 | 140.598 |
| Linear accelerator | 0 | 0 | 0 | 0.000 |
| Telecobalt unit (Cobalt-60) | 0 | 0 | 0 | 0.000 |
| Radiotherapy | 0 | 0 | 0 | 0.000 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ:

In conclusion we need to organize our park of medical devices. We would like to make a national inventory for medical equipment, asses the needs, and organizing technical guidelines for procurement in order to elaborate a clear plan of medical devices management. We think it is time to develop legislation for medical devices.

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

Cameroon



Country indicators

| | | | | | |
|---------------------------------|--------|---|-----|--------------------------------------|--------------|
| Population (000s)* | 22'254 | Life expectancy at birth (years) ^a | 56 | World Bank income group ^β | Lower-middle |
| Internet users (%) ^γ | 6.4% | Per capita total health expenditure (PPP Int \$) ^δ | 120 | GNI per capita (US\$) ^ε | 1'290 |



National policy on health technology

Health technology (medical device) national policy: Yes, and it is part of the National Health Program/Plan or Policy

Web site: —

Language(s): Français et Anglais

MOH responsible for health technology policy implementation: Direction de l'Organisation des Soins et de la Technologie Sanitaire



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: —

Web site: <http://www.minsante.cm/site/?q=fr>



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: DOSTS

Web site: <http://www.minsante.cm>

OTHER: Planning of medical equipment allocation

Unit/department: DEP

Web site: <http://www.minsante.cm>

OTHER: Planning of medical equipment allocation

Unit/department: DRFP

Web site: <http://www.minsante.cm>



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: —

National level procurement: Yes

Web site: —

DONATIONS

Policy or guideline: No

Web site: —

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: Yes, but not publically available

Web site: —

Medical device incorporation comments^λ:

Procurement: Il existe des directives générales concernant tous les marchés publics. Les hôpitaux et autres formations disposent aussi de budgets propores pour l'achat de dispositifs médicaux



Inventory and maintenance

Type of inventories available: None

Comments: Les bailleurs de fonds réalisent des inventaires dans leurs zones d'intervention, mais il n'existe pas d'inventaire national

Medical equipment management unit: Yes

National level = 1

Regional level = 10

Hospital level = 32

Management software: No

Software and comments^λ: —



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:

Lists comments^λ: —

Lists available: No

Unit: —

Web site: —

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: For different healthcare facilities

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: —

| | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|--------|-----------------------|---------------------------|----------|------------------------------------|



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 1'653 | n/a | 1653 | 7.428 |
| Health centre | 141 | n/a | 141 | 0.634 |
| District hospital | 150 | n/a | 150 | 0.674 |
| Provincial hospital | 12 | 5 | 17 | 0.076 |
| Regional hospital | 8 | 1 | 9 | 0.040 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 1 | 0 | 1 | 0.045 |
| Computerized Tomography Scanner | 10 | 4 | 14 | 0.629 |
| Positron Emission Tomography Scanner | 0 | 0 | 0 | 0.000 |
| Nuclear medicine | 1 | 0 | 1 | 0.045 |
| Mammograph* | 12 | 3 | 15 | 17.399 |
| Linear accelerator | 0 | 0 | 0 | 0.000 |
| Telecobalt unit (Cobalt-60) | 2 | 1 | 3 | 0.135 |
| Radiotherapy | 2 | 1 | 3 | 0.135 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ:

L'étude devrait inclure la formation dans le domaine. Le Cameroun dispose d'un cycle de formation de techniciens en maintenance hospitalière qui fonctionne depuis deux ans dans trois lycées techniques, le diplôme de sortie délivré au bout de trois ans est l'équivalent du baccalauréat. Il existe également des cycles de formation dans le domaine en enseignement supérieur.

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

Central African Republic



Country indicators

| | | | | | |
|---------------------------------|-------|---|----|--------------------------------------|-----|
| Population (000s)* | 4'616 | Life expectancy at birth (years) ^a | 51 | World Bank income group ^β | Low |
| Internet users (%) ^γ | 3.5% | Per capita total health expenditure (PPP Int \$) ^δ | 32 | GNI per capita (US\$) ^ε | 320 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Direction des infrastructures sanitaires

Web site: —



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): No

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: —

National level procurement: Yes

Web site: —

DONATIONS

Policy or guideline: No

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ:

Achat groupé par les partenaires, passation de marché. Longue durée entre la commande et la réception,



Inventory and maintenance

Type of inventories available: National inventory for medical equipment, National functional inventory for medical equipment

Comments: Réalisée par la direction des infrastructures sanitaires

Medical equipment management unit: Yes

National level = 0

Regional level = 0

Hospital level = 0

Management software: No

Software and comments^λ: —



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:

Lists available: Yes

Unit: Unité de cession des médicaments et équipements médicaux

Web site: —

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: For different healthcare facilities and specific procedures

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: —

Types:

| |
|-----------------------|
| Communicable diseases |
|-----------------------|

| |
|---------------------------|
| Non-communicable diseases |
|---------------------------|

| |
|----------|
| Injuries |
|----------|

| |
|------------------------------------|
| Public health emergency situations |
|------------------------------------|

Lists comments^λ:

En concernant lists de procedures: Arrêté du ministre de la santé publique et de la population Profil des participants: Médecin, chirurgiens, techniciens de santé, techniciens bio médicaux Date de révision: Mars 2010. En concernant acquisition il ya une longue durée entre la commande et la réception



Healthcare facility

| | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 445 | 117 | 562 | 12.174 |
| Health centre | 64 | 28 | 92 | 1.993 |
| District hospital | 13 | n/a | 13 | 0.282 |
| Provincial hospital | 5 | n/a | 5 | 0.108 |
| Regional hospital | 4 | n/a | 4 | 0.087 |



Medical equipment

| | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 0 | 0 | 0 | 0.000 |
| Computerized Tomography Scanner | 0 | 0 | 0 | 0.000 |
| Positron Emission Tomography Scanner | 0 | 0 | 0 | 0.000 |
| Nuclear medicine | 0 | 0 | 0 | 0.000 |
| Mammograph* | 0 | 1 | 1 | 4.681 |
| Linear accelerator | 0 | 0 | 0 | 0.000 |
| Telecobalt unit (Cobalt-60) | 0 | 0 | 0 | 0.000 |
| Radiotherapy | 0 | 0 | 0 | 0.000 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ:

Concerning HT national policy we provide the following doc.: POLITINACIONALSAUDE_VERSÃOVALIDADA 2020.doc

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|--------|---|----|--------------------------------------|-------|
| Population (000s)* | 12'825 | Life expectancy at birth (years) ^a | 51 | World Bank income group ^β | Low |
| Internet users (%) ^γ | 2.3% | Per capita total health expenditure (PPP Int \$) ^δ | 42 | GNI per capita (US\$) ^ε | 1'030 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: No

Name of principal institution: —

Web site: —



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): No

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: —

National level procurement: Yes

Web site: —

DONATIONS

Policy or guideline: Yes

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ: —



Inventory and maintenance

Type of inventories available: None

Comments: Aucun inventaire des dispositifs médicaux n'a été effectué

Medical equipment management unit: Yes

National level = 1

Regional level = 0

Hospital level = 1

Management software: No

Software and comments^λ: —



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^δ:

Lists available: No

Unit: —

Web site: —

Lists comments^λ:

We do not have any available for communicable and non communicable diseases, injuries, and public health emergency situations.

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES OR SPECIFIC PROCEDURES^δ: Lists available: No list available

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS^δ:

Lists available: No list available

Web site: —

Types:

Communicable diseases

Non-communicable diseases

Injuries

Public health emergency situations



Healthcare facility

| | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 603 | 151 | 754 | 5.879 |
| Health centre | n/a | n/a | 0 | 0.000 |
| District hospital | 58 | 6 | 64 | 0.499 |
| Provincial hospital | 19 | n/a | 19 | 0.148 |
| Regional hospital | n/a | 1 | 1 | 0.008 |



Medical equipment

| | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | n/a | n/a | n/a | n/a |
| Computerized Tomography Scanner | n/a | 1 | 1 | 0.078 |
| Positron Emission Tomography Scanner | n/a | n/a | n/a | n/a |
| Nuclear medicine | n/a | n/a | n/a | n/a |
| Mammograph* | 1 | 1 | 2 | 4.674 |
| Linear accelerator | n/a | n/a | n/a | n/a |
| Telecobalt unit (Cobalt-60) | n/a | n/a | n/a | n/a |
| Radiotherapy | n/a | n/a | n/a | n/a |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ:

Lack of national policy in matters of health technology does not allow the access to information on medical devices that could support the action plan with regard to training of users, specialists and maintenance technicians.

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|------|---|----|--------------------------------------|-----|
| Population (000s)* | 735 | Life expectancy at birth (years) ^a | 62 | World Bank income group ^β | Low |
| Internet users (%) ^γ | 6.5% | Per capita total health expenditure (PPP Int \$) ^δ | 56 | GNI per capita (US\$) ^ε | 840 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Direction des Etablissements de soins Publics et privés

Web site: —



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): No

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: Yes

Web site: —

DONATIONS

Policy or guideline: No

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ:

La Evaluación de Tecnologías se reglamentó en el año 2011 mediante la Ley 1438, lo cual será competencia del Instituto Nacional de Evaluación de tecnologías, el cual está en proceso de creación



Inventory and maintenance

Type of inventories available: None

Comments: —

Medical equipment management unit: Yes

National level = 0

Regional level = 0

Hospital level = 1

Management software: No

Software and comments^λ: —

Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^δ:Lists comments^λ: —

Lists available: No

Unit: —

Web site: —

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES OR SPECIFIC PROCEDURES: Lists available: For different healthcare facilities

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: —

Types:

| | | | |
|-----------------------|---------------------------|----------|------------------------------------|
| Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|-----------------------|---------------------------|----------|------------------------------------|



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 47 | 5 | 52 | 7.076 |
| Health centre | 10 | 2 | 12 | 1.633 |
| District hospital | 2 | n/a | 2 | 0.272 |
| Provincial hospital | 2 | n/a | 2 | 0.272 |
| Regional hospital | 1 | n/a | 1 | 0.136 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 0 | 0 | 0 | 0.000 |
| Computerized Tomography Scanner | 0 | 1 | 1 | 1.361 |
| Positron Emission Tomography Scanner | 0 | 0 | 0 | 0.000 |
| Nuclear medicine | 0 | 0 | 0 | 0.000 |
| Mammograph* | 0 | 1 | 1 | 31.271 |
| Linear accelerator | 0 | 0 | 0 | 0.000 |
| Telecobalt unit (Cobalt-60) | 0 | 0 | 0 | 0.000 |
| Radiotherapy | 0 | 0 | 0 | 0.000 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: —

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|-------|---|-----|--------------------------------------|--------------|
| Population (000s)* | 4'448 | Life expectancy at birth (years) ^a | 59 | World Bank income group ^β | Lower-middle |
| Internet users (%) ^γ | 6.6% | Per capita total health expenditure (PPP Int \$) ^δ | 140 | GNI per capita (US\$) ^ε | 2'590 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Direction des laboratoires

Web site: —



National health technology assessment unit

Unit/department: Direction des laboratoires

Web site: —



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: Direction des infrastructures, des équipements et de la maintenance

Web site: —

OTHER: Planning of medical equipment allocation/Application/user training

Unit/department: Direction des laboratoires

Web site: —

OTHER: Planning of medical equipment allocation/Application/user training

Unit/department: Direction des infrastructures, des équipements et de la maintenance

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: Yes

Web site: —

DONATIONS

Policy or guideline: Yes

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ:

L'achat des dispositifs médicaux est décentralisé. il peut se faire au niveau national comme à l'étranger.



Inventory and maintenance

Type of inventories available: —

Comments: —

Medical equipment management unit: Yes

National level = 1

Regional level = —

Hospital level = 5

Management software: No

Software and comments^λ: —

Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^δ:Lists comments^λ: —

Lists available: No

Unit: —

Web site: —

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES OR SPECIFIC PROCEDURES: Lists available: No list available

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: —

Types:

| | | | |
|-----------------------|---------------------------|----------|------------------------------------|
| Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|-----------------------|---------------------------|----------|------------------------------------|



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | n/a | n/a | n/a | n/a |
| Health centre | n/a | n/a | n/a | n/a |
| District hospital | n/a | n/a | n/a | n/a |
| Provincial hospital | n/a | n/a | n/a | n/a |
| Regional hospital | n/a | n/a | n/a | n/a |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | n/a | n/a | n/a | n/a |
| Computerized Tomography Scanner | n/a | n/a | n/a | n/a |
| Positron Emission Tomography Scanner | n/a | n/a | n/a | n/a |
| Nuclear medicine | n/a | n/a | n/a | n/a |
| Mammograph* | n/a | n/a | n/a | n/a |
| Linear accelerator | n/a | n/a | n/a | n/a |
| Telecobalt unit (Cobalt-60) | n/a | n/a | n/a | n/a |
| Radiotherapy | n/a | n/a | n/a | n/a |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: —

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|--------|---|-----|--------------------------------------|--------------|
| Population (000s)* | 20'316 | Life expectancy at birth (years) ^a | 53 | World Bank income group ^β | Lower-middle |
| Internet users (%) ^γ | 2.6% | Per capita total health expenditure (PPP Int \$) ^δ | 144 | GNI per capita (US\$) ^ε | 1'450 |



National policy on health technology

Health technology (medical device) national policy: Yes, and it is part of the National Health Program/Plan or Policy

Web site: —

Language(s): Français

MOH responsible for health technology policy implementation: Direction des Infrastructures, de l'Équipement et de la Maintenance



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Direction des infrastructures, de l'équipement, et de la maintenance

Web site: —



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: Direction des infrastructures de l'équipement et de la maintenance

Web site: —

OTHER: Planning/Maintenance/Application/Management/training of medical equipment

Unit/department: Direction des infrastructures de l'équipement et de la maintenance

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: —

National level procurement: No

Web site: —

DONATIONS

Policy or guideline: No

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ:

Il s'agit du Guide de la Direction des Marchés Publics



Inventory and maintenance

Type of inventories available: None

Comments: La base nationale de données n'est pas fonctionnelle

Medical equipment management unit: Yes

National level = 1

Regional level = 6

Hospital level = 15

Management software: No

Software and comments^λ: —



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^δ

Lists available: Yes, but it is only a recommendation

Unit: DIEM

Web site: —

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES OR SPECIFIC PROCEDURES^δ: Lists available: For different healthcare facilities and specific procedures

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS^δ:

Lists available: No list available

Web site: —

| | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|--------|-----------------------|---------------------------|----------|------------------------------------|

Lists comments^λ:

Lists de HC services: ListeTypeEquip CHR_HG_CSU_CSR: document de travail de la DIEM. Par contre les listes des procédures et directives sont dans le manuel de directives à l'attention du personnel des établissements de soins. il n'existe pas de liste spécifique à un domaine ou un programme de santé. Les listes d'acquisition provient du Plan National de



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | n/a | n/a | n/a | n/a |
| Health centre | 1'591 | 813 | 2404 | 11.833 |
| District hospital | 60 | 175 | 235 | 1.157 |
| Provincial hospital | 17 | 75 | 92 | 0.453 |
| Regional hospital | 9 | 11 | 20 | 0.098 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 0 | 3 | 3 | 0.148 |
| Computerized Tomography Scanner | 4 | 10 | 14 | 0.689 |
| Positron Emission Tomography Scanner | 0 | 0 | 0 | 0.000 |
| Nuclear medicine | 0 | 0 | 0 | 0.000 |
| Mammograph* | 0 | 0 | 0 | 0.000 |
| Linear accelerator | 0 | 0 | 0 | 0.000 |
| Telecobalt unit (Cobalt-60) | 0 | 0 | 0 | 0.000 |
| Radiotherapy | 0 | 0 | 0 | 0.000 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: —

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

Democratic Republic of the Congo



Country indicators

| | | | | | |
|---------------------------------|--------|---|----|--------------------------------------|-----|
| Population (000s)* | 67'514 | Life expectancy at birth (years) ^a | 52 | World Bank income group ^β | Low |
| Internet users (%) ^γ | 2.2% | Per capita total health expenditure (PPP Int \$) ^δ | 24 | GNI per capita (US\$) ^ε | 430 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: La Direction des laboratoires de Santé /Ministère de la Santé

Web site: <http://www.minisanterdc.cd/new/index.php>



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: Direction des laboratoires de santé

Web site: —

OTHER: Development of technical specifications for procurement purposes

Unit/department: Direction des Equipements et Materiels Médicaux

Web site: —

OTHER: Planning of medical equipment allocation

Unit/department: Direction des laboratoires de santé

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: No

Web site: —

DONATIONS

Policy or guideline: No

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ:

En RDC , les achats se font à tous les niveaux . L'Etat n'a pas pu reglementer ce secteur les achats se font à tous les niveaux et surtout les bailleurs de fonds pour leurs programmes spécifiques qu'ils appuient. Le directives à ce niveau sont fonction d'un appel offre, c'est en ce moment que celui qui lance l'offre dresse un certains critères des dispositifs qu'il veut acquérir.



Inventory and maintenance

Type of inventories available: National inventory for medical equipment

Comments: On est dans le processus de créer de pool de maintenance avec des ingenieurs sanitaires et de rehabiliter les ateliers qui existent . Il y a un programme de formation des ingenieurs et des utilisateurs

Medical equipment management unit: Yes

National level = 1

Regional level = 1

Hospital level = 2

Management software: No

Software and comments^λ: —



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:

Lists available: No

Unit: —

Web site: —

Lists comments^λ:

Il existe des listes de materiel dressé au niveau periphérique approuvé (district sanitaire). Pour le niceu intermediaires et et niveau tertiaire cette liste est en élaboration.

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES OR SPECIFIC PROCEDURES: Lists available: For different healthcare facilities

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: —

| | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|--------|-----------------------|---------------------------|----------|------------------------------------|



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | n/a | n/a | n/a | n/a |
| Health centre | n/a | n/a | n/a | n/a |
| District hospital | 290 | n/a | 290 | 0.430 |
| Provincial hospital | 11 | n/a | 11 | 0.016 |
| Regional hospital | n/a | n/a | n/a | n/a |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 0 | 0 | 0 | 0.000 |
| Computerized Tomography Scanner | 0 | 5 | 5 | 0.074 |
| Positron Emission Tomography Scanner | 0 | 0 | 0 | 0.000 |
| Nuclear medicine | 1 | 0 | 1 | 0.015 |
| Mammograph* | 1 | 1 | 2 | 0.739 |
| Linear accelerator | 0 | 1 | 1 | 0.015 |
| Telecobalt unit (Cobalt-60) | 0 | 0 | 0 | 0.000 |
| Radiotherapy | 0 | 1 | 1 | 0.015 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ:

En tant pays post-conflit , dans le processus de l'organisation de son système national de santé ,le gouvernement dispose déjà d'une strategie de renforcement du système de santé qui est une strategie sectorielle. Ensuite, le pays vient de se doter d'un plan stragegique de développement sanitaire pour 5 ans avec un cadre des dépenses à moyen terme ou toutes ces technologies sont planifiées.

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|-------|---|----|--------------------------------------|-----|
| Population (000s)* | 6'333 | Life expectancy at birth (years) ^a | 63 | World Bank income group ^β | Low |
| Internet users (%) ^γ | 0.9% | Per capita total health expenditure (PPP Int \$) ^δ | 17 | GNI per capita (US\$) ^ε | 490 |



National policy on health technology

Health technology (medical device) national policy: Yes, and it is part of the National Health Program/Plan or Policy

Web site: —

Language(s): English

MOH responsible for health technology policy implementation: Department of Regulatory services, Medicine and Medical devices control division



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Ministry of Health, Department of Regulatory services

Web site: —



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: Department of Regulatory services, Medicine and Medical devices control division

Web site: —

OTHER: Planning of medical equipment allocation

Unit/department: Department of Health services

Web site: —

OTHER: HTA/Application/user training

Unit/department: Department of Regulatory services, Service control and Quality Assurance division, Biomedical Engineering unit

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: Yes

Web site: —

DONATIONS

Policy or guideline: No

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ: —



Inventory and maintenance

Type of inventories available: National inventory for medical equipment

Comments: National medical devices inventory on the six zones has started on 2008, and currently it is on the process of finalization (only one zone is partially remaining)

Medical equipment management unit: Yes

National level = 1

Regional level = 6

Hospital level = 0

Management software: No

Software and comments^λ: –



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:

Lists available: No

Unit: –

Web site: –

Lists comments^λ:

Guidelines and lists managed by:
Ministry of Health, Department of
Regulatory services, Medicine and
Medical devices control division

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: For different healthcare facilities

Web site - facilities: –

Web site - procedures: –

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: –

| | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|--------|-----------------------|---------------------------|----------|------------------------------------|



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 158 | 27 | 185 | 2.921 |
| Health centre | 46 | 10 | 56 | 0.884 |
| District hospital | 15 | 1 | 16 | 0.253 |
| Provincial hospital | 6 | n/a | 6 | 0.095 |
| Regional hospital | 1 | n/a | 1 | 0.016 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 0 | 1 | 1 | 0.158 |
| Computerized Tomography Scanner | 1 | 1 | 2 | 0.316 |
| Positron Emission Tomography Scanner | 0 | 0 | 0 | 0.000 |
| Nuclear medicine | 0 | 0 | 0 | 0.000 |
| Mammograph* | 2 | 2 | 4 | 16.564 |
| Linear accelerator | 0 | 0 | 0 | 0.000 |
| Telecobalt unit (Cobalt-60) | 0 | 0 | 0 | 0.000 |
| Radiotherapy | 0 | 0 | 0 | 0.000 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: –

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

Ethiopia



Country indicators

| | | | | | |
|---------------------------------|--------|---|----|--------------------------------------|-----|
| Population (000s)* | 94'101 | Life expectancy at birth (years) ^a | 64 | World Bank income group ^β | Low |
| Internet users (%) ^γ | 1.9% | Per capita total health expenditure (PPP Int \$) ^δ | 44 | GNI per capita (US\$) ^ε | 470 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: Food, Medicine and Health Care Administration Control Agency



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Food, medical & health Administration and Control Authority

Web site: www.fmhaca.gov.et



National health technology assessment unit

Unit/department: Pharmaceutical and Medical Equipment Directorate

Web site: <http://www.moh.gov.et>



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: Medical Devices Management

Web site: <http://www.moh.gov.et/>

OTHER: —

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Nationally developed Use: For procurement

Nomenclature system name: — Web site: www.fmhaca.gov.et



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: www.pfsa.gov.et

National level procurement: Yes

Web site: —

DONATIONS

Policy or guideline: Yes

Web site: www.fmhaca.gov.et

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: Yes, but not publically available

Web site: www.pfsa.gov.et

Medical device incorporation comments^λ: —



Inventory and maintenance

Type of inventories available: None

Comments: AAU, Tikur Anbesa specialized Hospital update medical Inventory & Equipment history file in 2013

Medical equipment management unit: Yes

National level = 2

Regional level = 0

Hospital level = 0

Management software: Yes

Software and comments^λ: HARVEST Dimo



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:

Lists comments^λ:

Lists available: Yes

Actually there is a revision for national lists.

Unit: Pharmaceutical Fund & Supply Agency

Web site: —

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: For different healthcare facilities and specific procedures

Web site - facilities: —

Web site - procedures: www.fmhaca.gov.et

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: One or more

Web site: www.fmhaca.gov.et

Types: Communicable diseases Non-communicable diseases Injuries Public health emergency situations



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 14'250 | n/a | 14250 | 15.143 |
| Health centre | 2 | n/a | 1.75 | 0.002 |
| District hospital | 181 | n/a | 181 | 0.192 |
| Provincial hospital | n/a | n/a | n/a | n/a |
| Regional hospital | 6 | 19 | 25 | 0.027 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 2 | 5 | 7 | 0.074 |
| Computerized Tomography Scanner | 12 | 22 | 34 | 0.361 |
| Positron Emission Tomography Scanner | 0 | 0 | 0 | 0.000 |
| Nuclear medicine | 1 | 0 | 1 | 0.011 |
| Mammograph* | n/a | n/a | n/a | n/a |
| Linear accelerator | 0 | 0 | 0 | 0.000 |
| Telecobalt unit (Cobalt-60) | 2 | 0 | 2 | 0.021 |
| Radiotherapy | 2 | 0 | 2 | 0.021 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ:

Concerning HT national policy we provide the following doc.: [National Health Policy.pdf](#)

Concerning Infrastructure section: The targets of the government are to expand the current infrastructure capacity.

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|-------|---|-----|--------------------------------------|--------------|
| Population (000s)* | 1'672 | Life expectancy at birth (years) ^a | 63 | World Bank income group ^β | Upper-middle |
| Internet users (%) ^γ | 9.2% | Per capita total health expenditure (PPP Int \$) ^δ | 558 | GNI per capita (US\$) ^ε | 10'650 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: No

Name of principal institution: —

Web site: —



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: Direction des équipements biomédicaux

Web site: —

OTHER: Planning of medical equipment allocation

Unit/department: Direction générale de la planification, des infrastructures et des équipements

Web site: —

OTHER: Application/user training

Unit/department: Direction des équipements biomédicaux

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: No

Web site: —

DONATIONS

Policy or guideline: Yes

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ: —



Inventory and maintenance

Type of inventories available: —

Comments: —

Medical equipment management unit: Yes

National level = 2

Regional level = —

Hospital level = —

Management software: No

Software and comments^λ: —

Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^δ:Lists comments^λ:

Lists available: No

Unit: —

Web site: —

Lists available for communicable and non communicable diseases.

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES OR SPECIFIC PROCEDURES: Lists available: For different healthcare facilities

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: One or more

Web site: —

Types:

| | | | | | | | |
|-----------------------|---|---------------------------|---|----------|--|------------------------------------|--|
| Communicable diseases | x | Non-communicable diseases | x | Injuries | | Public health emergency situations | |
|-----------------------|---|---------------------------|---|----------|--|------------------------------------|--|



Healthcare facility

| | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 413 | 79 | 492 | 29.431 |
| Health centre | 18 | 19 | 37 | 2.213 |
| District hospital | 41 | n/a | 41 | 2.453 |
| Provincial hospital | 9 | 3 | 12 | 0.718 |
| Regional hospital | 5 | 1 | 6 | 0.359 |



Medical equipment

| | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 1 | 1 | 2 | 1.196 |
| Computerized Tomography Scanner | 3 | 3 | 6 | 3.589 |
| Positron Emission Tomography Scanner | 0 | 0 | 0 | 0.000 |
| Nuclear medicine | 0 | 0 | 0 | 0.000 |
| Mammograph* | 2 | 4 | 6 | 73.116 |
| Linear accelerator | 0 | 0 | 0 | 0.000 |
| Telecobalt unit (Cobalt-60) | 1 | 0 | 1 | 0.598 |
| Radiotherapy | 1 | 0 | 1 | 0.598 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: —

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|-------|---|----|--------------------------------------|-----|
| Population (000s)* | 1'849 | Life expectancy at birth (years) ^a | 61 | World Bank income group ^β | Low |
| Internet users (%) ^γ | 14.0% | Per capita total health expenditure (PPP Int \$) ^δ | 98 | GNI per capita (US\$) ^ε | 500 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: No

Name of principal institution: —

Web site: —



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: National Public Health laboratories

Web site: —

OTHER: Development of technical specifications/Application/user training/ Servicing and maintenance

Unit/department: Royal Victoria Teaching Hospital

Web site: —

OTHER: Development of technical specifications/Application/user training

Unit/department: National Public Health laboratories

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on more than one system Use: Not specified

Nomenclature system name: UMDNS adapted to national needs. Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: No

Web site: —

DONATIONS

Policy or guideline: Yes

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ: —



Inventory and maintenance

Type of inventories available: National inventory for medical equipment

Comments: Recently inventories have been compiled for the National Laboratory Services. However, those for Hospital/Clinical equipment is not available as of yet. The Medical Research Council (UK) the Gambia has a full inventory of its biomedical equipment. It is comprised of 1,500 devices including minor clinical equipment and high cost diagnostic and research laboratory equipment. We use a proprietary equipment management program from Phoenix Data Systems Inc. called AIMS. (I can not seem to upload our inventory in addition the National Laboratories inventory, but can send by email if requested.)

Medical equipment management unit: Yes

National level = 1

Regional level = 2

Hospital level = 4

Management software: No

Software and comments^λ: Again, the Medical Research Council (UK) the Gambia uses the AIMS program by Phoenix Data Systems Inc. (www.goaims.com/).



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:

Lists comments^λ: —

Lists available: No

Unit: —

Web site: —

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES OR SPECIFIC PROCEDURES: Lists available: No list available

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: —

Types:

Communicable diseases

Non-communicable diseases

Injuries

Public health emergency situations



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 492 | n/a | 492 | 26.605 |
| Health centre | 31 | n/a | 31 | 1.676 |
| District hospital | 7 | n/a | 7 | 0.379 |
| Provincial hospital | 4 | n/a | 4 | 0.216 |
| Regional hospital | 2 | n/a | 2 | 0.108 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 1 | 0 | 1 | 0.541 |
| Computerized Tomography Scanner | 2 | 0 | 2 | 1.081 |
| Positron Emission Tomography Scanner | n/a | 0 | 0 | 0.000 |
| Nuclear medicine | n/a | 0 | 0 | 0.000 |
| Mammograph* | 1 | 0 | 1 | 16.492 |
| Linear accelerator | n/a | 0 | 0 | 0.000 |
| Telecobalt unit (Cobalt-60) | n/a | 0 | 0 | 0.000 |
| Radiotherapy | n/a | 0 | 0 | 0.000 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ:

Concerning the Infrastructure section: the PRIVATE SECTOR section correspond to the responses for Medical Research Council (UK) the Gambia.

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

Ghana



Country indicators

| | | | | | |
|---------------------------------|--------|---|-----|--------------------------------------|--------------|
| Population (000s)* | 25'905 | Life expectancy at birth (years) ^a | 62 | World Bank income group ^β | Lower-middle |
| Internet users (%) ^γ | 12.3% | Per capita total health expenditure (PPP Int \$) ^δ | 106 | GNI per capita (US\$) ^ε | 1'770 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): English

MOH responsible for health technology policy implementation: Clinical Engineering Department and the Biomedical Engineering Unit



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Food and Drugs Authority Ghana

Web site: <http://www.fdaghana.gov.gh/>



National health technology assessment unit

Unit/department: Clinical Engineering Department

Web site: <http://ghanahealthservice.org/division.php?data=unit&un=23&um=Clinical%20Engineering%20Department&dsion=Health Administration and Support Services&dd=30>



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: Clinical Engineering Department

Web site: <http://ghanahealthservice.org>

OTHER: Planning of medical equipment allocation/development of technical specifications/advisory and policy issues

Unit/department: Biomedical Engineering Department

Web site: <http://www.moh-ghana.org>

OTHER: Planning of medical equipment allocation/HTA/development of technical specifications/application/user training/maintenance, installation, advisory

Unit/department: Clinical Engineering Department

Web site: <http://ghanahealthservice.org>



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: http://www.ppbghana.org/story_detail.asp?story_id=18

National level procurement: Yes

Web site: <http://www.ghanahealthservice.org/division.php?dsion=Supplies,Stores and Drugs Management&dd=32>

DONATIONS

Policy or guideline: Yes

Web site: —

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: Yes

Web site: —

Medical device incorporation comments^λ:

Ghana National Procurement law as well as the MoH. Depending on the value of the procurement package, the health facilities are allowed to procure sometimes, the unit of the MoH also procure some of the capital equipment especially for the turnkey projects. All procurement of medical devices are carried out with the technical support of the Clinical Engineering Dpt. of the Ghana Health Service or the Biomedical Engineering Unit of the MoH.



Inventory and maintenance

Type of inventories available: National inventory only for high cost technologies (such as MRI, CT or PET scanners)

Comments: Most inventories are held at the regional and institutional level. We are yet to acquire software for the management of the inventory at the national level

Medical equipment management unit: Yes

National level = 2

Regional level = 10

Hospital level = 11

Management software: No

Software and comments^λ: —



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:

Lists comments^λ:

Lists available: Yes, but it is only a recommendation

Unit: Clinical Engineering Department

Web site: —

The standard list serves as a guide. The actual procurement is based on the need of health facility, availability of utilities, and availability of professional user staff

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: For different healthcare facilities

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: —

| | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|--------|-----------------------|---------------------------|----------|------------------------------------|



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 285 | 2 | 287 | 1.108 |
| Health centre | 1'133 | 1'231 | 2364 | 9.126 |
| District hospital | 115 | 221 | 336 | 1.297 |
| Provincial hospital | 8 | n/a | 8 | 0.031 |
| Regional hospital | 9 | n/a | 9 | 0.035 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 2 | n/a | 2 | 0.077 |
| Computerized Tomography Scanner | 4 | n/a | 4 | 0.154 |
| Positron Emission Tomography Scanner | n/a | n/a | n/a | n/a |
| Nuclear medicine | 2 | n/a | 2 | 0.077 |
| Mammograph* | n/a | n/a | n/a | n/a |
| Linear accelerator | n/a | n/a | n/a | n/a |
| Telecobalt unit (Cobalt-60) | 2 | n/a | 2 | 0.077 |
| Radiotherapy | 2 | n/a | 2 | 0.077 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ:

There is no written or published national health technology policy yet but there are policies available that have been established by the systems and structures unit for health technology in Ghana. Ghana Health Service has drafted its operational policy for healthcare equipment and needs to be finalised.

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|--------|---|----|--------------------------------------|-----|
| Population (000s)* | 11'745 | Life expectancy at birth (years) ^a | 58 | World Bank income group ^β | Low |
| Internet users (%) ^γ | 1.6% | Per capita total health expenditure (PPP Int \$) ^δ | 67 | GNI per capita (US\$) ^ε | 460 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Division Equipement et Maintenance de la DNEHS

Web site: —



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: Division Equipement et Maintenance (DEM)

Web site: —

OTHER: Planning of medical equipment allocation/Development of technical specifications

Unit/department: Section Equipement (SE)

Web site: —

OTHER: Planning of medical equipment allocation

Unit/department: Direction Nationale des Etablissements Hospitaliers et de Soins (DNEHS)

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: Yes

Web site: —

DONATIONS

Policy or guideline: Yes

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ:

For procurement on donations: Nous procédons par appel d'offres national ou international



Inventory and maintenance

Type of inventories available: National inventory for medical equipment

Comments: L'inventaire disponible n'est pas exhaustif

Medical equipment management unit: Yes

National level = 2

Regional level = 4

Hospital level = 5

Management software: —

Software and comments^λ: —



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^δ

Lists available: No

Unit: —

Web site: —

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES OR SPECIFIC PROCEDURES^δ: Lists available: For different healthcare facilities and specific procedures

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS^δ:

Lists available: One or more

Web site: —

Types:

| | | | | |
|-----------------------|---------------------------|----------|------------------------------------|---|
| Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations | x |
|-----------------------|---------------------------|----------|------------------------------------|---|

Lists comments^λ:

Document de normes d'équipements par niveau de structures sanitaires hors hôpitaux nationaux. Les Normes ont été définies pour les formations sanitaires de base (postes, centres de santé), les Centres de santé améliorés, les Hôpitaux préfectoraux /districts sanitaires et les Hôpitaux Régionaux (normes ne sont pas disponibles pour toutes les unités fonctionnelles des hôpitaux nationaux). Nous avons



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 733 | n/a | 733 | 6.241 |
| Health centre | 410 | 4 | 414 | 3.525 |
| District hospital | 31 | n/a | 31 | 0.264 |
| Provincial hospital | 7 | 3 | 10 | 0.085 |
| Regional hospital | 3 | n/a | 3 | 0.026 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 0 | n/a | 0 | 0.000 |
| Computerized Tomography Scanner | 0 | n/a | 0 | 0.000 |
| Positron Emission Tomography Scanner | 0 | n/a | 0 | 0.000 |
| Nuclear medicine | 0 | n/a | 0 | 0.000 |
| Mammograph* | 0 | n/a | 0 | 0.000 |
| Linear accelerator | 0 | n/a | 0 | 0.000 |
| Telecobalt unit (Cobalt-60) | 0 | n/a | 0 | 0.000 |
| Radiotherapy | 0 | n/a | 0 | 0.000 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: —

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

Guinea-Bissau



Country indicators

| | | | | | |
|---------------------------------|-------|---|----|--------------------------------------|-----|
| Population (000s)* | 1'704 | Life expectancy at birth (years) ^a | 54 | World Bank income group ^β | Low |
| Internet users (%) ^γ | 3.1% | Per capita total health expenditure (PPP Int \$) ^δ | 66 | GNI per capita (US\$) ^ε | 590 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: No

Name of principal institution: —

Web site: —



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: Direcção de Infraestruturas e Equipamentos

Web site: —

OTHER: Instalação, manutenção preventiva, reparações of medical equipment

Unit/department: Serviço Manutenção Técnica de Equipamentos Médicos

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: No

Web site: —

DONATIONS

Policy or guideline: No

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ: —



Inventory and maintenance

Type of inventories available: —

Comments: Inventário Nacional de Equipamentos Médicos: Trabalho curso e dados parciais para o Sul do País

Medical equipment management unit: Yes

National level = 1

Regional level = 1

Hospital level = —

Management software: No

Software and comments^λ: —



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:

Lists comments^λ: —

Lists available: No

Unit: —

Web site: —

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES OR SPECIFIC PROCEDURES: Lists available: For different healthcare facilities

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: —

| | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|--------|-----------------------|---------------------------|----------|------------------------------------|



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 96 | n/a | 96 | 5.633 |
| Health centre | 562 | n/a | 562 | 32.976 |
| District hospital | 437 | n/a | 437 | 25.642 |
| Provincial hospital | n/a | n/a | 0 | 0.000 |
| Regional hospital | 525 | n/a | 525 | 30.805 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 0 | 0 | 0 | 0.000 |
| Computerized Tomography Scanner | 0 | 0 | 0 | 0.000 |
| Positron Emission Tomography Scanner | 0 | 0 | 0 | 0.000 |
| Nuclear medicine | 0 | 0 | 0 | 0.000 |
| Mammograph* | 0 | 0 | 0 | 0.000 |
| Linear accelerator | 0 | 0 | 0 | 0.000 |
| Telecobalt unit (Cobalt-60) | 0 | 0 | 0 | 0.000 |
| Radiotherapy | 0 | 0 | 0 | 0.000 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: —

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

Kenya



Country indicators

| | | | | | |
|---------------------------------|--------|---|----|--------------------------------------|-------|
| Population (000s)* | 44'354 | Life expectancy at birth (years) ^a | 61 | World Bank income group ^β | Low |
| Internet users (%) ^γ | 39.0% | Per capita total health expenditure (PPP Int \$) ^δ | 84 | GNI per capita (US\$) ^ε | 1'160 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Kenya Pharmacy and Poisons Board

Web site: <http://pharmacyboardkenya.org/>



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: Biomedical Engineering Division

Web site: —

OTHER: Planning of medical equipment allocation/application/user training

Unit/department: Biomedical Engineering Division

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Nationally developed Use: Not specified

Nomenclature system name: Local registry nomenclature Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: —

National level procurement: Yes

Web site: <http://www.kemsa.co.ke/>

DONATIONS

Policy or guideline: Yes

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: Yes, but not publically available

Web site: —

Medical device incorporation comments^λ:

Procurement at national level is specific to MoH.
Guidelines for donations: IEC 60601, ISO 13485,
Directive 93/42/EEC



Inventory and maintenance

Type of inventories available: National inventory for medical equipment

Comments: Locally Developed. sample of our inventory system is attached

Medical equipment management unit: Yes

National level = 1

Regional level = 8

Hospital level = 150

Management software: No

Software and comments^λ: —



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^δ:

Lists available: Yes, but it is only a recommendation

Unit: Biomedical engineering Department

Web site: —

Lists comments^λ:

Lists are developed locally and available in hard copy only. Lists for procedures only cover surgical procedures

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: For different healthcare facilities and specific procedures

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: —

| | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|--------|-----------------------|---------------------------|----------|------------------------------------|



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 2'592 | 758 | 3350 | 7.553 |
| Health centre | 532 | 2'123 | 2655 | 5.986 |
| District hospital | 246 | 381 | 627 | 1.414 |
| Provincial hospital | 12 | 4 | 16 | 0.036 |
| Regional hospital | 2 | 5 | 7 | 0.016 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 2 | 5 | 7 | 0.158 |
| Computerized Tomography Scanner | 3 | 8 | 11 | 0.248 |
| Positron Emission Tomography Scanner | 0 | 0 | 0 | 0.000 |
| Nuclear medicine | 2 | 0 | 2 | 0.045 |
| Mammograph* | 12 | n/a | 12 | 6.825 |
| Linear accelerator | 0 | 0 | 0 | 0.000 |
| Telecobalt unit (Cobalt-60) | 1 | 0 | 1 | 0.023 |
| Radiotherapy | 1 | 0 | 1 | 0.023 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ:

We provide technical specifications, as well as donation guidelines in soft copy (not pdf versions).

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|-------|---|-----|--------------------------------------|-----|
| Population (000s)* | 4'294 | Life expectancy at birth (years) ^a | 62 | World Bank income group ^β | Low |
| Internet users (%) ^γ | 4.6% | Per capita total health expenditure (PPP Int \$) ^δ | 102 | GNI per capita (US\$) ^ε | 410 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: No

Name of principal institution: —

Web site: —



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): No

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: No

Web site: —

DONATIONS

Policy or guideline: Yes

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ:

Procurements are based on the WHO guidelines and mainly organized through partners



Inventory and maintenance

Type of inventories available: National functional inventory for medical equipment

Comments: Work is on-going with the functional inventory of medical equipment. The focus is to take inventory of all equipment in the Public health facilities

Medical equipment management unit: No

National level = 0

Regional level = 0

Hospital level = 0

Management software: No

Software and comments^λ: –



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:

Lists available: No

Unit: –

Web site: –

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES OR SPECIFIC PROCEDURES: Lists available: –

Web site - facilities: –

Web site - procedures: –

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: –

Types:

Communicable diseases

Non-communicable diseases

Injuries

Public health emergency situations

Lists comments^λ:

Lists of standards and lists are: “Basic Package of Health Services” which contains list of equipment at the annex. However, the list is subject to revision. We use WHO guidelines are being used for the donations. Process initiated for the adaptation of the guidelines



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 300 | 100 | 400 | 9.315 |
| Health centre | 45 | n/a | 45 | 1.048 |
| District hospital | 15 | n/a | 15 | 0.349 |
| Provincial hospital | n/a | n/a | n/a | n/a |
| Regional hospital | 1 | n/a | 1 | 0.023 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | n/a | n/a | n/a | n/a |
| Computerized Tomography Scanner | n/a | n/a | n/a | n/a |
| Positron Emission Tomography Scanner | n/a | n/a | n/a | n/a |
| Nuclear medicine | n/a | n/a | n/a | n/a |
| Mammograph* | n/a | n/a | n/a | n/a |
| Linear accelerator | n/a | n/a | n/a | n/a |
| Telecobalt unit (Cobalt-60) | n/a | n/a | n/a | n/a |
| Radiotherapy | n/a | n/a | n/a | n/a |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: –

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

Madagascar



Country indicators

| | | | | | |
|---------------------------------|--------|---|----|--------------------------------------|-----|
| Population (000s)* | 22'925 | Life expectancy at birth (years) ^a | 64 | World Bank income group ^β | Low |
| Internet users (%) ^γ | 2.2% | Per capita total health expenditure (PPP Int \$) ^δ | 40 | GNI per capita (US\$) ^ε | 440 |



National policy on health technology

Health technology (medical device) national policy: Yes, and it is part of the National Health Program/Plan or Policy

Web site: —

Language(s): Français

MOH responsible for health technology policy implementation: Service des Equipements et de la Maintenance



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: No

Name of principal institution: —

Web site: —



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: SEM

Web site: —

OTHER: Planning of medical equipment allocation

Unit/department: SAHRNR

Web site: —

OTHER: Planning of medical equipment allocation/HTA

Unit/department: SAHRD

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Nationally developed Use: Not specified

Nomenclature system name: Nomenclature nationale pour la comptabilité matière du patrimoine de l'Etat (codification pour l'inventaire technique) Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: —

National level procurement: Yes

Web site: —

DONATIONS

Policy or guideline: Yes

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: Yes, but not publically available

Web site: —

Medical device incorporation comments^λ:

Specifications techniques pour: Matériels et équipements pour les Centres de Santé de base ; Matériels et équipements de laboratoire pour les Centres Hospitaliers de Districts de niveau 2 ; Matériels et équipements biomédicaux et hospitaliers pour les Centres Hospitaliers de Districts de niveau 2



Inventory and maintenance

Type of inventories available: National functional inventory for medical equipment

Comments: Inventaire effectué en 2007 avec le projet CRESAN 2 (55 Centre Hospitalier de District de niveau 1 (CHD1), 29 Centres Hospitaliers de Districts de niveau 2 (CHD2), 18 Centres Hospitalier de Référence Régionale (CHRR), 10 Centre Hospitalier Universitaire (CHU) et Etablissements Sanitaires ; Mise à jour en cours

Medical equipment management unit: Yes

National level = 1

Regional level = 5

Hospital level = 6

Management software: No

Software and comments^λ: —



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:

Lists available: No

Unit: —

Web site: —

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: For different healthcare facilities

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: —

| | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|--------|-----------------------|---------------------------|----------|------------------------------------|

Lists comments^λ:

Nous avons normes et standards en matière de Laboratoire ; Politique Nationale de Santé Bucco-dentaire ; Normes et Standards au niveau des Districts Sanitaires de Madagascar



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 2'435 | 537 | 2972 | 12.964 |
| Health centre | 57 | 6 | 63 | 0.275 |
| District hospital | 30 | 46 | 76 | 0.332 |
| Provincial hospital | 18 | 7 | 25 | 0.109 |
| Regional hospital | 6 | n/a | 6 | 0.026 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 0 | n/a | 0 | 0.000 |
| Computerized Tomography Scanner | 0 | 3 | 3 | 0.131 |
| Positron Emission Tomography Scanner | 0 | n/a | 0 | 0.000 |
| Nuclear medicine | 0 | n/a | 0 | 0.000 |
| Mammograph* | 3 | 3 | 6 | 6.229 |
| Linear accelerator | 0 | n/a | 0 | 0.000 |
| Telecobalt unit (Cobalt-60) | 1 | 0 | 1 | 0.044 |
| Radiotherapy | 1 | 0 | 1 | 0.044 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ:

Formation en maintenance biomédicale a Madagascar: Depuis 1980, la multiplication des établissements hospitaliers et l'avènement des nouvelles technologies au service de santé ont induit une arrivée massive et diversifiée d'appareillages biomédicaux et ont fait apparaître le problème crucial de leur maintenance. La dernière action de recyclage (formation continue) des techniciens date de 2001.

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|--------|---|----|--------------------------------------|-----|
| Population (000s)* | 16'363 | Life expectancy at birth (years) ^a | 59 | World Bank income group ^β | Low |
| Internet users (%) ^γ | 5.4% | Per capita total health expenditure (PPP Int \$) ^δ | 83 | GNI per capita (US\$) ^ε | 270 |



National policy on health technology

Health technology (medical device) national policy: Yes, and it is part of the National Health Program/Plan or Policy

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: Physical Assets Management Division



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: No

Name of principal institution: —

Web site: —



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: Physical Assets Management

Web site: —

OTHER: Planning of medical equipment allocation/Application/user training

Unit/department: Physical Assets Management

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: —

National level procurement: Yes

Web site: —

DONATIONS

Policy or guideline: Yes

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: Yes

Web site: —

Medical device incorporation comments^λ:

We have Public Procurement Act (2003), Desk Instructions, and Procurement Regulations on pdf files.



Inventory and maintenance

Type of inventories available: National inventory for medical equipment

Comments: The inventory is in a database known as Planning and Management of Assets in Health Sector (PLAMAHS) and is not online yet.

Medical equipment management unit: Yes

National level = –

Regional level = –

Hospital level = –

Management software: Yes

Software and comments^λ: Planning and Management of Assets in Health Sector (PLAMAHS)



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:

Lists available: Yes

Unit: Physical Assets Management

Web site: –

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES OR SPECIFIC PROCEDURES: Lists available: For different healthcare facilities

Web site - facilities: –

Web site - procedures: –

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: –

Web site: –

| | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|--------|-----------------------|---------------------------|----------|------------------------------------|

Lists comments^λ:

The standard list provided is for health centres, community hospitals and district hospitals.

The standard list for central hospitals is being developed and will be published very soon (jica.cdr customer.pdf).



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 73 | n/a | 73 | 0.446 |
| Health centre | 377 | n/a | 377 | 2.304 |
| District hospital | 37 | n/a | 37 | 0.226 |
| Provincial hospital | 23 | n/a | 23 | 0.141 |
| Regional hospital | 5 | n/a | 5 | 0.031 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 0 | 1 | 1 | 0.061 |
| Computerized Tomography Scanner | 2 | 3 | 5 | 0.306 |
| Positron Emission Tomography Scanner | 0 | 0 | 0 | 0.000 |
| Nuclear medicine | 0 | 0 | 0 | 0.000 |
| Mammograph* | 0 | n/a | 0 | 0.000 |
| Linear accelerator | 0 | 0 | 0 | 0.000 |
| Telecobalt unit (Cobalt-60) | 0 | 0 | 0 | 0.000 |
| Radiotherapy | 0 | 0 | 0 | 0.000 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: –

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|--------|---|----|--------------------------------------|-----|
| Population (000s)* | 15'302 | Life expectancy at birth (years) ^a | 57 | World Bank income group ^β | Low |
| Internet users (%) ^γ | 2.3% | Per capita total health expenditure (PPP Int \$) ^δ | 74 | GNI per capita (US\$) ^ε | 670 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Division établissements sanitaires et réglementation - Direction nationale de la Santé

Web site: pas de site



National health technology assessment unit

Unit/department: Cellule de Planification et de Statistique

Web site: www.sante.gov.ml



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: DNS

Web site: —

OTHER: Planning of medical equipment allocation/Approvisionnement DAF/HTA/development of technical specifications

Unit/department: DAF

Web site: —

OTHER: Technical specifications and maintenance/application/user training

Unit/department: SEPAUMAT

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Nationally developed Use: Not specified

Nomenclature system name: Nomenclature sommaire ou les différents produits sont classés par catégories. Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: Yes

Web site: —

DONATIONS

Policy or guideline: No

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: Yes, but not publically available

Web site: —

Medical device incorporation comments^λ:

Guidelines for procurement: existe un document de projet de politique nationale en matière d'équipements et d'infrastructures sanitaires qui traite ces cas , mais il reste à être validé. Jusqu'à l'adoption de la loi hospitalière La DAF était le seul organe d'achat de dispositifs médicaux . Vue que cette loi accorde un statut particulier à certaines structures sanitaires notamment l'autonomie de gestion, mais aussi dans le cadre de la décentralisation il y a le transfert de compétences entre le Ministère de la Santé et les collectivités territoriales , de sorte que ces structures peuvent acheter indépendamment .



Inventory and maintenance

Type of inventories available: National functional inventory for medical equipment

Comments: Chaque année le Ministère de la santé à travers la DAF organise des inventaires mixtes dans lesquels participent comptables matières et techniciens biomédicaux, dans toutes les structures sanitaires du pays [centres de santé communautaire (cscm) , centre de santé de référence (csréf) et hôpitaux régionaux (HR)]. Ensuite les différentes fiches sont compilées et informatisés au niveau de la division comptabilité matières .

Medical equipment management unit: Yes

National level = 4

Regional level = 4

Hospital level = 4

Management software: No

Software and comments^λ: —



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:

Lists comments^λ:

Lists available: Yes

Unit: —

Web site: —

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: For different healthcare facilities

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: —

| | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|--------|-----------------------|---------------------------|----------|------------------------------------|

Il n'existe pas de normes nationales pour des procédures spécifiques, en général elles sont traitées au cas par cas. Non, comme décrit précédemment , il n'existe pas de liste spécifique de dispositifs médicaux pour les cas cités. La liste de dispositifs médicaux approuvée est en fait par niveau de structures sanitaires . A ce jour nous disposons de listes standard d'équipements pour



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | n/a | n/a | n/a | n/a |
| Health centre | 873 | n/a | 873 | 5.705 |
| District hospital | 59 | n/a | 59 | 0.386 |
| Provincial hospital | 7 | n/a | 7 | 0.046 |
| Regional hospital | 4 | n/a | 4 | 0.026 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 0 | 0 | 0 | 0.000 |
| Computerized Tomography Scanner | 3 | n/a | 3 | 0.196 |
| Positron Emission Tomography Scanner | 0 | n/a | 0 | 0.000 |
| Nuclear medicine | 1 | n/a | 1 | 0.065 |
| Mammograph* | 2 | 1 | 3 | 5.422 |
| Linear accelerator | 1 | 0 | 1 | 0.065 |
| Telecobalt unit (Cobalt-60) | 0 | 0 | 0 | 0.000 |
| Radiotherapy | 1 | 0 | 1 | 0.065 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ:

Concerning HT national policy we provide the following doc.: PAM Policy: final signed version Nov.2002 - incl cover le.pdf. Concerning the Infrastructure section: Nous n'avons pas encore une politique nationale pour les équipements mais nous y travaillons , nous avons tenu deux ateliers : l'un pour l'élaboration des éléments de la politique et l'autre pour la rédaction du document de politique . Le document attend sa validation lors d'un atelier national pour être soumis à l'Assemblée Nationale . Concerning the Section Infrastructure: la Division établissements sanitaires et réglementation (DESR) à la Direction Nationale de la Santé s'occupe également des établissements privés de santé mais ne dispose pas de données à jour (2010) sur leur nombre exact .

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|-------|---|-----|--------------------------------------|--------------|
| Population (000s)* | 3'890 | Life expectancy at birth (years) ^a | 63 | World Bank income group ^β | Lower-middle |
| Internet users (%) ^γ | 6.2% | Per capita total health expenditure (PPP Int \$) ^δ | 122 | GNI per capita (US\$) ^ε | 1'060 |



National policy on health technology

Health technology (medical device) national policy: Yes, and it is part of the National Health Program/Plan or Policy

Web site: —

Language(s): Français

MOH responsible for health technology policy implementation: Des Infrastructures ,du Materiel et de la Maintenance(DIMM)



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Direction de la Medecine Hospitaliere (DMH)

Web site: www.sante.gov.mr/MSAS/Left/Presentation_dmin07.htm



National health technology assessment unit

Unit/department: Direction des Affaires Financieres

Web site: <http://www.sante.gov.mr/MSAS/Left/Presentation/admin07.htm>



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: Direction des Infrastructures ,du Materiel et de la Maintenance

Web site: <http://www.sante.gov.mr/MSAS/Left/Presentation/admin07.htm/>

OTHER: Recéption des équipements/maintenance préventive et curative/planning of medical equipment allocation/HTA/development of technical specifications/application/user training

Unit/department: Direction des Infrastructures ,du Materiel et de la Maintenance

Web site: <http://www.sante.gov.mr/MSAS/Left/Presentation/admin07.htm/>

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: <http://www.sante.gov.mr/MSAS/>

National level procurement: Yes

Web site: <http://www.sante.gov.mr/MSAS/>

DONATIONS

Policy or guideline: No

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

[Medical device incorporation comments^λ:](#)

Il existe un plan de passation des Marchés (see following document [Presentation/admin07.htm](#)).



Inventory and maintenance

Type of inventories available: None

Comments: Un inventaire technique national etait disponible dans une base de donnée informatisée(GMAO) qui est malheureusement dectueuse depuis 2004, et qui n'a jamais été actualisé au niveau national.

Medical equipment management unit: Yes

National level = 1

Regional level = 5

Hospital level = 3

Management software: No

Software and comments^λ: —



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:

Lists available: No

Unit: —

Web site: —

Lists comments^λ:

Il existe des paquets d'activités par niveau des soins de la pyramide sanitaire.

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: No list available

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: —

| | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|--------|-----------------------|---------------------------|----------|------------------------------------|



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 411 | 42 | 453 | 11.646 |
| Health centre | 67 | 81 | 148 | 3.805 |
| District hospital | 7 | 20 | 27 | 0.694 |
| Provincial hospital | 6 | n/a | 6 | 0.154 |
| Regional hospital | 7 | n/a | 7 | 0.180 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 1 | 2 | 3 | 0.771 |
| Computerized Tomography Scanner | 5 | 1 | 6 | 1.542 |
| Positron Emission Tomography Scanner | n/a | n/a | n/a | n/a |
| Nuclear medicine | n/a | n/a | n/a | n/a |
| Mammograph* | 2 | 2 | 4 | 22.415 |
| Linear accelerator | n/a | n/a | n/a | n/a |
| Telecobalt unit (Cobalt-60) | n/a | n/a | n/a | n/a |
| Radiotherapy | n/a | n/a | n/a | n/a |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ:

Le suivi de la maintenance des équipements, est une mission confiée à la Direction des Infrastructures, du Matériel et de la Maintenance (DIMM) et mis en œuvre par le service de la Maintenance.

Le service de la maintenance comprend deux divisions :- Division de la maintenance des infrastructures;- Division de la maintenance des équipements et des matériels. Le service de la maintenance dispose d'un plateau technique composé, au niveau central de : 7 techniciens biomédicaux, de 2 ingénieurs biomédicaux et d'un ingénieur électrotechnicien, au niveau périphérique de : 5 unités régionale, qui assurent une maintenance de proximité....

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|-------|---|-----|--------------------------------------|--------------|
| Population (000s)* | 1'244 | Life expectancy at birth (years) ^a | 74 | World Bank income group ^β | Upper-middle |
| Internet users (%) ^γ | 39.0% | Per capita total health expenditure (PPP Int \$) ^δ | 784 | GNI per capita (US\$) ^ε | 9'290 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: EQUIPMENT COMMITTEE under chairmanship of DIRECTOR, HEALTH SERVICES



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: No

Name of principal institution: —

Web site: —



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: Flacq Hospital

Web site: —

OTHER: Planning of medical equipment allocation/development of technical specifications/application/user training

Unit/department: SSR National Hospital

Web site: —

OTHER: Planning of medical equipment allocation/development of technical specifications/application/user training

Unit/department: Victoria Hospital

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: No

Web site: —

DONATIONS

Policy or guideline: No

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: Yes, but not publically available

Web site: —

Medical device incorporation comments^λ:

Central Procurement Board has a policy. However, there is an equipment committee which looks after procurement of equipment spare parts. For public sector: procurement is done at a level of MoH and central procurement board. Private equipment is done by direct purchase. In the public sector, we recommend certification based on FDA, CE, TUV approved systems



Inventory and maintenance

Type of inventories available: National inventory for medical equipment

Comments: Each hospital has a separate inventory.

Medical equipment management unit: Yes

National level = 1

Regional level = 5

Hospital level = 5

Management software: No

Software and comments^λ: There is one developed locally which is currently on trial. e-health in preparation.



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^δ:

Lists available: No

Unit: —

Web site: —

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES OR SPECIFIC PROCEDURES^δ: Lists available: No list available

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS^δ:

Lists available: No list available

Web site: —

| | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|--------|-----------------------|---------------------------|----------|------------------------------------|

Lists comments^λ:

Some lists are available for certain specific conditions e.g Pandemic, fogging, sprayers,etc (specific Plan in preparation), there are not specific lists for Non-communicable or communicable diseases. It must be pointed out that the Ministry does not accept all donations except from friendly countries.



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 110 | n/a | 110 | 8.840 |
| Health centre | 2 | n/a | 2 | 0.161 |
| District hospital | 2 | n/a | 2 | 0.161 |
| Provincial hospital | 5 | n/a | 5 | 0.402 |
| Regional hospital | 5 | n/a | 5 | 0.402 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 2 | 4 | 6 | 4.822 |
| Computerized Tomography Scanner | 3 | 5 | 8 | 6.429 |
| Positron Emission Tomography Scanner | 0 | 0 | 0 | 0.000 |
| Nuclear medicine | 2 | 1 | 3 | 2.411 |
| Mammograph* | 3 | 4 | 7 | 49.677 |
| Linear accelerator | 1 | 0 | 1 | 0.804 |
| Telecobalt unit (Cobalt-60) | 2 | 0 | 2 | 1.607 |
| Radiotherapy | 3 | 0 | 3 | 2.411 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ:

Concerning HT national policy we provide the following doc.: politique santé.doc

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

Mozambique



Country indicators

| | | | | | |
|---------------------------------|--------|---|----|--------------------------------------|-----|
| Population (000s)* | 25'834 | Life expectancy at birth (years) ^a | 53 | World Bank income group ^β | Low |
| Internet users (%) ^γ | 5.4% | Per capita total health expenditure (PPP Int \$) ^δ | 66 | GNI per capita (US\$) ^ε | 610 |



National policy on health technology

Health technology (medical device) national policy: Yes, and it is part of the National Health Program/Plan or Policy

Web site: —

Language(s): Portuguese

MOH responsible for health technology policy implementation: Direcçao Nacional Assistencia Medica



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: No

Name of principal institution: —

Web site: —



National health technology assessment unit

Unit/department: DIS

Web site: —



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: Centro de Abastecimento

Web site: —

OTHER: Planning of medical equipment allocation

Unit/department: Centro de Abastecimento

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Nationally developed Use: Not specified

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: —

National level procurement: Yes

Web site: —

DONATIONS

Policy or guideline: Yes

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: Yes, but not publically available

Web site: —

Medical device incorporation comments^λ: —



Inventory and maintenance

Type of inventories available: National inventory only for high cost technologies (such as MRI, CT or PET scanners)

Comments: –

Medical equipment management unit: No

National level = 0

Regional level = 0

Hospital level = 0

Management software: Yes

Software and comments^λ: simorganizer



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^δ

Lists available: No

Unit: –

Web site: –

Lists comments^λ:

Lists available for communicable diseases and public health emergency situations.

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: For different healthcare facilities and specific procedures

Web site - facilities: –

Web site - procedures: –

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: One or more

Web site: –

Types:

| | |
|-----------------------|---|
| Communicable diseases | x |
|-----------------------|---|

| | |
|---------------------------|--|
| Non-communicable diseases | |
|---------------------------|--|

| | |
|----------|--|
| Injuries | |
|----------|--|

| | |
|------------------------------------|---|
| Public health emergency situations | x |
|------------------------------------|---|



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | n/a | n/a | n/a | n/a |
| Health centre | n/a | n/a | n/a | n/a |
| District hospital | n/a | n/a | n/a | n/a |
| Provincial hospital | n/a | n/a | n/a | n/a |
| Regional hospital | n/a | n/a | n/a | n/a |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | n/a | n/a | n/a | n/a |
| Computerized Tomography Scanner | n/a | n/a | n/a | n/a |
| Positron Emission Tomography Scanner | n/a | n/a | n/a | n/a |
| Nuclear medicine | n/a | n/a | n/a | n/a |
| Mammograph* | n/a | n/a | n/a | n/a |
| Linear accelerator | n/a | n/a | n/a | n/a |
| Telecobalt unit (Cobalt-60) | n/a | n/a | n/a | n/a |
| Radiotherapy | n/a | n/a | n/a | n/a |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: –

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|-------|---|-----|--------------------------------------|--------------|
| Population (000s)* | 2'303 | Life expectancy at birth (years) ^a | 67 | World Bank income group ^β | Upper-middle |
| Internet users (%) ^γ | 13.9% | Per capita total health expenditure (PPP Int \$) ^δ | 619 | GNI per capita (US\$) ^ε | 5'870 |



National policy on health technology

Health technology (medical device) national policy: Yes, and it is part of the National Health Program/Plan or Policy

Web site: <http://www.healthnet.org.na>

Language(s): English

MOH responsible for health technology policy implementation: Directorate of Tertiary Health Care & clinical Support Services (THC & CSS)



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Directorate of Atomic Energy & Radiation Protection Authority

Web site: —



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: Radiographic Services

Web site: —

OTHER: Service, repair and maintenance of Medical Equipment/Technical specifications/planning/user training

Unit/department: Medical Equipement Management (MEM)

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: —

Web site: <http://www.healthnet.org.na>

National level procurement: Yes

Web site: —

DONATIONS

Policy or guideline: Yes

Web site: <http://www.healthnet.org.na>

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ:

There are guidelines for Implementation of the National Health care Technology Policy & Medical Equipment Management. Since finances have been decentralised, each of the 13 political regions is responsible for budgeting and procuring medical equipment for the health facilities in that region. Advise on budgeting and tender specifications can be obtained from MEM at the National Level.



Inventory and maintenance

Type of inventories available: National inventory for medical equipment

Comments: Medical Equipment Management System Software (MEMS)

Medical equipment management unit: Yes

National level = 1

Regional level = 4

Hospital level = 0

Management software: Yes

Software and comments^λ: Medical Equipment Management System Software (MEMS)



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:

Lists comments^λ: —

Lists available: No

Unit: —

Web site: —

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES OR SPECIFIC PROCEDURES: Lists available: —

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: —

| | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|--------|-----------------------|---------------------------|----------|------------------------------------|



Healthcare facility

| | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 267 | 27 | 294 | 12.764 |
| Health centre | 44 | 9 | 53 | 2.301 |
| District hospital | 30 | n/a | 30 | 1.302 |
| Provincial hospital | 3 | 1 | 4 | 0.174 |
| Regional hospital | 1 | 9 | 10 | 0.434 |



Medical equipment

| | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 0 | 2 | 2 | 0.868 |
| Computerized Tomography Scanner | 4 | 7 | 11 | 4.776 |
| Positron Emission Tomography Scanner | 0 | 0 | 0 | 0.000 |
| Nuclear medicine | 1 | 1 | 2 | 0.868 |
| Mammograph* | 2 | 3 | 5 | 42.298 |
| Linear accelerator | 0 | 0 | 0 | 0.000 |
| Telecobalt unit (Cobalt-60) | 1 | 0 | 1 | 0.434 |
| Radiotherapy | 1 | 0 | 1 | 0.434 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: —

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|--------|---|----|--------------------------------------|-----|
| Population (000s)* | 17'831 | Life expectancy at birth (years) ^a | 59 | World Bank income group ^β | Low |
| Internet users (%) ^γ | 1.7% | Per capita total health expenditure (PPP Int \$) ^δ | 44 | GNI per capita (US\$) ^ε | 400 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: No

Name of principal institution: —

Web site: —



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: Division des Equipements biomédicaux

Web site: —

OTHER: Development of technical specifications/Application/user training/

Unit/department: Direction des Infrastructures et Equipements Sanitaires

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: Yes

Web site: —

DONATIONS

Policy or guideline: No

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: Yes, but not publically available

Web site: —

Medical device incorporation comments^λ:

Toutes les acquisitions réalisées dans le cadre des projets et programmes passent par la DIES. Mais certaines (ONG et associations caritatives) ne passent pas.



Inventory and maintenance

Type of inventories available: National inventory for medical equipment

Comments: Il ya eu plusieurs tentatives d'installation de logiciel de GMAO (Gestion de la Maintenance Assistée par Ordinateur) dont Gestmat (par la Société Deloitte et Touch Consulting) et OPTIM (par le Bureau BEEM Engineering France). Aucun logiciel n'est totalement fonctionnel en ce moment.

Medical equipment management unit: Yes

National level = 0

Regional level = 8

Hospital level = 42

Management software: No

Software and comments^λ: —



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:

Lists available: No

Unit: —

Web site: —

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: For different healthcare facilities

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: —

| | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|--------|-----------------------|---------------------------|----------|------------------------------------|

Lists comments^λ:

Les premiers documents de normes et Standards datent de 1995 réalisés avec l'appui du Cabinet Planning Assistance. Ces normes concernent les Centres de santé Intégrés et les Hôpitaux de District mais ne concernent pas les Hôpitaux régionaux et nationaux. Le Ministère a élaboré en 2010 de nouvelles normes.



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 2'344 | 149 | 2493 | 13.981 |
| Health centre | 801 | 85 | 886 | 4.969 |
| District hospital | 42 | 35 | 77 | 0.432 |
| Provincial hospital | 6 | 5 | 11 | 0.062 |
| Regional hospital | 6 | 4 | 10 | 0.056 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 0 | 0 | 0 | 0.000 |
| Computerized Tomography Scanner | 3 | 0 | 3 | 0.168 |
| Positron Emission Tomography Scanner | 0 | 0 | 0 | 0.000 |
| Nuclear medicine | 0 | 0 | 0 | 0.000 |
| Mammograph* | 7 | 0 | 7 | 10.936 |
| Linear accelerator | 0 | 0 | 0 | 0.000 |
| Telecobalt unit (Cobalt-60) | 0 | 0 | 0 | 0.000 |
| Radiotherapy | 0 | 0 | 0 | 0.000 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ:

Le Niger dispose d'une stratégie nationale de maintenance adoptée depuis avril 2008 (document mentioned above sent via email).

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|---------|---|-----|--------------------------------------|--------------|
| Population (000s)* | 173'615 | Life expectancy at birth (years) ^a | 54 | World Bank income group ^β | Lower-middle |
| Internet users (%) ^γ | 38.0% | Per capita total health expenditure (PPP Int \$) ^δ | 161 | GNI per capita (US\$) ^ε | 2'710 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: Food and Drug Services



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: National Agency for Food and Drug Administration and Control

Web site: <http://www.nafdac.gov.ng/>



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: —

Web site: —

OTHER: Medical Devices Management and Standardization Unit

Unit/department: Medical Devices Management and Standardization Unit

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: No

Web site: —

DONATIONS

Policy or guideline: No

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ: —



Inventory and maintenance

Type of inventories available: None

Comments: —

Medical equipment management unit: Yes

National level = —

Regional level = —

Hospital level = —

Management software: No

Software and comments^λ: —

Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:Lists comments^λ: —

Lists available: No

Unit: —

Web site: —

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES OR SPECIFIC PROCEDURES: Lists available: For different healthcare facilities

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: —

Types:

| | | | |
|-----------------------|---------------------------|----------|------------------------------------|
| Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|-----------------------|---------------------------|----------|------------------------------------|



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | n/a | n/a | n/a | n/a |
| Health centre | n/a | n/a | n/a | n/a |
| District hospital | n/a | n/a | n/a | n/a |
| Provincial hospital | n/a | n/a | n/a | n/a |
| Regional hospital | n/a | n/a | n/a | n/a |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | n/a | n/a | n/a | n/a |
| Computerized Tomography Scanner | n/a | n/a | n/a | n/a |
| Positron Emission Tomography Scanner | n/a | n/a | n/a | n/a |
| Nuclear medicine | n/a | n/a | n/a | n/a |
| Mammograph* | n/a | n/a | n/a | n/a |
| Linear accelerator | n/a | n/a | n/a | n/a |
| Telecobalt unit (Cobalt-60) | n/a | n/a | n/a | n/a |
| Radiotherapy | n/a | n/a | n/a | n/a |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: —

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

Sao Tome and Principe



Country indicators

| | | | | | |
|---------------------------------|-------|---|-----|--------------------------------------|--------------|
| Population (000s)* | 193 | Life expectancy at birth (years) ^a | 67 | World Bank income group ^β | Lower-middle |
| Internet users (%) ^γ | 23.0% | Per capita total health expenditure (PPP Int \$) ^δ | 144 | GNI per capita (US\$) ^ε | 1'470 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: No

Name of principal institution: —

Web site: —



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): No

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: No

Web site: —

DONATIONS

Policy or guideline: No

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ: —



Inventory and maintenance

Type of inventories available: None

Comments: L'inventaire des équipements médicaux existant est caduque (2002) Après cette date un nombre considérable des équipements ont rentres en charge.

Medical equipment management unit: No

National level = 0

Regional level = 0

Hospital level = 0

Management software: No

Software and comments^λ: —



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:

Lists available: No

Unit: —

Web site: —

Lists comments^λ:

Il n'existe pas au niveau national aucune liste recommandant des technologies de santé.

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: No list available

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: —

| | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|--------|-----------------------|---------------------------|----------|------------------------------------|



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 28 | n/a | 28 | 14.508 |
| Health centre | 4 | n/a | 4 | 2.073 |
| District hospital | n/a | n/a | n/a | n/a |
| Provincial hospital | n/a | n/a | n/a | n/a |
| Regional hospital | n/a | n/a | n/a | n/a |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | n/a | n/a | n/a | n/a |
| Computerized Tomography Scanner | n/a | n/a | n/a | n/a |
| Positron Emission Tomography Scanner | n/a | n/a | n/a | n/a |
| Nuclear medicine | n/a | n/a | n/a | n/a |
| Mammograph* | n/a | n/a | n/a | n/a |
| Linear accelerator | n/a | n/a | n/a | n/a |
| Telecobalt unit (Cobalt-60) | n/a | n/a | n/a | n/a |
| Radiotherapy | n/a | n/a | n/a | n/a |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: —

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|--------|---|----|--------------------------------------|--------------|
| Population (000s)* | 14'133 | Life expectancy at birth (years) ^a | 64 | World Bank income group ^β | Lower-middle |
| Internet users (%) ^γ | 20.9% | Per capita total health expenditure (PPP Int \$) ^δ | 97 | GNI per capita (US\$) ^ε | 1'050 |



National policy on health technology

Health technology (medical device) national policy: Yes, and it is part of the National Health Program/Plan or Policy

Web site: <http://www.sante.gouv.sn>

Language(s): French

MOH responsible for health technology policy implementation: Direction des Equipements et de la Maintenance



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Direction des Equipements et de la Maintenance(DEM)

Web site: <http://www.sante.gouv.sn>



National health technology assessment unit

Unit/department: DEM

Web site: <http://www.sante.gouv.sn>



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: DEM

Web site: <http://www.sante.gouv.sn>

OTHER: Planning of medical equipment allocation/HTA/development of technical specifications/application/user training

Unit/department: DEM

Web site: <http://www.sante.gouv.sn>

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Nationally developed Use: For procurement

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: <http://www.sante.gouv.sn>

National level procurement: No

Web site: —

DONATIONS

Policy or guideline: Yes

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: Yes, but not publically available

Web site: —

Medical device incorporation comments^λ:

On procède à des appels d'offres nationaux et les representants des fabricants étrangers fournissent les équipements



Inventory and maintenance

Type of inventories available: National inventory for medical equipment

Comments: We have an inventaire national des équipements médicaux 2009

Medical equipment management unit: Yes

National level = 1

Regional level = 4

Hospital level = 22

Management software: Yes

Software and comments^λ: SIM (logiciel de Système Informatique de Maintenance)



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^δ:

Lists available: Yes, but it is only a recommendation

Unit: DEM (Direction des Equipements et de la Maintenance)

Web site: –

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES OR SPECIFIC PROCEDURES^δ: Lists available: For different healthcare facilities and specific procedures

Web site - facilities: –

Web site - procedures: –

NATIONAL LIST FOR DISEASES AND SITUATIONS^δ:

Lists available: No list available

Web site: –

Types:

Communicable diseases

Non-communicable diseases

Injuries

Public health emergency situations

Lists comments^λ:

Nous avons des listes standard des équipements pour toutes les structures sanitaires. Les spécifications techniques des équipements sont réalisées par la Direction des Equipements et de la Maintenance



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 971 | n/a | 971 | 6.870 |
| Health centre | 76 | n/a | 76 | 0.538 |
| District hospital | 22 | n/a | 22 | 0.156 |
| Provincial hospital | n/a | n/a | n/a | n/a |
| Regional hospital | n/a | n/a | n/a | n/a |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 2 | n/a | 2 | 0.142 |
| Computerized Tomography Scanner | 5 | n/a | 5 | 0.354 |
| Positron Emission Tomography Scanner | 0 | n/a | 0 | 0.000 |
| Nuclear medicine | 1 | n/a | 1 | 0.071 |
| Mammograph* | 3 | n/a | 3 | 5.192 |
| Linear accelerator | 0 | n/a | 0 | 0.000 |
| Telecobalt unit (Cobalt-60) | 1 | n/a | 1 | 0.071 |
| Radiotherapy | 1 | n/a | 1 | 0.071 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: –

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|-------|---|------|--------------------------------------|--------------|
| Population (000s)* | 93 | Life expectancy at birth (years) ^a | 74 | World Bank income group ^β | Upper-middle |
| Internet users (%) ^γ | 50.4% | Per capita total health expenditure (PPP Int \$) ^δ | 1197 | GNI per capita (US\$) ^ε | 13'210 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: No

Name of principal institution: —

Web site: —



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): No

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: Yes

Web site: —

DONATIONS

Policy or guideline: No

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ:

It is a small committee that meet to discuss equipment request by various unit within the ministry of health. Please note that Seychelles has a small population and we donot purchase equipment on a big scale.



Inventory and maintenance

Type of inventories available: National inventory for medical equipment

Comments: —

Medical equipment management unit: Yes

National level = 1

Regional level = 0

Hospital level = 0

Management software: No

Software and comments^λ: —



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:

Lists comments^λ: —

Lists available: Yes, but it is only a recommendation

Unit: —

Web site: —

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES OR SPECIFIC PROCEDURES: Lists available: No list available

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: —

| | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|--------|-----------------------|---------------------------|----------|------------------------------------|



Healthcare facility

| | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 13 | 6 | 19 | 20.466 |
| Health centre | 4 | 1 | 5 | 5.386 |
| District hospital | n/a | n/a | n/a | n/a |
| Provincial hospital | n/a | n/a | n/a | n/a |
| Regional hospital | 1 | n/a | 1 | 1.077 |



Medical equipment

| | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 1 | n/a | 1 | 10.771 |
| Computerized Tomography Scanner | 1 | n/a | 1 | 10.771 |
| Positron Emission Tomography Scanner | n/a | n/a | n/a | n/a |
| Nuclear medicine | n/a | n/a | n/a | n/a |
| Mammograph* | 1 | n/a | 1 | 127.730 |
| Linear accelerator | n/a | n/a | n/a | n/a |
| Telecobalt unit (Cobalt-60) | n/a | n/a | n/a | n/a |
| Radiotherapy | n/a | n/a | n/a | n/a |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ:

Concerning HT national policy we provide the following doc.: polmainte.pdf

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

Sierra Leone



Country indicators

| | | | | | |
|---------------------------------|-------|---|-----|--------------------------------------|-----|
| Population (000s)* | 6'092 | Life expectancy at birth (years) ^a | 46 | World Bank income group ^β | Low |
| Internet users (%) ^γ | 1.7% | Per capita total health expenditure (PPP Int \$) ^δ | 205 | GNI per capita (US\$) ^ε | 660 |



National policy on health technology

Health technology (medical device) national policy: Yes, and it is part of the National Health Program/Plan or Policy

Web site: —

Language(s): English

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: The Pharmacy Board of Sierra Leone, Ministry of Health and Sanitation

Web site: <http://www.pharmacyboard.gov.sl>



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: Procurement Unit

Web site: —

OTHER: Planning of medical equipment allocation/development of technical specifications

Unit/department: Procurement Unit

Web site: —

OTHER: Maintenance/Applicacion/User training

Unit/department: Facilities & Maintenance Unit

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on UMDNS (Universal Medical Device Nomenclature System) Use: For procurement

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: —

National level procurement: Yes

Web site: —

DONATIONS

Policy or guideline: Yes

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ:

Most of the equipments have been used and found incomplete, which makes installation difficult. Procurement of medical devices are carried out without involving the specialists.



Inventory and maintenance

Type of inventories available: National inventory for medical equipment

Comments: The last inventory was done twelve years ago. Looking forward to start another one.

Medical equipment management unit: Yes

National level = 1

Regional level = 0

Hospital level = 1

Management software: —

Software and comments^λ: —



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^δ:

Lists available: Yes

Unit: Procurement Unit

Web site: —

Lists comments^λ:

Lists for procurements are still being worked on not yet completed. However we do have public health emergency situations lists.

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES OR SPECIFIC PROCEDURES: Lists available: For specific procedures

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: One or more

Web site: —

| | | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|---|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations | x |
|--------|-----------------------|---------------------------|----------|------------------------------------|---|



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | n/a | n/a | n/a | n/a |
| Health centre | 74 | n/a | 74 | 1.215 |
| District hospital | n/a | n/a | n/a | n/a |
| Provincial hospital | n/a | n/a | n/a | n/a |
| Regional hospital | n/a | n/a | n/a | n/a |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | n/a | n/a | n/a | n/a |
| Computerized Tomography Scanner | 1 | 1 | 2 | 0.328 |
| Positron Emission Tomography Scanner | n/a | n/a | n/a | n/a |
| Nuclear medicine | 1 | n/a | 1 | 0.164 |
| Mammograph* | n/a | n/a | n/a | n/a |
| Linear accelerator | n/a | n/a | n/a | n/a |
| Telecobalt unit (Cobalt-60) | n/a | n/a | n/a | n/a |
| Radiotherapy | n/a | n/a | n/a | n/a |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ:

Limited number of technical personnel to meet service demand. Most of the equipment supplied by donors is obsolete and out of order.

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

South Africa



Country indicators

| | | | | | |
|---------------------------------|--------|---|-----|--------------------------------------|--------------|
| Population (000s)* | 52'776 | Life expectancy at birth (years) ^a | 59 | World Bank income group ^β | Upper-middle |
| Internet users (%) ^γ | 48.9% | Per capita total health expenditure (PPP Int \$) ^δ | 982 | GNI per capita (US\$) ^ε | 7'190 |



National policy on health technology

Health technology (medical device) national policy: Yes, and it is part of the National Health Program/Plan or Policy

Web site: —

Language(s): English

MOH responsible for health technology policy implementation: Health Technology Directorate



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Directorate: Radiation Control

Web site: <http://www.doh.gov.za/show.php?id=2961>



National health technology assessment unit

Unit/department: HTWC

Web site: —



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: HTKZN

Web site: —

OTHER: Planning of medical equipment allocation/HTA/development of technical specifications/application/user training

Unit/department: HTFS

Web site: —

OTHER: Planning of medical equipment allocation/HTA/development of technical specifications/application/user training

Unit/department: HTWC

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: <http://www.treasury.gov.za/legislation/pfma/Default.aspx>

National level procurement: No

Web site: —

DONATIONS

Policy or guideline: Yes

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: Yes, but not publically available

Web site: —

Medical device incorporation comments^λ: —



Inventory and maintenance

Type of inventories available: None

Comments: No National inventory but some hospitals do have. We are currently compiling a national inventory.

Medical equipment management unit: Yes

National level = 1

Regional level = 8

Hospital level = 18

Management software: Yes

Software and comments^λ: But No National system. Different systems used in different hospitals. Currently acquiring a system to be implemented nationally



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:

Lists available: Yes

Unit: —

Web site: —

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES OR SPECIFIC PROCEDURES: Lists available: For different healthcare facilities

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: —

Types:

| |
|-----------------------|
| Communicable diseases |
|-----------------------|

| |
|---------------------------|
| Non-communicable diseases |
|---------------------------|

| |
|----------|
| Injuries |
|----------|

| |
|------------------------------------|
| Public health emergency situations |
|------------------------------------|

Lists comments^λ:

We don't have any lists of the mentioned above. The list is only for the private sector funders (not government). National Dept of Health is engaging with private sector to establish a national system.



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 3'105 | n/a | 3105 | 5.883 |
| Health centre | 289 | n/a | 289 | 0.548 |
| District hospital | 279 | n/a | 279 | 0.529 |
| Provincial hospital | 63 | n/a | 63 | 0.119 |
| Regional hospital | 14 | n/a | 14 | 0.027 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 12 | n/a | 12 | 0.227 |
| Computerized Tomography Scanner | 51 | n/a | 51 | 0.966 |
| Positron Emission Tomography Scanner | 3 | n/a | 3 | 0.057 |
| Nuclear medicine | 28 | n/a | 28 | 0.531 |
| Mammograph* | 32 | n/a | 32 | 7.777 |
| Linear accelerator | 21 | n/a | 21 | 0.398 |
| Telecobalt unit (Cobalt-60) | 9 | n/a | 9 | 0.171 |
| Radiotherapy | 30 | n/a | 30 | 0.568 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: —

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

Swaziland



Country indicators

| | | | | | |
|---------------------------------|-------|---|-----|--------------------------------------|--------------|
| Population (000s)* | 1'250 | Life expectancy at birth (years) ^a | 54 | World Bank income group ^β | Lower-middle |
| Internet users (%) ^γ | 24.7% | Per capita total health expenditure (PPP Int \$) ^δ | 448 | GNI per capita (US\$) ^ε | 2'990 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: No

Name of principal institution: —

Web site: —



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: —

Web site: —

OTHER: Planning of medical equipment allocation

Unit/department: Biomedical unit

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: Yes

Web site: —

DONATIONS

Policy or guideline: Yes

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ:

National guidelines on procurement yet to be developed. The unit together with the biomedical department form a comitee which recommends purchasing of needed equipment. or rather requested equipment.



Inventory and maintenance

Type of inventories available: National inventory for medical equipment

Comments: This inventory though is still under development, we have only covered hospitals and health centres will proceed to clinics(health posts for swaziland).

Medical equipment management unit: Yes

National level = 0

Regional level = 0

Hospital level = 0

Management software: No

Software and comments^λ: —



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:

Lists available: No

Unit: —

Web site: —

Lists comments^λ:

We have only public health emergency situations, and they are till being developed by the Emergency preparedness group.

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: No list available

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: One or more

Web site: —

| | | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|---|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations | x |
|--------|-----------------------|---------------------------|----------|------------------------------------|---|



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 162 | n/a | 162 | 12.965 |
| Health centre | 5 | 3 | 8 | 0.640 |
| District hospital | n/a | 2 | 2 | 0.160 |
| Provincial hospital | 3 | 3 | 6 | 0.480 |
| Regional hospital | 1 | 1 | 2 | 0.160 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 0 | 0 | 0 | 0.000 |
| Computerized Tomography Scanner | 1 | 2 | 3 | 2.401 |
| Positron Emission Tomography Scanner | 0 | 0 | 0 | 0.000 |
| Nuclear medicine | 0 | 0 | 0 | 0.000 |
| Mammograph* | 0 | 2 | 2 | 33.619 |
| Linear accelerator | 0 | 0 | 0 | 0.000 |
| Telecobalt unit (Cobalt-60) | 0 | 0 | 0 | 0.000 |
| Radiotherapy | 0 | 0 | 0 | 0.000 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ:

Concerning HT national policy we provide the following doc.: HEALTH TECHNOLOGY STRATEGY - VERSION 1.pdf.

Concerning infrastructure section: In swaziland Health centres may have more than 20 beds. the referral levels are being defined by the on going essential health care package that is being developed.

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|-------|---|----|--------------------------------------|-----|
| Population (000s)* | 6'817 | Life expectancy at birth (years) ^a | 58 | World Bank income group ^β | Low |
| Internet users (%) ^γ | 4.5% | Per capita total health expenditure (PPP Int \$) ^δ | 75 | GNI per capita (US\$) ^ε | 530 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Direction des Pharmacies Laboratoires et Equipements Techniques, Ministère de la Santé et de la Population

Web site: —



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: Direction Affaires Communes

Web site: —

OTHER: Maintenance of medical devices

Unit/department: Service de la Maintenance

Web site: —

OTHER: Planning of medical equipment allocation

Unit/department: Direction Affaires Communes

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: —

National level procurement: No

Web site: —

DONATIONS

Policy or guideline: No

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ:

La politique suivi en terme d'achat de dispositif est celle du code des marchés publiques. L'achat ne se fait au niveau central que si l'Etat définit ponctuellement un programme d'intervention suite à une urgence nationale



Inventory and maintenance

Type of inventories available: None

Comments: Bien que cela soit le point de départ de toute gestion en terme de maintenance des parcs biomédicaux, cette opération n'existe pas au plan national sauf par endroit mais aussi de façon sommaire. Les données ainsi consignées ne permettent pas de l'exploiter pour proposer des plans de renouvellement ou de développement de parcs biomédicaux. En bref aucun inventaire digne de ce nom n'existe pas sur le plan national.

Medical equipment management unit: Yes

National level = 1

Regional level = 6

Hospital level = 26

Management software: No

Software and comments^λ: —



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:

Lists available: No

Unit: —

Web site: —

Lists comments^λ:

Aucune organisation dans ce sens n'existe malgré toutes les propositions formulées dans ce sens rien ne semble mouvoir la volonté politique à évoluer dans ce sens.

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: For different healthcare facilities and specific procedures

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: —

| | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|--------|-----------------------|---------------------------|----------|------------------------------------|



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | n/a | n/a | n/a | n/a |
| Health centre | 730 | 16 | 746 | 10.943 |
| District hospital | 35 | n/a | 35 | 0.513 |
| Provincial hospital | n/a | n/a | 0 | 0.000 |
| Regional hospital | 6 | n/a | 6 | 0.088 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | n/a | 1 | 1 | 0.147 |
| Computerized Tomography Scanner | 2 | 3 | 5 | 0.733 |
| Positron Emission Tomography Scanner | n/a | n/a | n/a | n/a |
| Nuclear medicine | n/a | n/a | n/a | n/a |
| Mammograph* | 1 | 2 | 3 | 10.388 |
| Linear accelerator | n/a | n/a | n/a | n/a |
| Telecobalt unit (Cobalt-60) | n/a | n/a | n/a | n/a |
| Radiotherapy | n/a | n/a | n/a | n/a |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ:

Compte tenue des difficultés que nous rencontrons pour la prise en compte adéquate des plateaux techniques dans nos formations sanitaires malgré les recommandations régionales pour une politique commune en matière de maintenance et la gestion durable des infrastructures sociales je veux bien croire que cette enquête nous ouvrira l' horizon de nouvelles politiques adptées à nos réalités.

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

Uganda



Country indicators

| | | | | | |
|---------------------------------|--------|---|-----|--------------------------------------|-----|
| Population (000s)* | 37'579 | Life expectancy at birth (years) ^a | 57 | World Bank income group ^β | Low |
| Internet users (%) ^γ | 16.2% | Per capita total health expenditure (PPP Int \$) ^δ | 108 | GNI per capita (US\$) ^ε | 550 |



National policy on health technology

Health technology (medical device) national policy: Yes, and it is part of the National Health Program/Plan or Policy

Web site: —

Language(s): English

MOH responsible for health technology policy implementation: Health Infrastructure Division



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: National Drug Authority

Web site: <http://www.nda.or.ug>



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: Health Infrastructure division

Web site: <http://www.health.go.ug>

OTHER: Planning of medical equipment allocation/Technical Specifications/Application/ user training

Unit/department: Health Infrastructure division

Web site: <http://www.health.go.ug>

OTHER: Technical specifications/application/user training

Unit/department: National advisory committee on medical equipment

Web site: <http://www.health.go.ug>



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Nationally developed Use: Not specified

Nomenclature system name: List of medical equipment by level. Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: —

National level procurement: Yes

Web site: <http://www.health.go.ug>

DONATIONS

Policy or guideline: Yes

Web site: <http://www.health.go.ug>

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: Yes, but not publically available

Web site: —

Medical device incorporation comments^λ:

The ministry acquires resources and procures in bulk although for the last 2 years development funds for infrastructure have been directly allocated to regional referral hospitals who procure equipment with guidance of the health infrastructure division and national advisory committee on medical equipment (NACME).



Inventory and maintenance

Type of inventories available: National functional inventory for medical equipment

Comments: Currently being updated

Medical equipment management unit: Yes

National level = 1

Regional level = 8

Hospital level = 1

Management software: No

Software and comments^λ: —



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^α:

Lists available: Yes

Unit: National Advisory Committee on Medical Equipment (NACME)

Web site: —

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES OR SPECIFIC PROCEDURES^β: Lists available: For different healthcare facilities

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS^γ:

Lists available: No list available

Web site: —

Types:

| | | | |
|-----------------------|---------------------------|----------|------------------------------------|
| Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|-----------------------|---------------------------|----------|------------------------------------|

Lists comments^λ:

Not aware of any standards or lists for specific procedures, neither lists for communicable and non-communicable diseases, injuries, and public health emergency situations. Usually we use WHO recommendations. List of equipment by health care level was already given.



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 1'696 | 1'909 | 3605 | 9.593 |
| Health centre | 1'107 | 365 | 1472 | 3.917 |
| District hospital | 48 | 88 | 136 | 0.362 |
| Provincial hospital | 14 | n/a | 14 | 0.037 |
| Regional hospital | 2 | n/a | 2 | 0.005 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 0 | 3 | 3 | 0.080 |
| Computerized Tomography Scanner | 2 | 15 | 17 | 0.452 |
| Positron Emission Tomography Scanner | 0 | 0 | 0 | 0.000 |
| Nuclear medicine | 1 | 1 | 2 | 0.053 |
| Mammograph* | 3 | 2 | 5 | 4.411 |
| Linear accelerator | 0 | 0 | 0 | 0.000 |
| Telecobalt unit (Cobalt-60) | 1 | 1 | 2 | 0.053 |
| Radiotherapy | 1 | 1 | 2 | 0.053 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ:

The policy guidelines on donations is at Chapter Chapter 5.1.5 of the medical equipment policy (see documentation).

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

Tanzania, United Republic of



Country indicators

| | | | | | |
|---------------------------------|--------|---|-----|--------------------------------------|-----|
| Population (000s)* | 49'253 | Life expectancy at birth (years) ^a | 61 | World Bank income group ^β | Low |
| Internet users (%) ^γ | 4.4% | Per capita total health expenditure (PPP Int \$) ^δ | 109 | GNI per capita (US\$) ^ε | 630 |



National policy on health technology

Health technology (medical device) national policy: Yes, but is not part of the National Health Program

Web site: —

Language(s): English

MOH responsible for health technology policy implementation: Diagnostic Services, Healthcare Technical Services under Director of Curative Services



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Tanzania Food and Drugs Authority (TFDA)

Web site: <http://www.tfa.or.tz>



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: Healthcare Technical Services

Web site: —

OTHER: Planning of medical equipment allocation/Application/ user training

Unit/department: Healthcare Technical Services

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on GMDN (Global Medical Device Nomenclature)

Use: Not specified

Nomenclature system name: — Web site: <http://www.gmdnagency.org>



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: <http://www.msd.or.tz>

National level procurement: Yes

Web site: <http://www.msd.or.tz>

DONATIONS

Policy or guideline: Yes

Web site: —

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ:

Medical Store Department (MSD) is responsible for procuring pharmaceuticals and medical devices for public and not for profit organization. It should also be noted that individual entities can also procure medical devices on their own as not all devices are covered by MSD. The private sector imports medical devices after obtaining approval from TFDA. The list of recommended is not available. However the guidelines for registration recommend the use of ISO standards and national standards if available.



Inventory and maintenance

Type of inventories available: National inventory only for high cost technologies (such as MRI, CT or PET scanners)

Comments: —

Medical equipment management unit: Yes

National level = 1

Regional level = 0

Hospital level = 0

Management software: No

Software and comments^λ: —



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^δ:

Lists available: Yes

Unit: Tanzania Food and Drugs Authority

Web site: —

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES OR SPECIFIC PROCEDURES: Lists available: No list available

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: —

| | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|--------|-----------------------|---------------------------|----------|------------------------------------|

Lists comments^λ:

Lists recommending health technology for different categories of diseases is not available. The Ministry is however planning to develop it. Registration of medical devices in Tanzania has started in January 2010. Registration will be carried out phasewise and 1st phase involves single use devices. The first phase involves limited number of devices in particular



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | n/a | n/a | n/a | n/a |
| Health centre | n/a | n/a | n/a | n/a |
| District hospital | n/a | n/a | n/a | n/a |
| Provincial hospital | n/a | n/a | n/a | n/a |
| Regional hospital | n/a | n/a | n/a | n/a |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 1 | 1 | 2 | 0.041 |
| Computerized Tomography Scanner | 3 | 3 | 6 | 0.122 |
| Positron Emission Tomography Scanner | 1 | n/a | 1 | 0.020 |
| Nuclear medicine | 4 | n/a | 4 | 0.081 |
| Mammograph* | 10 | 2 | 12 | 6.145 |
| Linear accelerator | n/a | n/a | n/a | n/a |
| Telecobalt unit (Cobalt-60) | 3 | n/a | 3 | 0.061 |
| Radiotherapy | 3 | n/a | 3 | 0.061 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ:

Concerning HT national policy we provide the following doc.: Medical Equipment Policy 2009.pdf

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|--------|---|-----|--------------------------------------|--------------|
| Population (000s)* | 14'539 | Life expectancy at birth (years) ^a | 57 | World Bank income group ^β | Lower-middle |
| Internet users (%) ^γ | 15.4% | Per capita total health expenditure (PPP Int \$) ^δ | 112 | GNI per capita (US\$) ^ε | 1'810 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: Medical Equipment Unit



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Zambia Medicines Regulatory Authority (ZAMRA)

Web site: <http://www.zamra.co.zm/>



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: Ministry of Health-Directorate of Clinical Care and Diagnostic services - Medical Equipment Unit

Web site: <http://www.moh.gov.zm>

OTHER: Planning of medical equipment/maintenance/management/development of technical specifications/application/user training

Unit/department: Medical Equipment Unit

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on UMDNS (Universal Medical Device Nomenclature System) Use: For regulatory purposes and procurement

Nomenclature system name: Standard Equipment List for Health Facilities Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: http://www.mofnp.gov.zm/index.php?option=com_content&task=view&id=98&Itemid=120

National level procurement: Yes

Web site: <http://www.tenderboard.gov.zm>

DONATIONS

Policy or guideline: Yes

Web site: —

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: Yes

Web site: —

Medical device incorporation comments^λ:

This is in reference to guidelines on procurement, on donations, replacement of equipment at end of lifespan. The Ministry of Health Procures under Mandate from ZPPA, the Ministry of Health develops the list, quantities and specifications. Public Procurement Authority sets the framework for the procurement mostly International Competitive Bidding. These are provided by the Medical equipment Unit but the developed SEL for the District facilities have specifications as well which are part of the planning documents used by the facilities for planning.



Inventory and maintenance

Type of inventories available: National inventory for medical equipment

Comments: The national data bank for equipment is in its infancy as regards development the data was collected three years ago during a project that was funded by JICA. We are currently upgrading this data this year. The information captured includes: Equipment Description, Model, Maker, Serial Number, Location, Functional Status, Age of Equipment. There are however hard copies at facility level which maintenance nits use. This needs to be computerised and accessible from anywhere which is not the case now.

Medical equipment management unit: Yes

National level = 1

Regional level = 9

Hospital level = 20

Management software: No

Software and comments^λ: We have no software for equipment management but have tried ECRI and another soft ware developed by a colleague in Holland.



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:

Lists comments^λ:

Lists available: Yes, but it is only a recommendation

Unit: Ministry of Health, Directorate of Clinical Care and Diagnostic Services-Medical Equipment Unit

Web site: —

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: For different healthcare facilities and specific procedures

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: —

| | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|--------|-----------------------|---------------------------|----------|------------------------------------|

The MoH has developed Standard Equipment Lists (SEL) for District facilities (Health Posts, Health Centres and Level One Hospitals) the SEL for the other levels is not yet developed because the Basic health Care Package which is the blueprint for health service delivery In Zambia has not been develop for thos levels.



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 161 | 10 | 171 | 1.176 |
| Health centre | 1'136 | 75 | 1211 | 8.330 |
| District hospital | 39 | 4 | 43 | 0.296 |
| Provincial hospital | 13 | 5 | 18 | 0.124 |
| Regional hospital | 5 | n/a | 5 | 0.034 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 1 | 0 | 1 | 0.069 |
| Computerized Tomography Scanner | 2 | 1 | 3 | 0.206 |
| Positron Emission Tomography Scanner | 0 | 0 | 0 | 0.000 |
| Nuclear medicine | 1 | 0 | 1 | 0.069 |
| Mammograph* | 1 | 1 | 2 | 4.562 |
| Linear accelerator | 1 | 0 | 1 | 0.069 |
| Telecobalt unit (Cobalt-60) | 1 | 0 | 1 | 0.069 |
| Radiotherapy | 2 | 0 | 2 | 0.138 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ:

WHO used to run training programs for maintenance technicians but stopped long ago, this has affected this field. There is need for WHO to come in strongly in support of maintenance of Medical equipment...

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|--------|---|----|--------------------------------------|-----|
| Population (000s)* | 14'150 | Life expectancy at birth (years) ^a | 58 | World Bank income group ^β | Low |
| Internet users (%) ^γ | 18.5% | Per capita total health expenditure (PPP Int \$) ^δ | | GNI per capita (US\$) ^ε | 860 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Medical Devices Unit, Medicines Control Authority of Zimbabwe

Web site: <http://www.mcaz.co.zw/index.php/component/content/article/40-uncategorised/86-medical-devices?highlight=YTozOntpOjA7czo3OiJtZWVpY2FsljtpOjE7czo3OiJkZXZpY2VzljtpOjI7czo3OntoibWVkaWNhbCBkZXZpY2Vzljt9>



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: HOSPITAL EQUIPMENT UNIT

Web site: —

OTHER: Planning of medical equipment allocation/development technical specification/application/user training

Unit/department: HOSPITAL EQUIPMENT UNIT

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: —

National level procurement: Yes

Web site: —

DONATIONS

Policy or guideline: Yes

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: Yes

Web site: —

Medical device incorporation comments^λ: —



Inventory and maintenance

Type of inventories available: National inventory for medical equipment

Comments: —

Medical equipment management unit: Yes

National level = 1

Regional level = 8

Hospital level = 5

Management software: No

Software and comments^λ: —



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^δ:

Lists available: Yes, but it is only a recommendation

Unit: HOSPITAL EQUIPMENT UNIT

Web site: —

Lists comments^λ:

We have lists available for communicable and non communicable diseases.

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES OR SPECIFIC PROCEDURES^δ: Lists available: No list available

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS^δ:

Lists available: One or more

Web site: —

| | | | | | | |
|--------|-----------------------|---|---------------------------|---|----------|------------------------------------|
| Types: | Communicable diseases | x | Non-communicable diseases | x | Injuries | Public health emergency situations |
|--------|-----------------------|---|---------------------------|---|----------|------------------------------------|



Healthcare facility

| | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | n/a | n/a | 0 | 0.000 |
| Health centre | 1'331 | n/a | 1331 | 9.407 |
| District hospital | 52 | n/a | 52 | 0.368 |
| Provincial hospital | 8 | 3 | 11 | 0.078 |
| Regional hospital | 5 | 6 | 11 | 0.078 |



Medical equipment

| | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 1 | 3 | 4 | 0.283 |
| Computerized Tomography Scanner | 2 | 4 | 6 | 0.424 |
| Positron Emission Tomography Scanner | 0 | 0 | 0 | 0.000 |
| Nuclear medicine | 3 | 1 | 4 | 0.283 |
| Mammograph* | 1 | 3 | 4 | 6.890 |
| Linear accelerator | 2 | 1 | 3 | 0.212 |
| Telecobalt unit (Cobalt-60) | 2 | 1 | 3 | 0.212 |
| Radiotherapy | 4 | 2 | 6 | 0.424 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ:

The country health technology policy document was initiated in 2007 with funding from US. This is currently being formulated into a policy document for diagnostic imaging and medical devices.

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

4.3 Region of the Americas facts and country profiles

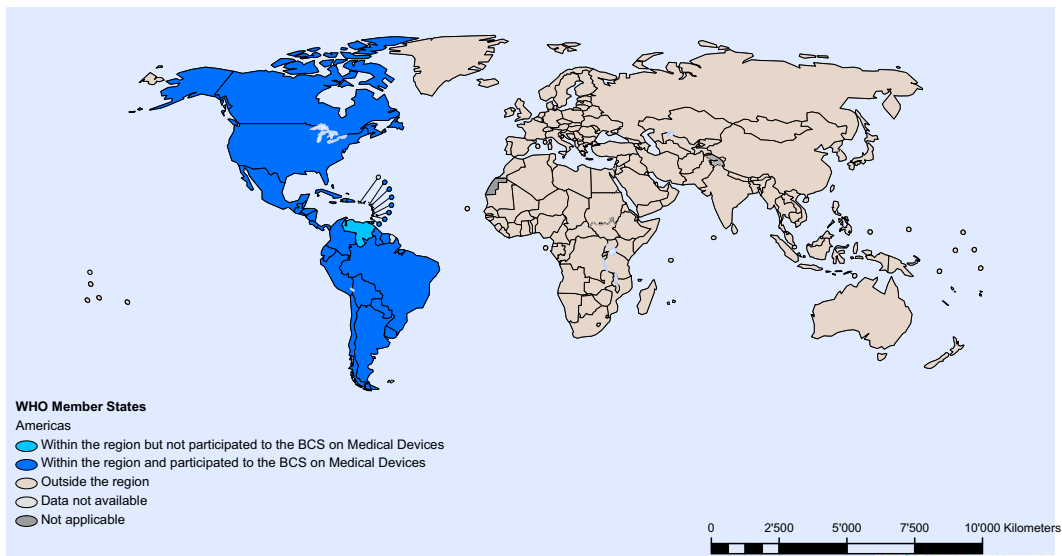


Fig. 4.3-1 Baseline Country Survey on Medical Devices Region of the Americas participation

Participation: The Region of the Americas' survey participation was 97% (34/35). Participating countries are shown in Fig. 4.3-1.

National policy on health technology: Almost 2 of 3 respondent AMR countries (62%: 21/34) do not have a Health Technology policy. However for 77% (10/13) of the countries which have a Health Technology policy it is also integrated in the national health programme.

Regulatory agency:²³ 63% of the AMR Member States (22/35) have a regulatory authority responsible for medical devices.

National health technology assessment unit:²⁴ 83% of the respondent countries (10/12) have a national agency/unit/committee that produces Health Technology Assessment (HTA) reports for the Ministry of Health.

National health technology management units: 65% of the respondent AMR states (22/34) have a national unit which technically manages medical devices. Of these countries, 95% (21/22) have a national unit in charge of technical specifications development for procurement process; 77% (17/22) have a unit in charge of planning medical devices allocation, and 59% (13/22) have a unit to support user/training of medical devices (Fig. 4.3-2).

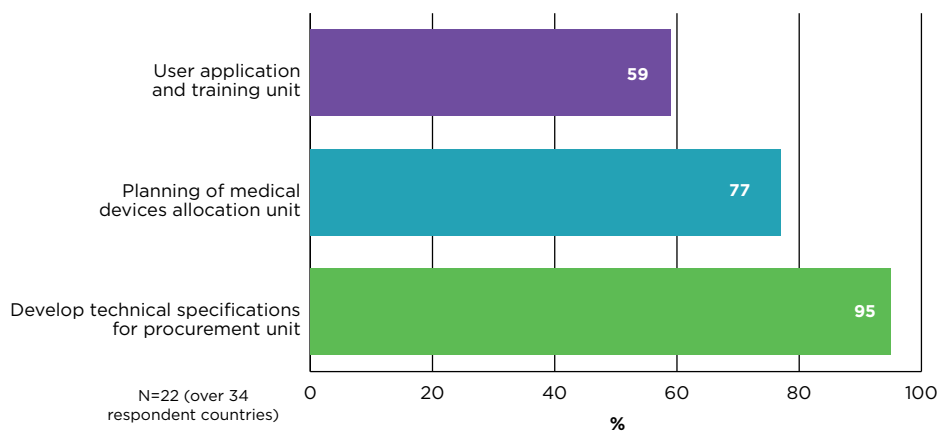


Fig 4.3-2. Proportion of AMR countries having different types of health technology units (percentages taken from countries that have at least one health technology management national unit)



Medical device nomenclature system: 53% of the respondent AMR states (18/34) have an official nomenclature system for medical devices. However, most of them 61% (11/18) did not specify the type (Fig. 4.3-3).

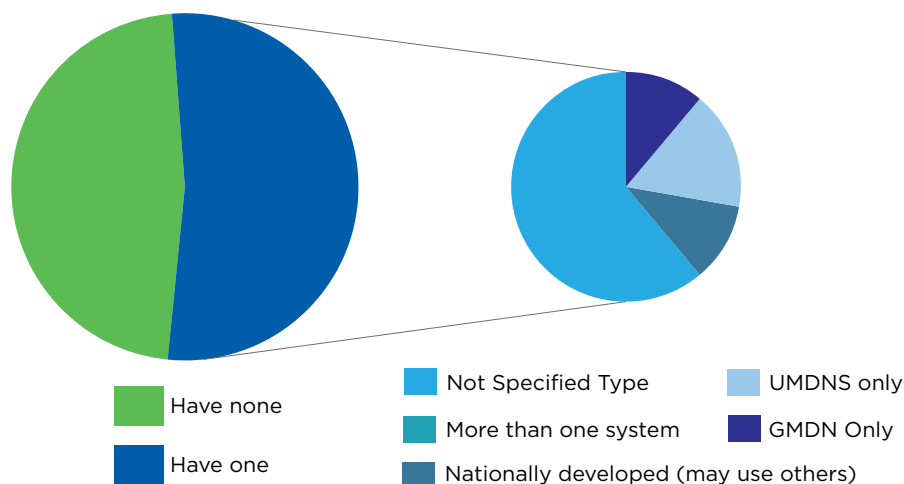


Fig. 4.3-3. Proportion of AMR countries with official nomenclature system for medical devices and their corresponding type (percentages taken from all respondent countries).

Medical device incorporation: 35% of the respondent AMR states (12/34) have national guidelines, policies or recommendations on the procurement of medical devices. 65% of the respondent states (22/34) carried out the procurement of medical devices at national level, however 65% of the respondent states (22/34) do not have recommended technical specifications of medical devices to support procurement or donations.

Inventory and maintenance: 55% of the respondent AMR states (17/31) indicated that they have an available inventory for medical devices. From those countries 76% (13/17) have a national inventory for medical equipment.

Lists of medical devices: 42% of the respondent AMR states (14/33) stated that they have national standards or recommended list(s) of medical devices for different types of healthcare facilities. 66% of the respondent states (21/32) have national list(s) of recommended medical devices for specific procedures, and 22% of the respondent states (11/33) have national list(s) of recommended medical devices for high burden diseases or injuries or health emergency situations.

Healthcare facilities: 96% of the respondent AMR countries have at least one health post per 100 000 population, and 29% of the respondent countries have at least one provincial hospital per 100 000 population. The regional density for health posts and provincial hospitals per 100 000 population is one of the highest among the six WHO regions (Figure 4.3-4).

| Healthcare facility | Have at least one per 100,000 pop. (%) | Number of responding countries | Regional Density per 100,000 pop. |
|--|--|--------------------------------|-----------------------------------|
| Health posts | 96% | 24 | 57.35 |
| Health centre | 43% | 23 | 1.75 |
| Distric/Rural hospitals | 22% | 23 | 0.53 |
| Regional/ Specialized/ Teaching and Research hospitals | 7% | 27 | 0.13 |

Figure 4.3-4. Proportion of AMR countries and regional densities regarding existence of healthcare facility units (percentages taken from all respondent countries)

Medical equipment: The regional density per million population of CT, Gamma camera, and Mammographs is one of the highest of the six regions (Figure 4.3-5).

| Medical Equipment | Have at least one per 1,000,000 pop. (%) | Number of responding countries | Regional density per 1,000,000 pop. |
|--|--|--------------------------------|-------------------------------------|
| Magnetic Resonance Imaging (MRI) | 64% | 25 | 2.42 |
| Computed Tomography (CT Scanner) | 88% | 26 | 5.53 |
| Positron Emission Tomography (PET Scanner) | 5% | 22 | 0.25 |
| Gamma Camera or Nuclear Medicine | 33% | 21 | 3.79 |
| *Mammographs | 100% | 23 | 5.27 |
| Radiotherapy Unit: Linear Accelerator (LA) | 33% | 21 | 0.56 |
| Radiotherapy Unit:Telecobalt Unit (TU) | 18% | 22 | 0.41 |
| Radiotherapy Unit (LA+TU) | 48% | 23 | 0.74 |

* Mammographs density is per 100,000 females aged between 50 and 69 years old, and the regional density per million females of the same age

Figure 4.3.5: Proportion of AMR countries and regional densities regarding high technology equipment (percentages taken from all respondent countries).



List of country profiles for WHO Region of the Americas

| | | | |
|----------------------------------|-----|----------------------------------|-----|
| Antigua and Barbuda | 188 | Guatemala | 222 |
| Argentina | 190 | Guyana | 224 |
| Bahamas | 192 | Haïti | 226 |
| Barbados | 194 | Honduras | 228 |
| Belize | 196 | Jamaica | 230 |
| Bolivia (Plurinational State of) | 198 | Mexico | 232 |
| Brazil | 200 | Nicaragua | 234 |
| Canada | 202 | Panama | 236 |
| Chile | 204 | Paraguay | 238 |
| Colombia | 206 | Peru | 240 |
| Costa Rica | 208 | Saint Kitts and Nevis | 242 |
| Cuba | 210 | Saint Lucia | 244 |
| Dominica | 212 | Saint Vincent and the Grenadines | 246 |
| Dominican Republic | 214 | Suriname | 248 |
| Ecuador | 216 | Trinidad and Tobago | 250 |
| El Salvador | 218 | United States of America | 252 |
| Grenada | 220 | Uruguay | 254 |

Antigua and Barbuda



Country indicators

| | | | | | |
|---------------------------------|-------|---|------|--------------------------------------|--------|
| Population (000s)* | 90 | Life expectancy at birth (years) ^a | 75 | World Bank income group ^β | High |
| Internet users (%) ^γ | 63.4% | Per capita total health expenditure (PPP Int \$) ^δ | 1029 | GNI per capita (US\$) ^ε | 13'050 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: No

Name of principal institution: —

Web site: —



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): No

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: Yes

Web site: —

DONATIONS

Policy or guideline: No

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ: —



Inventory and maintenance

Type of inventories available: None

Comments: –

Medical equipment management unit: Yes

National level = 0

Regional level = 0

Hospital level = 0

Management software: –

Software and comments^λ: –

Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^δ:Lists comments^λ: –

Lists available: No

Unit: –

Web site: –

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES OR SPECIFIC PROCEDURES: Lists available: No list available

Web site - facilities: –

Web site - procedures: –

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: –

Types:

| | | | |
|-----------------------|---------------------------|----------|------------------------------------|
| Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|-----------------------|---------------------------|----------|------------------------------------|



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | n/a | n/a | n/a | n/a |
| Health centre | n/a | n/a | n/a | n/a |
| District hospital | n/a | n/a | n/a | n/a |
| Provincial hospital | n/a | n/a | n/a | n/a |
| Regional hospital | 1 | n/a | 1 | 1.111 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | n/a | 1 | 1 | 11.113 |
| Computerized Tomography Scanner | 1 | 1 | 2 | 22.226 |
| Positron Emission Tomography Scanner | n/a | n/a | n/a | n/a |
| Nuclear medicine | n/a | n/a | n/a | n/a |
| Mammograph* | 1 | 1 | 2 | 272.146 |
| Linear accelerator | n/a | n/a | n/a | n/a |
| Telecobalt unit (Cobalt-60) | n/a | n/a | n/a | n/a |
| Radiotherapy | n/a | n/a | n/a | n/a |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: –

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

Argentina



Country indicators

| | | | | | |
|---------------------------------|--------|---|------|--------------------------------------|--------------|
| Population (000s)* | 41'446 | Life expectancy at birth (years) ^a | 76 | World Bank income group ^β | Upper-middle |
| Internet users (%) ^γ | 59.9% | Per capita total health expenditure (PPP Int \$) ^δ | 1551 | GNI per capita (US\$) ^ε | |



National policy on health technology

Health technology (medical device) national policy: Yes, and it is part of the National Health Program/Plan or Policy

Web site: <http://www.msal.gov.ar/pngcam/tecnologias.htm>

Language(s): Español

MOH responsible for health technology policy implementation: Secretaria de Politicas, Regulacion e Institutos.



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Dirección de Tecnología medica - dependiente de la Administracion de Medicamentos, alimentos y tecnología médica.

Web site: <http://www.anmat.gov.ar/productosmedicos.asp>



National health technology assessment unit

Unit/department: Unidad Coordinadora de evaluación y ejecución de tecnologías en salud

Web site: <http://www.msal.gov.ar/pngcam/institucional.htm>



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: Direccion de Tecnologia Medica

Web site: <http://www.anmat.gov.ar/productosmedicos.asp>

OTHER: Application/user training

Unit/department: Unidad Coordinadora de evaluación y ejecución de tecnologías en salud

Web site: <http://www.msal.gov.ar/pngcam/institucional.htm>

OTHER: Fiscalizacion y Control de Tecnologias/Application/User training

Unit/department: Direccion de Tecnologia Medica

Web site: <http://www.anmat.gov.ar/productosmedicos.asp>



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on UMDNS (Universal Medical Device Nomenclature System) Use: Not specified

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: http://www.anmat.gov.ar/webanmat/productos_medicos/recomendaciones_compraprod.medicos.asp

National level procurement: Yes

Web site: <http://www.msal.gov.ar/>

DONATIONS

Policy or guideline: Yes

Web site: <http://www.anmat.gov.ar/principal.asp>

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ:

Procurement of medical devices at national level we use: "lista licitaciones"



Inventory and maintenance

Type of inventories available: None

Comments: —

Medical equipment management unit: —

National level = 0

Regional level = 0

Hospital level = 0

Management software: —

Software and comments^λ: —

Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^δ

Lists available: Yes

Unit: Direccion de Tecnologia Medica

Web site: —

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES OR SPECIFIC PROCEDURES: Lists available: For different healthcare facilities and specific procedures

Web site - facilities: <http://www.msal.gov.ar/pngcam/grillas.htm>Web site - procedures: <http://www.msal.gov.ar/pngcam/grillas.htm>

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: One or more

Web site:

Types:

| | | | | | |
|-----------------------|---------------------------|---|----------|------------------------------------|---|
| Communicable diseases | Non-communicable diseases | x | Injuries | Public health emergency situations | x |
|-----------------------|---------------------------|---|----------|------------------------------------|---|

Lists comments^λ:

Existen listas en: cirugia, diagnostico por imagenes, laboratorio, terapia inintensiva, NCDs, and emergency situations. Lineamientos para guias disponibles en: http://www.msal.gov.ar/pngcam/pdf/GUIA_ADAPTACION.pdf and <http://www.msal.gov.ar/pngcam/resoluciones.htm> Existe una base de datos que contiene a las tecnologias sanitarias (denominados



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | n/a | n/a | n/a | n/a |
| Health centre | n/a | n/a | n/a | n/a |
| District hospital | n/a | n/a | n/a | n/a |
| Provincial hospital | n/a | n/a | n/a | n/a |
| Regional hospital | n/a | n/a | n/a | n/a |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | n/a | n/a | n/a | n/a |
| Computerized Tomography Scanner | n/a | n/a | n/a | n/a |
| Positron Emission Tomography Scanner | n/a | n/a | n/a | n/a |
| Nuclear medicine | n/a | n/a | n/a | n/a |
| Mammograph* | n/a | n/a | n/a | n/a |
| Linear accelerator | n/a | n/a | n/a | n/a |
| Telecobalt unit (Cobalt-60) | n/a | n/a | n/a | n/a |
| Radiotherapy | n/a | n/a | n/a | n/a |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ:

Moh want to push awareness/surveillance about health technology quality, technical specifications, etc.

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|-------|---|------|--------------------------------------|--------|
| Population (000s)* | 377 | Life expectancy at birth (years) ^a | 75 | World Bank income group ^β | High |
| Internet users (%) ^γ | 72.0% | Per capita total health expenditure (PPP Int \$) ^δ | 2377 | GNI per capita (US\$) ^ε | 21'570 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: No

Name of principal institution: —

Web site: —



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): No

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: Yes

Web site: <http://www.phabahamas.org/>

DONATIONS

Policy or guideline: No

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —



Inventory and maintenance

Type of inventories available: None

Comments: —

Medical equipment management unit: Yes

Management software: No

Software and comments^λ: —

National level = 0

Regional level = 0

Hospital level = 1

Medical device incorporation comments^λ:

Procurement entities: The Public Hospitals Authority, the corporate entity of the Ministry of Health responsible for managing the three (3) Public Hospitals within the Bahamas utilizes the services of the ECRI Institute (www.ecri.org) which assist in the procurement of medical devices.



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^α

Lists available: No

Unit: —

Web site: —

Lists comments^λ:

There are no lists recommending health technology for diseases or public health emergency situations.

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: No list available

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: —

| | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|--------|-----------------------|---------------------------|----------|------------------------------------|



Healthcare facility

| | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 150 | n/a | 150 | 39.748 |
| Health centre | n/a | n/a | 0 | 0.000 |
| District hospital | n/a | n/a | 0 | 0.000 |
| Provincial hospital | 2 | 1 | 3 | 0.795 |
| Regional hospital | 1 | n/a | 1 | 0.265 |



Medical equipment

| | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 0 | 1 | 1 | 2.650 |
| Computerized Tomography Scanner | 2 | 3 | 5 | 13.249 |
| Positron Emission Tomography Scanner | 0 | 0 | 0 | 0.000 |
| Nuclear medicine | 0 | n/a | 0 | 0.000 |
| Mammograph* | 2 | 2 | 4 | 106.607 |
| Linear accelerator | 0 | 1 | 1 | 2.650 |
| Telecobalt unit (Cobalt-60) | 0 | n/a | 0 | 0.000 |
| Radiotherapy | 0 | 1 | 1 | 2.650 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: —

* UNPD as of 1 July 2012 (2013 update)

^α WHO 2012 data

^β WB 2014 classification

^γ WB 2013 data (2014 update)

^δ WHO 2012 data

^ε WB 2013 (2014 update)

n/a not applicable

^λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|-------|---|------|--------------------------------------|------|
| Population (000s)* | 285 | Life expectancy at birth (years) ^a | 78 | World Bank income group ^β | High |
| Internet users (%) ^γ | 75.0% | Per capita total health expenditure (PPP Int \$) ^δ | 1307 | GNI per capita (US\$) ^ε | |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: No

Name of principal institution: —

Web site: —



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): No

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: Yes

Web site: —

DONATIONS

Policy or guideline: No

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: Yes, but not publically available

Web site: —

Medical device incorporation comments^λ:

Procurement queries, comments, and information needs should be addresses to the Chief Supply Officer (joness@gob.bb)



Inventory and maintenance

Type of inventories available: —

Comments: There is no national inventory but the Queen Elizabeth Hospital Engineering Services maintain an inventory for high cost technologies and for medical equipment for that institution thus there is an institutional inventory there. Also all polyclinics keep institutional inventory for medical equipment only. The institutional inventories at the hospital and polyclinics are audited annually.

Medical equipment management unit: Yes

National level = —

Regional level = —

Hospital level = 1

Management software: No

Software and comments^λ: Equipment management software is currently being installed at the Queen Elizabeth Hospital.



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^δ:

Lists available: No

Unit: —

Web site: —

Lists comments^λ:

There were no electronic copies of the different lists available i.e.: procedures, communicable and non communicable diseases, and injuries.

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: For specific procedures

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: One or more

Web site: —

Types: Communicable diseases x Non-communicable diseases x Injuries x Public health emergency situations



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 9 | 2 | 11 | 3.864 |
| Health centre | n/a | n/a | 0 | 0.000 |
| District hospital | n/a | n/a | 0 | 0.000 |
| Provincial hospital | 1 | 1 | 2 | 0.703 |
| Regional hospital | 1 | n/a | 1 | 0.351 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 0 | n/a | 0 | 0.000 |
| Computerized Tomography Scanner | 2 | n/a | 2 | 7.026 |
| Positron Emission Tomography Scanner | 0 | n/a | 0 | 0.000 |
| Nuclear medicine | 1 | n/a | 1 | 3.513 |
| Mammograph* | 1 | n/a | 1 | 28.960 |
| Linear accelerator | 0 | n/a | 0 | 0.000 |
| Telecobalt unit (Cobalt-60) | 1 | n/a | 1 | 3.513 |
| Radiotherapy | 1 | n/a | 1 | 3.513 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^ε:

Concerning Section Healthcare infrastructure: it exist many single and grouped medical centers and general practice clinics/offices offering primary care including emergency care services and some secondary care services in the private sector

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|-------|---|-----|--------------------------------------|--------------|
| Population (000s)* | 332 | Life expectancy at birth (years) ^a | 75 | World Bank income group ^β | Upper-middle |
| Internet users (%) ^γ | 31.7% | Per capita total health expenditure (PPP Int \$) ^δ | 458 | GNI per capita (US\$) ^ε | 4'510 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): English

MOH responsible for health technology policy implementation: Regulatory Unit



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: No

Name of principal institution: —

Web site: —



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: N.E.M.C.

Web site: —

OTHER: —

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: No

Web site: —

DONATIONS

Policy or guideline: No

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ:
NEMC is trying to standardize equipment, and has suggested to set up a procurement committee. No follow up.



Inventory and maintenance

Type of inventories available: National inventory for medical equipment

Comments: NEMC is in the process of up-dating the Inventory. Only for the public health facilities. KHMH has his own Inventory System.

Medical equipment management unit: No

National level = 1

Regional level = 3

Hospital level = 1

Management software: No

Software and comments^λ: —



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:

Lists available: No

Unit: —

Web site: —

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES OR SPECIFIC PROCEDURES: Lists available: For different healthcare facilities

Web site - facilities: <http://health.gov.bz/www/publications/quality-assurance/373-licensing-a-accreditation-standards-for-inpatient-health-facilities>

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: <http://www.health.gov.bz>

Types:

| |
|-----------------------|
| Communicable diseases |
|-----------------------|

| |
|---------------------------|
| Non-communicable diseases |
|---------------------------|

| |
|----------|
| Injuries |
|----------|

| |
|------------------------------------|
| Public health emergency situations |
|------------------------------------|

Lists comments^λ:

Policy Analysis & Planning Unit, MoH gives recommendations for health care facilities lists. In relation to other lists there is no centralized info about which lists are available.



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 40 | n/a | 40 | 12.052 |
| Health centre | 40 | n/a | 40 | 12.052 |
| District hospital | 3 | 1 | 4 | 1.205 |
| Provincial hospital | 1 | n/a | 1 | 0.301 |
| Regional hospital | n/a | 2 | 2 | 0.603 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 0 | 1 | 1 | 3.013 |
| Computerized Tomography Scanner | 1 | 3 | 4 | 12.052 |
| Positron Emission Tomography Scanner | 0 | 0 | 0 | 0.000 |
| Nuclear medicine | 0 | 0 | 0 | 0.000 |
| Mammograph* | 1 | 3 | 4 | 257.998 |
| Linear accelerator | 0 | 0 | 0 | 0.000 |
| Telecobalt unit (Cobalt-60) | 0 | 0 | 0 | 0.000 |
| Radiotherapy | 0 | 0 | 0 | 0.000 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: —

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

Bolivia (Plurinational State of)



Country indicators

| | | | | | |
|---------------------------------|--------|---|-----|--------------------------------------|--------------|
| Population (000s)* | 10'671 | Life expectancy at birth (years) ^a | 68 | World Bank income group ^β | Lower-middle |
| Internet users (%) ^γ | 39.5% | Per capita total health expenditure (PPP Int \$) ^δ | 305 | GNI per capita (US\$) ^ε | 2'550 |



National policy on health technology

Health technology (medical device) national policy: Yes, and it is part of the National Health Program/Plan or Policy

Web site: <http://www.sns.gov.bo/dinamed>

Language(s): Español

MOH responsible for health technology policy implementation: Unidad de Medicamentos y Tecnologia en Salud, Unidad de Servicios de Salud



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Unidad de Medicamentos y Tecnologia en Salud

Web site: <http://www.sns.gov.bo/dinamed>



National health technology assessment unit

Unit/department: Unidad de Medicamentos y Tecnologia en Salud

Web site: <http://sns.gov.bo/dinamed>



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: Unidad de Medicamentos y Tecnologia en Salud

Web site: <http://sns.gov.bo/dinamed>

OTHER: Consolidacion de protocolos para el seguro Universal

Unit/department: Unidad de Seguros publicos

Web site: —

OTHER: Inventario, caracterizacion de equipos

Unit/department: Unidad de Servicios de Salud

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on UMDNS (Universal Medical Device Nomenclature System) Use: Not specified

Nomenclature system name: — Web site: <http://www.sns.gov.bo/dinamed>



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: No

Web site: —

DONATIONS

Policy or guideline: Yes

Web site: <http://www.sns.gov.bo>

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: Yes

Web site: <http://www.sns.gov.bo>

Medical device incorporation comments^λ:

Se cuenta con la propuesta de la norma " pliego de especificaciones tecnicas para la adquisicion de dispositivos medicos" DBC. La adquisicion se realiza a traves de los gobiernos municipales (ley del Medicamento 1737, Reglamento a la ley del Medicamento 25235).



Inventory and maintenance

Type of inventories available: National inventory for medical equipment

Comments: El inventario de equipos, y la aplicacion del plan para la adquisicion de equipo medico solo se realizo para los departamentos de Oruro, Beni y Pando.

Medical equipment management unit: No

National level = –

Regional level = –

Hospital level = –

Management software: No

Software and comments^λ: –



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:

Lists available: No

Unit: –

Web site: –

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: For different healthcare facilities and specific procedures

Web site - facilities: <http://www.sns.gov.bo>

Web site - procedures: –

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: One or more

Web site: –

Types:

| | |
|-----------------------|---|
| Communicable diseases | x |
|-----------------------|---|

| | |
|---------------------------|---|
| Non-communicable diseases | x |
|---------------------------|---|

| | |
|----------|--|
| Injuries | |
|----------|--|

| | |
|------------------------------------|---|
| Public health emergency situations | x |
|------------------------------------|---|

Lists comments^λ:

Norma de caracterizacion de establecimientos de salud de primer nivel, La Paz, Bolivia , 2008.

Lists available for communicable and non communicable diseases, and public health emergency situations.



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 1'472 | n/a | 1472 | 13.794 |
| Health centre | 937 | n/a | 937 | 8.781 |
| District hospital | 83 | n/a | 83 | 0.778 |
| Provincial hospital | n/a | n/a | n/a | n/a |
| Regional hospital | 31 | n/a | 31 | 0.291 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | n/a | n/a | n/a | n/a |
| Computerized Tomography Scanner | n/a | n/a | n/a | n/a |
| Positron Emission Tomography Scanner | n/a | n/a | n/a | n/a |
| Nuclear medicine | n/a | n/a | n/a | n/a |
| Mammograph* | n/a | n/a | n/a | n/a |
| Linear accelerator | n/a | n/a | n/a | n/a |
| Telecobalt unit (Cobalt-60) | n/a | n/a | n/a | n/a |
| Radiotherapy | n/a | n/a | n/a | n/a |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: –

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

Brazil



Country indicators

| | | | | | |
|---------------------------------|---------|---|------|--------------------------------------|--------------|
| Population (000s)* | 200'362 | Life expectancy at birth (years) ^a | 74 | World Bank income group ^β | Upper-middle |
| Internet users (%) ^γ | 51.6% | Per capita total health expenditure (PPP Int \$) ^δ | 1109 | GNI per capita (US\$) ^ε | 11'690 |



National policy on health technology

Health technology (medical device) national policy: Yes, and it is part of the National Health Program/Plan or Policy

Web site: http://portal.saude.gov.br/portal/arquivos/pdf/politica_portugues.pdf

Language(s): Portuguese

MOH responsible for health technology policy implementation: Secretariat of Science, Technology and Strategic Inputs



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: ANVISA- Brazilian Health Surveillance Agency/ General Office of Medical Devices

Web site: <http://www.anvisa.gov.br>



National health technology assessment unit

Unit/department: DECIT

Web site: <http://portal.saude.gov.br>



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: CITEC

Web site: <http://portal.saude.gov.br>

OTHER: Planning of medical equipment allocation/Application/user training

Unit/department: DECIT

Web site: <http://portal.saude.gov.br>

OTHER: Planning of medical equipment allocation/Application/user training

Unit/department: CITEC

Web site: <http://portal.saude.gov.br>



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on GMDN (Global Medical Device Nomenclature)

Use: For regulatory purposes

Nomenclature system name: — Web site: http://www.anvisa.gov.br/datavisa/nomestecnicosggtps/consulta_ggtps.asp



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: <http://portalsaude.saude.gov.br/portalsaude/>

National level procurement: Yes

Web site: http://portal.saude.gov.br/portal/saude/gestor/area.cfm?id_area1504

DONATIONS

Policy or guideline: No

Web site: —

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: Yes

Web site: —

Medical device incorporation comments^λ:

Go to the website and look for the corresponding documents in procurement field. They are Lists of OPM, Procedures and Protocols.



Inventory and maintenance

Type of inventories available: None

Comments: —

Medical equipment management unit: Yes

National level = 0

Regional level = 0

Hospital level = 0

Management software: No

Software and comments^λ: Even though there is no standardized software for medical equipment management in Brazil, some hospitals and other health facilities have developed and implemented their own. Besides that, the Post Market Surveillance of Medical Devices Unit of ANVISA, the Brazilian Regulatory Authority, intends to develop a software to address the main needs related to medical electrical equipment management (information related to the history of the medical equipment).



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:

Lists comments^λ:

Lists available: Yes

Lists for diseases are SAS unit competence. Other lists are not available for the moment.

Unit: —

Web site: —

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES OR SPECIFIC PROCEDURES: Lists available: For specific procedures

Web site - facilities: —

Web site - procedures: <http://portal.saude.gov.br/portal/saude/profissional/default.cfm>

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: —

Types:

| | | | |
|-----------------------|---------------------------|----------|------------------------------------|
| Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|-----------------------|---------------------------|----------|------------------------------------|



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | n/a | n/a | n/a | n/a |
| Health centre | n/a | n/a | n/a | n/a |
| District hospital | n/a | n/a | n/a | n/a |
| Provincial hospital | n/a | n/a | n/a | n/a |
| Regional hospital | n/a | n/a | n/a | n/a |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | n/a | n/a | n/a | n/a |
| Computerized Tomography Scanner | n/a | n/a | n/a | n/a |
| Positron Emission Tomography Scanner | n/a | n/a | n/a | n/a |
| Nuclear medicine | n/a | n/a | n/a | n/a |
| Mammograph* | n/a | n/a | n/a | n/a |
| Linear accelerator | n/a | n/a | n/a | n/a |
| Telecobalt unit (Cobalt-60) | n/a | n/a | n/a | n/a |
| Radiotherapy | n/a | n/a | n/a | n/a |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ:

Concerning HT national policy we provide the following doc.: http://www.who.int/medical_devices/survey_resources/health_technology_national_policy_bolivia.pdf. This survey was answered by Secretaria de Ciência, Tecnologia e Insumos Estratégicos, Ministério da Saúde in joint with ANVISA Contributing experts and Secretaria de Ciência, Tecnologia e Insumos Estratégicos, Ministério da Saúde experts.

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|--------|---|------|--------------------------------------|--------|
| Population (000s)* | 35'182 | Life expectancy at birth (years) ^a | 82 | World Bank income group ^β | High |
| Internet users (%) ^γ | 85.8% | Per capita total health expenditure (PPP Int \$) ^δ | 4676 | GNI per capita (US\$) ^ε | 52'200 |



National policy on health technology

Health technology (medical device) national policy: Yes, but is not part of the National Health Program

Web site: http://www.cadth.ca/media/policy_forum_section/1_health_tech_strategy_1.0_nov-2004_e.pdf

Language(s): English and French

MOH responsible for health technology policy implementation: Canadian Agency for Drugs and Technologies in Health (CADTH)



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Health Canada, Health Products and Food Branch, Therapeutic Products Directorate, Medical Devices Bureau

Web site: <http://www.hc-sc.gc.ca/dhp-mps/md-im/index-eng.php>



National health technology assessment unit

Unit/department: CADTH

Web site: www.cadth.ca



National health technology management units

National health technology unit(s): No

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Nationally developed Use: For regulatory purposes

Nomenclature system name: Prefix Name Codes are based on US FDA Panel Codes Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: No

Web site: —

DONATIONS

Policy or guideline: No

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ:

Given the nature of the Canadian Constitution, these are of provincial jurisdiction and not at the federal or national jurisdictional level.



Inventory and maintenance

Type of inventories available: National inventory for medical equipment

Comments: Given the nature of the Canadian Constitution, these are of provincial jurisdiction and not at the federal or national jurisdictional level. While there are no national inventories, the Canadian Institute for Health Information produces regular reports on selected imaging technologies in Canada. The most recent report is available at: http://www.cihi.ca/cihiweb/dispPage.jsp?cw_page=AR_1043_E

Medical equipment management unit: Yes

National level = —

Regional level = —

Hospital level = —

Management software: —

Software and comments^λ: —



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:

Lists available: No

Unit: —

Web site: —

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: No list available

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: —

| | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|--------|-----------------------|---------------------------|----------|------------------------------------|

Lists comments^λ:

Given the nature of the Canadian Constitution, these are of provincial jurisdiction and not at the federal or national jurisdictional level.



Healthcare facility

| | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | n/a | n/a | n/a | n/a |
| Health centre | n/a | n/a | n/a | n/a |
| District hospital | 299 | n/a | 299 | 0.850 |
| Provincial hospital | 453 | n/a | 453 | 1.288 |
| Regional hospital | 46 | n/a | 46 | 0.131 |



Medical equipment

| | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 218 | 63 | 281 | 7.987 |
| Computerized Tomography Scanner | 460 | 24 | 484 | 13.757 |
| Positron Emission Tomography Scanner | 33 | 7 | 40 | 1.137 |
| Nuclear medicine | 617 | 99 | 716 | 20.351 |
| Mammograph* | n/a | n/a | n/a | n/a |
| Linear accelerator | n/a | n/a | n/a | n/a |
| Telecobalt unit (Cobalt-60) | n/a | n/a | n/a | n/a |
| Radiotherapy | n/a | n/a | n/a | n/a |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ:

In several survey's sections (ex: section 1.3.1), we were not able to reflect the shared governance approach that Canada has evolved towards as several as the key organisations, namely the Canadian Agency for Drugs and Health Technologies are neither national or provincial but entities whose governance and financing is shared among the Deputy Minister of Health of Canada's 14 jurisdictions (e.g. Federal, 10 provinces and 3 Territories). In addition the survey did not allow for the identification of existing provincial capacities which would have resulted in having to fill 13 separate surveys to accurately reflect Canada's reality.

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|--------|---|------|--------------------------------------|--------|
| Population (000s)* | 17'620 | Life expectancy at birth (years) ^a | 80 | World Bank income group ^β | High |
| Internet users (%) ^γ | 66.5% | Per capita total health expenditure (PPP Int \$) ^δ | 1606 | GNI per capita (US\$) ^ε | 15'230 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Instituto de Salud Pública de Chile

Web site: <http://www.ispch.cl>



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): No

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: Yes

Web site: <http://www.minsal.cl>

DONATIONS

Policy or guideline: No

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ:

Procurement guidelines: para emergencia y para afrontar las garantía explícitas en salud



Inventory and maintenance

Type of inventories available: National inventory only for high cost technologies (such as MRI, CT or PET scanners)

Comments: —

Medical equipment management unit: Yes

National level = 0

Regional level = 0

Hospital level = 60

Management software: No

Software and comments^λ: —



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^δ

Lists comments^λ:

Lists available: Yes, but it is only a recommendation

Unit: Sección dispositivos médicos - Instituto de Salud Pública de Chile

Web site: —

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: No list available

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: —

Types:

Communicable diseases

Non-communicable diseases

Injuries

Public health emergency situations

No se dispone de las listas de tecnologías sanitarias. Existen 5 listas de los dispositivos médicos que están bajo control obligatorio (Guantes de examinación, guantes quirúrgicos, preservativos, aguja hipodérmicas de un solo uso y jeringas hipodérmicas de un solo uso) en el país y se encuentra disponible en la dirección [Http://www.ispch.cl/dispositivos-medicos](http://www.ispch.cl/dispositivos-medicos)



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 1'883 | n/a | 1883 | 10.687 |
| Health centre | 21 | n/a | 21 | 0.119 |
| District hospital | 100 | n/a | 100 | 0.568 |
| Provincial hospital | 22 | n/a | 22 | 0.125 |
| Regional hospital | 62 | n/a | 62 | 0.352 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 7 | 70 | 77 | 4.370 |
| Computerized Tomography Scanner | 47 | 175 | 222 | 12.600 |
| Positron Emission Tomography Scanner | 0 | n/a | 0 | 0.000 |
| Nuclear medicine | n/a | n/a | n/a | n/a |
| Mammograph* | 58 | n/a | 58 | 32.184 |
| Linear accelerator | 12 | n/a | 12 | 0.681 |
| Telecobalt unit (Cobalt-60) | 4 | n/a | 4 | 0.227 |
| Radiotherapy | 16 | n/a | 16 | 0.908 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ:

Concerning HT national policy we provide the following doc.: http://www.who.int/medical_devices/survey_resources/health_technology_national_policy_canada.pdf. Concerning Infrastructure section: Los 21 centros de salud están incorporados en los 100 hospitales distritales/rurales. Los Centros de Referencia de Salud (CRS) = 7 considera los Hospitales de Chile denominados de Mediana Complejidad, y que se ubican en la región metropolitana y demás regiones del país. ...

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|--------|---|-----|--------------------------------------|--------------|
| Population (000s)* | 48'321 | Life expectancy at birth (years) ^a | 79 | World Bank income group ^β | Upper-middle |
| Internet users (%) ^γ | 51.7% | Per capita total health expenditure (PPP Int \$) ^δ | 723 | GNI per capita (US\$) ^ε | 7'590 |



National policy on health technology

Health technology (medical device) national policy: Yes, and it is part of the National Health Program/Plan or Policy

Web site: —

Language(s): Español

MOH responsible for health technology policy implementation: GRUPO MEDICAMENTOS E INSUMOS DE LA DIRECCION GENERAL DE CALIDAD DE SERVICIOS



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: INSTITUTO NACIONAL DE VIGILANCIA DE MEDICAMENTOS Y ALIMENTOS

Web site: <http://www.invima.gov.co>



National health technology assessment unit

Unit/department: INVIMA

Web site: <http://www.invima.gov.co>



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: VICEMINISTERIO DE SALUD PUBLICA Y PRESTACION DE SERVICIOS

Web site: <http://www.minsalud.gov.co>

OTHER: Planning of medical equipment allocation/development of technical specifications for procurement purposes

Unit/department: DIRECCION DE MEDICAMENTOS Y TECNOLOGIAS EN SALUD

Web site: <http://.minsalud.gov.co>

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Nationally developed Use: For regulatory purposes and procurement

Nomenclature system name: GMDN adapted to national needs Web site: <http://www.minsalud.gov.co/Normatividad/RESOLUCI%C3%93N%202981%20DE%202011.pdf>



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: No

Web site: —

DONATIONS

Policy or guideline: Yes

Web site: <http://www.invima.gov.co>

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ: —



Inventory and maintenance

Type of inventories available: None

Comments: Actualmente no hay inventario nacional, se ha intentado elaborar mediante catastro de equipamiento físico. La normatividad vigente, el Decreto 4725 de 2005, establece que los equipos biomédicos de tecnología controlada deben contar con registro sanitario o permiso de comercialización en Colombia

Medical equipment management unit: No

National level = 0

Regional level = 0

Hospital level = 0

Management software: No

Software and comments^λ: —



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:

Lists available: No

Unit: COMISION DE REGULACION EN SALUD

Web site: —

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: No list available

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: —

| | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|--------|-----------------------|---------------------------|----------|------------------------------------|

Lists comments^λ:

No existe unlistado oficial, el acuerdo No.008 de la CRES dice que los dispositivos médicos usados en los procedimientos listados son reembolsados dentro del Plan Obligatorio de Salud



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | n/a | n/a | n/a | n/a |
| Health centre | n/a | n/a | n/a | n/a |
| District hospital | n/a | n/a | n/a | n/a |
| Provincial hospital | n/a | n/a | n/a | n/a |
| Regional hospital | n/a | n/a | n/a | n/a |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | n/a | n/a | n/a | n/a |
| Computerized Tomography Scanner | n/a | n/a | n/a | n/a |
| Positron Emission Tomography Scanner | n/a | n/a | n/a | n/a |
| Nuclear medicine | n/a | n/a | n/a | n/a |
| Mammograph* | n/a | n/a | n/a | n/a |
| Linear accelerator | n/a | n/a | n/a | n/a |
| Telecobalt unit (Cobalt-60) | n/a | n/a | n/a | n/a |
| Radiotherapy | n/a | n/a | n/a | n/a |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ:

Actualmente se tiene reglamentado y en fase de implementación el Programa Nacional de Tecnovigilancia post-mercado liderado por INVIMA (importantes para la gestión y manejo de los dispositivos médicos, también es importante dar normas sobre los productos importados, que son la mayoría). Otros temas relevantes son el de trazabilidad y manejo de los dispositivos médicos en el territorio nacional, al igual que lo relacionado con el manejo y aprobación de los equipos repotenciados, su control y uso (este mercado necesita formas alternativas de control, definir requisitos para su uso, etc.)

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

Costa Rica



Country indicators

| | | | | | |
|---------------------------------|-------|---|------|--------------------------------------|--------------|
| Population (000s)* | 4'872 | Life expectancy at birth (years) ^a | 79 | World Bank income group ^β | Upper-middle |
| Internet users (%) ^γ | 46.0% | Per capita total health expenditure (PPP Int \$) ^δ | 1311 | GNI per capita (US\$) ^ε | 9'550 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Ministerio de Salud

Web site: <http://www.ministeriodesalud.go.cr/index.php/menu-superior-empresas-ms>



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: Dirección de Infraestructura y Tecnologías

Web site: —

OTHER: Dirigir el Sistema de Desarrollo Tecnológico en Salud (correcta utilización de las tecnologías sanitarias apropiadas)

Unit/department: Unidad de Gestión de Tecnologías en Salud/Dirección de Desarrollo Científico y Tecnológico en Salud

Web site: —

OTHER: Registro de equipo y material biomédico

Unit/department: Dirección de Atención al Cliente

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Nationally developed Use: For regulatory purposes and procurement

Nomenclature system name: GMDN adapted to national needs. Web site: <http://www.ministeriodesalud.go.cr/index.php/normativas-equipo-biomedico-ms>



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: Yes

Web site: <http://ccss.sa.cr>

DONATIONS

Policy or guideline: Yes

Web site: <http://www.ministeriodesalud.go.cr> and <http://www.portal.ccss.sa.cr>

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ:

La Caja Costarricense de Seguro Social brinda cobertura universal a la población y es el mayor proveedor de servicios de salud del país, tanto en hospitales, clínicas y áreas de salud, por lo que se considera que hace la adquisición a nivel nacional. También hay adquisiciones en el sector privado de dispositivos médicos en menor escala, pero de la cual no se tiene acceso a inventario.



Inventory and maintenance

Type of inventories available: National inventory for medical equipment

Comments: El MoH cuenta con la base de datos de los productos de equipo y material biomédico registrados para el país. Para cualquier adquisición en el país es necesario contar con su registro, pero no es tipo inventario pues no se contabiliza y un registro tiene cinco años de vigencia. En el caso de la CCSS se tiene un inventario por establecimiento (en los tres niveles de atención), tanto a nivel hospitalario, como en clínicas y áreas de salud. En el sector privado, han reportado que cuentan con inventarios de equipos por institución, sin embargo no se tiene acceso a ese inventario pues se maneja como información discrecional en algunos de los casos y es difícil de monitorearlo en su totalidad (more info on: http://www.ccss.sa.cr/organizacion/gestion/gerencias/administrativa/dcss/13_dcsc.html).

Medical equipment management unit: Yes

National level = 0

Regional level = 0

Hospital level = 3

Management software: Yes

Software and comments^λ: En el Ministerio de Salud para el Registro de equipo y material biomédico se utiliza el Visual Basic 6.0, Base de datos SQL Server 2005. En la Caja Costarricense de Seguro Social para la gestión del equipo médico se utiliza el ACCESS.



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:

Lists available: No

Unit: —

Web site: —

Lists comments^λ:

Existen protocolos y procedimientos para las enfermedades y situaciones de emergencias en mención, pero no existen listas de dispositivos médicos como tal.

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: For different healthcare facilities and specific procedures

Web site - facilities: <http://www.ccss.sa.cr>

Web site - procedures: <http://www.ccss.sa.cr>

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: —

| | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|--------|-----------------------|---------------------------|----------|------------------------------------|



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 103 | n/a | 103 | 2.114 |
| Health centre | 29 | 5 | 34 | 0.698 |
| District hospital | 13 | n/a | 13 | 0.267 |
| Provincial hospital | 7 | 7 | 14 | 0.287 |
| Regional hospital | 9 | 5 | 14 | 0.287 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 2 | 2 | 4 | 0.821 |
| Computerized Tomography Scanner | 10 | 15 | 25 | 5.131 |
| Positron Emission Tomography Scanner | 0 | 1 | 1 | 0.205 |
| Nuclear medicine | 4 | 2 | 6 | 1.231 |
| Mammograph* | 20 | 40 | 60 | 150.264 |
| Linear accelerator | 4 | 2 | 6 | 1.231 |
| Telecobalt unit (Cobalt-60) | 3 | 2 | 5 | 1.026 |
| Radiotherapy | 7 | 4 | 11 | 2.258 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ:

Concerning HT national policy we provide the following doc.: Decreto 4725 de 2005.pdf. Es difícil que las instituciones...

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|--------|---|-----|--------------------------------------|--------------|
| Population (000s)* | 11'266 | Life expectancy at birth (years) ^a | 79 | World Bank income group ^β | Upper-middle |
| Internet users (%) ^γ | 25.7% | Per capita total health expenditure (PPP Int \$) ^δ | 405 | GNI per capita (US\$) ^ε | |



National policy on health technology

Health technology (medical device) national policy: Yes, and it is part of the National Health Program/Plan or Policy

Web site: <http://salud2015.sld.cu/proyecciones-para-el-2015-1.pdf/download>

Language(s): Español

MOH responsible for health technology policy implementation: Centro de Control Estatal de Equipos Médicos, Centro Nacional de Electromedicina, Asistencia Médica, Dirección de Ciencia y Evaluación de Tecnologías



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Centro para el Control Estatal de Medicamentos, Equipos y Dispositivos Medicos (CECMED)

Web site: <http://www.cecmecmed.cu/>



National health technology assessment unit

Unit/department: CEDMED

Web site: <http://www.eqmed.sld.cu>



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: Asistencia Médica

Web site: <http://www.infomed.sld.cu>

OTHER: Planning of medical equipment allocation/development of technical specifications for procurement purposes/application/user training

Unit/department: Centro Nacional de Electromedicina

Web site: <http://www.electromedicina.sld.cu>

OTHER: Development of technical specifications for procurement purposes

Unit/department: Empresa Suministro Médicos

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Nationally developed Use: For procurement

Nomenclature system name: GMDN and UMDNS adapted to national needs. Web site: <http://www.electromedicina.sld.cu>



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: <http://salud2015.sld.cu/proyecciones-para-el-2015.1pdf/hload>

National level procurement: Yes

Web site: —

DONATIONS

Policy or guideline: Yes

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: Yes, but not publically available

Web site: —

Medical device incorporation comments^λ:

Basado en la política de salud, los equipos médicos deben contar con el Registro Sanitario para su utilización en el Sistema Nacional de Salud (see www.bvscuba.sld.cu) y en la Gaceta Oficial de la República de Cuba www.gacetaoficial.cu. Para el proceso de importación se realiza una evaluación entre las autoridades competentes donde se efectúa previamente un análisis entre asistencia médica y electromedicina. La ficha técnica para facilitar el proceso de adquisición no están publicadas.



Inventory and maintenance

Type of inventories available: National inventory only for high cost technologies (such as MRI, CT or PET scanners), National inventory for medical equipment, National functional inventory for medical equipment

Comments: —

Medical equipment management unit: Yes

National level = 1

Regional level = 15

Hospital level = 217

Management software: Yes

Software and comments^λ: En fase de desarrollo en el Programa de Informatización de la Salud



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:

Lists comments^λ:

Lists available: Yes

Unit: Subdirección Equipos Médicos del CECMED

Web site: —

Existe un listado de modelo de equipamiento médico destinado para cada nivel de atención, y que no está refrendado en ninguna web (n/a). Cada especialidad médica tiene establecida normas y programas a través de las recomendaciones de los grupos nacionales y apoyo del Consejo de Sociedades Científicas. Lists available for communicable and non communicable diseases,

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: For different healthcare facilities and specific procedures

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: One or more

Web site: —

Types:

| | | | | | | | |
|-----------------------|---|---------------------------|---|----------|---|------------------------------------|---|
| Communicable diseases | x | Non-communicable diseases | x | Injuries | x | Public health emergency situations | x |
|-----------------------|---|---------------------------|---|----------|---|------------------------------------|---|



Healthcare facility

| | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 848 | n/a | 848 | 7.527 |
| Health centre | 72 | n/a | 72 | 0.639 |
| District hospital | 17 | n/a | 17 | 0.151 |
| Provincial hospital | 165 | n/a | 165 | 1.465 |
| Regional hospital | 48 | n/a | 48 | 0.426 |



Medical equipment

| | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 9 | n/a | 9 | 0.799 |
| Computerized Tomography Scanner | 54 | n/a | 54 | 4.793 |
| Positron Emission Tomography Scanner | n/a | n/a | n/a | n/a |
| Nuclear medicine | 14 | n/a | 14 | 1.243 |
| Mammograph* | 20 | n/a | 20 | 15.567 |
| Linear accelerator | 4 | n/a | 4 | 0.355 |
| Telecobalt unit (Cobalt-60) | 9 | 0 | 9 | 0.799 |
| Radiotherapy | 13 | 0 | 13 | 1.154 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ:

En términos de aclaración general indicamos que en Cuba como es conocido el Sistema de Salud tiene características de ser único, centralizado, público, gratuito y universal, refrendado en la Constitución de la República. La demanda de equipos médicos se realiza sobre la base de requerimientos acorde al desarrollo científico-técnico mundial, y de los índices de consumo, para los insumos y obedece a las políticas sanitarias establecidas. Con relación al 3.3.1 las Directrices se basan en la Resolución del Ministerio del Comercio Exterior No. 15 del 2006, no obstante se conocen las Directrices de la OMS.

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|-------|---|-----|--------------------------------------|--------------|
| Population (000s)* | 72 | Life expectancy at birth (years) ^a | 75 | World Bank income group ^β | Upper-middle |
| Internet users (%) ^γ | 59.0% | Per capita total health expenditure (PPP Int \$) ^δ | 740 | GNI per capita (US\$) ^ε | 6'930 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: No

Name of principal institution: —

Web site: —



National health technology assessment unit

Unit/department: Biomedical Department, PMH

Web site: —



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: PMH Equipment Committee

Web site: —

OTHER: Planning of medical equipment allocation/HTA/procurement of equipment

Unit/department: Central Medical Stores

Web site: —

OTHER: Planning of medical equipment allocation/HTA/procurement of equipment

Unit/department: Private Sector Foundation for Health

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: No

Web site: —

DONATIONS

Policy or guideline: No

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ: —



Inventory and maintenance

Type of inventories available: None

Comments: —

Medical equipment management unit: Yes

National level = 3

Regional level = 3

Hospital level = 3

Management software: Yes

Software and comments^λ: Currently awaiting set-up of

Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^δ:Lists comments^λ: —

Lists available: No

Unit: —

Web site: —

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES OR SPECIFIC PROCEDURES^δ: Lists available: No list available

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS^δ:

Lists available: No list available

Web site: —

Types:

Communicable diseases

Non-communicable diseases

Injuries

Public health emergency situations



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 60 | 1 | 61 | 84.719 |
| Health centre | n/a | n/a | 0 | 0.000 |
| District hospital | 2 | n/a | 2 | 2.778 |
| Provincial hospital | 1 | 1 | 2 | 2.778 |
| Regional hospital | n/a | n/a | 0 | 0.000 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 0 | 0 | 0 | 0.000 |
| Computerized Tomography Scanner | 1 | 0 | 1 | 13.888 |
| Positron Emission Tomography Scanner | 0 | 0 | 0 | 0.000 |
| Nuclear medicine | 0 | 0 | 0 | 0.000 |
| Mammograph* | 1 | 1 | 2 | 206.694 |
| Linear accelerator | 0 | 0 | 0 | 0.000 |
| Telecobalt unit (Cobalt-60) | 0 | 0 | 0 | 0.000 |
| Radiotherapy | 0 | 0 | 0 | 0.000 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ:

A manual to govern issues related to medical devices exists in draft form. It is still supposed to have a final review and then to begin the process for adoption and then implementation.

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

Dominican Republic



Country indicators

| | | | | | |
|---------------------------------|--------|---|-----|--------------------------------------|--------------|
| Population (000s)* | 10'404 | Life expectancy at birth (years) ^a | 77 | World Bank income group ^β | Upper-middle |
| Internet users (%) ^γ | 45.9% | Per capita total health expenditure (PPP Int \$) ^δ | 553 | GNI per capita (US\$) ^ε | 5'770 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Viceministerio de Garantía de la Calidad

Web site: <http://www.sespas.gov.do>



National health technology assessment unit

Unit/department: Electromedicina

Web site: —



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: Equipos Medicos (REDES)

Web site: —

OTHER: Mantenimiento Correctivo

Unit/department: Electromedicina

Web site: —

OTHER: Planning of medical equipment allocation

Unit/department: Equipos Medicos (REDES)

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: —

National level procurement: Yes

Web site: <http://www.sespas.gov.do>

DONATIONS

Policy or guideline: Yes

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ:

En cuanto a procurement solo existen recomendaciones de acuerdo a la complejidad del establecimiento, dada en fichas técnicas.



Inventory and maintenance

Type of inventories available: None

Comments: —

Medical equipment management unit: Yes

National level = 1

Regional level = 0

Hospital level = 0

Management software: No

Software and comments^λ: —

Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^δ:Lists comments^λ: —

Lists available: No

Unit: —

Web site: —

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES OR SPECIFIC PROCEDURES^δ: Lists available: No list available

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS^δ:

Lists available: One or more

Web site: —

Types:

| | | | | | | | |
|-----------------------|---|---------------------------|---|----------|---|------------------------------------|---|
| Communicable diseases | x | Non-communicable diseases | x | Injuries | x | Public health emergency situations | x |
|-----------------------|---|---------------------------|---|----------|---|------------------------------------|---|



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | n/a | n/a | n/a | n/a |
| Health centre | n/a | n/a | n/a | n/a |
| District hospital | n/a | n/a | n/a | n/a |
| Provincial hospital | n/a | n/a | n/a | n/a |
| Regional hospital | n/a | n/a | n/a | n/a |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | n/a | n/a | n/a | n/a |
| Computerized Tomography Scanner | n/a | n/a | n/a | n/a |
| Positron Emission Tomography Scanner | n/a | n/a | n/a | n/a |
| Nuclear medicine | n/a | n/a | n/a | n/a |
| Mammograph* | n/a | n/a | n/a | n/a |
| Linear accelerator | n/a | n/a | n/a | n/a |
| Telecobalt unit (Cobalt-60) | n/a | n/a | n/a | n/a |
| Radiotherapy | n/a | n/a | n/a | n/a |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: —

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|--------|---|-----|--------------------------------------|--------------|
| Population (000s)* | 15'738 | Life expectancy at birth (years) ^a | 75 | World Bank income group ^β | Upper-middle |
| Internet users (%) ^γ | 40.4% | Per capita total health expenditure (PPP Int \$) ^δ | 652 | GNI per capita (US\$) ^ε | 5'760 |



National policy on health technology

Health technology (medical device) national policy: Yes, and it is part of the National Health Program/Plan or Policy

Web site: —

Language(s): Español

MOH responsible for health technology policy implementation: Dirección de Inteligencia en Salud



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Coordinación Nacional de Desarrollo Estratégico Dirección de Inteligencia, Instituto nacional de Higiene y Medicina Tropical

Web site: <http://www.msp.gob.ec> <http://www.inh.gob.ec>



National health technology assessment unit

Unit/department: Coordinacion de Desarrollo Estratégico

Web site: <http://www.salud.gob.ec/direccion-de-inteligencia-de-la-salud/>



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: Infraestructura

Web site: <http://www.msp.gob.ec>

OTHER: Planning of medical equipment allocation/development of technical specifications for procurement/application/user training

Unit/department: Red de hospitales

Web site: <http://www.msp.gob.ec>

OTHER: HTA

Unit/department: Dirección de Inteligencia

Web site: <http://www.msp.gob.ec>



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: —

National level procurement: Yes

Web site: <http://www.msp.gob.ec>

DONATIONS

Policy or guideline: Yes

Web site: <http://www.msp.gob.ec/>

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: Yes, but not publically available

Web site: —

Medical device incorporation comments^λ:

Policy for procurement estan en proceso de implementación por la Dirección de Inteligencia y Economía de la salud.

Programa Mi hospital: Adquisición de equipos para 8 hospitales declarados en emergencia sanitaria.



Inventory and maintenance

Type of inventories available: National inventory only for high cost technologies (such as MRI, CT or PET scanners), National inventory for medical equipment

Comments: El inventario de los Hospitales declarados en emergencia se lo está actualizando

Medical equipment management unit: Yes

National level = 2

Regional level = —

Hospital level = —

Management software: No

Software and comments^λ: —



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:

Lists available: No

Unit: —

Web site: —

Lists comments^λ:

Concerning lists for health care facilities: Estatuto del MSP; Licenciamiento por Area en el I y II nivel

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: For different healthcare facilities and specific procedures

Web site - facilities: www.msp.gob.ec

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: —

Web site: —

| | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|--------|-----------------------|---------------------------|----------|------------------------------------|



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 458 | n/a | 458 | 2.910 |
| Health centre | 56 | n/a | 56 | 0.356 |
| District hospital | 8 | n/a | 8 | 0.051 |
| Provincial hospital | 29 | n/a | 29 | 0.184 |
| Regional hospital | 15 | n/a | 15 | 0.095 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 2 | n/a | 2 | 0.127 |
| Computerized Tomography Scanner | 25 | n/a | 25 | 1.589 |
| Positron Emission Tomography Scanner | 2 | n/a | 2 | 0.127 |
| Nuclear medicine | 2 | n/a | 2 | 0.127 |
| Mammograph* | n/a | n/a | n/a | n/a |
| Linear accelerator | n/a | n/a | n/a | n/a |
| Telecobalt unit (Cobalt-60) | 2 | n/a | 2 | 0.127 |
| Radiotherapy | 2 | n/a | 2 | 0.127 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ:

La regulación y control de la publicidad de dispositivos médicos se realiza mediante el “Reglamento para la publicidad y promoción de medicamentos en General, Productos Naturales procesados de uso medicinal, medicamentos homeopáticos y dispositivos médicos” Reg Oficial 416, acuerdo ministerial 179 del 30 de marzo de 2011.

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

El Salvador



Country indicators

| | | | | | |
|---------------------------------|-------|---|-----|--------------------------------------|--------------|
| Population (000s)* | 6'340 | Life expectancy at birth (years) ^a | 72 | World Bank income group ^β | Lower-middle |
| Internet users (%) ^γ | 23.1% | Per capita total health expenditure (PPP Int \$) ^δ | 475 | GNI per capita (US\$) ^ε | 3'720 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Director de Regulación y Legislación en Salud - Ministerio de Salud

Web site: —



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: Departamento de Mantenimiento General

Web site: —

OTHER: Regulación de fuentes emisoras de radiaciones ionizantes/Application/user training

Unit/department: Unidad Nacional de Radiaciones Ionizantes

Web site: —

OTHER: Planning/Adquisition/Technical Specifications of medical equipment

Unit/department: Dirección de Desarrollo de Infraestructura Sanitaria a través de la Unidad de Proyectos

Web site: N/D



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Nationally developed Use: For procurement

Nomenclature system name: Catalogue of medical equipment. Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: No

Web site: —

DONATIONS

Policy or guideline: No

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: Yes, but not publically available

Web site: —

Medical device incorporation comments^λ: —



Inventory and maintenance

Type of inventories available: National inventory only for high cost technologies (such as MRI, CT or PET scanners)

Comments: Para el control de equipos con fuente de radiaciones ionizantes, la Dirección de Regulación a través de la UNRA tienen el inventario de los equipos como TC, Rayos X, Angiografía, Gamma Cámara, etc. Autorizados a nivel nacional en la actualidad, se remitirá el listado actualizado a la fecha posteriormente a la OMS

Medical equipment management unit: Yes

National level = 3

Regional level = 5

Hospital level = 30

Management software: No

Software and comments^λ: —



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:

Lists available: No

Unit: —

Web site: —

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: For different healthcare facilities and specific procedures

Web site - facilities: http://asp.salud.gob.sv/regulacion/pdf/norma/Norma_diseno_y_equipamiento_casas_salud.pdf

Web site - procedures^λ: http://asp.salud.gob.sv/regulacion/pdf/norma/Norma_radiologia_diagnostica.pdf ; http://asp.salud.gob.sv/regulacion/pdf/norma/Norma_fuentes_radiactivas_braquiterapia.pdf..

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: One or more

Web site^λ: http://asp.salud.gob.sv/regulacion/pdf/guia/Guia_edan_salud.pdf; http://asp.salud.gob.sv/regulacion/pdf/guia/Guia_servicios_atencion_prehospitalaria.pdf; http://asp.salud.gob.sv/regulacion/pdf/guia/Guia_atencion_influenza_....

Types:

| | | | | | | | |
|-----------------------|---|---------------------------|---|----------|---|------------------------------------|---|
| Communicable diseases | x | Non-communicable diseases | x | Injuries | x | Public health emergency situations | x |
|-----------------------|---|---------------------------|---|----------|---|------------------------------------|---|

Lists comments^λ:

Recommended lists: Norma técnica para el diseño y equipamiento de Casas de Salud. Available lists for for communicable and non communicable diseases, injuries, and public health emergency situations (available at www.salud.gob.sv)



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 624 | n/a | 624 | 9.842 |
| Health centre | 3 | n/a | 3 | 0.047 |
| District hospital | 25 | n/a | 25 | 0.394 |
| Provincial hospital | 2 | n/a | 2 | 0.032 |
| Regional hospital | 3 | n/a | 3 | 0.047 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 2 | 5 | 7 | 1.104 |
| Computerized Tomography Scanner | 10 | 20 | 30 | 4.732 |
| Positron Emission Tomography Scanner | 0 | 0 | 0 | 0.000 |
| Nuclear medicine | 3 | 3 | 6 | 0.946 |
| Mammograph* | 10 | 20 | 30 | 69.990 |
| Linear accelerator | 1 | 1 | 2 | 0.315 |
| Telecobalt unit (Cobalt-60) | 4 | 1 | 5 | 0.789 |
| Radiotherapy | 5 | 2 | 7 | 1.104 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ:

Las respuestas aportadas corresponden exclusivamente a la información disponible en la Unidad de Proyectos del Ministerio de Salud Pública y Asistencia Social. Agradecemos permitirnos participar de tan importante encuesta que...

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|-------|---|-----|--------------------------------------|--------------|
| Population (000s)* | 106 | Life expectancy at birth (years) ^a | 73 | World Bank income group ^β | Upper-middle |
| Internet users (%) ^γ | 35.0% | Per capita total health expenditure (PPP Int \$) ^δ | 691 | GNI per capita (US\$) ^ε | 7'490 |



National policy on health technology

Health technology (medical device) national policy: Yes, but is not part of the National Health Program

Web site: —

Language(s): English

MOH responsible for health technology policy implementation: Administration and Biomedical Engineering Dept.



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: No

Name of principal institution: —

Web site: —



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: Biomedical Engineering Department

Web site: —

OTHER: —

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Nationally developed Use: For procurement

Nomenclature system name: National system for medical equipment Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: —

National level procurement: Yes

Web site: —

DONATIONS

Policy or guideline: No

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: Yes, but not publically available

Web site: —

Medical device incorporation comments^λ:

There are procurement guidelines but not implemented or followed. The procurement of medical devices are carried out at a national level by the Central Medical Stores Unit (CMS). No specific devices have been selected but the need assessment was done. Specification can be submitted separately



Inventory and maintenance

Type of inventories available: National inventory for medical equipment

Comments: The inventory for all medical equipment in the island can be found in the Biomedical Engineering Department, General Hospital

Medical equipment management unit: Yes

National level = 1

Regional level = 1

Hospital level = 1

Management software: Yes

Software and comments^λ: The system was locally developed and installed but just called The Medical device management system software



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:

Lists available: Yes

Unit: —

Web site: —

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: No list available

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: —

Types:

| | | | |
|-----------------------|---------------------------|----------|------------------------------------|
| Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|-----------------------|---------------------------|----------|------------------------------------|

Lists comments^λ:

We do not have any available lists for communicable and non-communicable diseases, injuries, and public health emergency situations. Yes, we the primary need are in the areas of Radiology, Sterilization, Incinerators, Oncology and Dialysis for the MoH. The list can be requested from the management of the Hospital services. However there is no web to guideline because was



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 36 | n/a | 36 | 33.995 |
| Health centre | 5 | n/a | 5 | 4.722 |
| District hospital | 1 | n/a | 1 | 0.944 |
| Provincial hospital | n/a | n/a | 0 | 0.000 |
| Regional hospital | n/a | n/a | 0 | 0.000 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 0 | 1 | 1 | 9.443 |
| Computerized Tomography Scanner | 0 | 2 | 2 | 18.886 |
| Positron Emission Tomography Scanner | 0 | 0 | 0 | 0.000 |
| Nuclear medicine | 0 | 0 | 0 | 0.000 |
| Mammograph* | 1 | 0 | 1 | 134.608 |
| Linear accelerator | 0 | 0 | 0 | 0.000 |
| Telecobalt unit (Cobalt-60) | 0 | 0 | 0 | 0.000 |
| Radiotherapy | 0 | 0 | 0 | 0.000 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: —

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

Guatemala



Country indicators

| | | | | | |
|---------------------------------|--------|---|-----|--------------------------------------|--------------|
| Population (000s)* | 15'468 | Life expectancy at birth (years) ^a | 72 | World Bank income group ^β | Lower-middle |
| Internet users (%) ^γ | 19.7% | Per capita total health expenditure (PPP Int \$) ^δ | 346 | GNI per capita (US\$) ^ε | 3'340 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Departamento de Regulacion y Control de Productos Farmaceuticos y Afines

Web site: http://portal.mspas.gob.gt/nuevo_o_renovacion_de_la_inscripcion_sanitaria_de_productos_afines.html



National health technology assessment unit

Unit/department: Unidad de Planificacion Estrategica/SIGSA/OPS-OMS/OSAR

Web site: <https://sico.in.minfin.gob.gt>, <https://siges.minfin.gob.gt>, <http://sigsa.mspas.gob.gt>



National health technology management units

National health technology unit(s): No

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Nationally developed Use: Not specified

Nomenclature system name: Segun Clase: Anexo de la Norma Tecnica No. 37. Web site: <http://portal.mspas.gob.gt/>



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: Yes

Web site: www.guatecompras.gob.gt

DONATIONS

Policy or guideline: Yes

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ:

Procurement done by Sistema de Adquisiciones del Estado de Guatemala a nivel general.



Inventory and maintenance

Type of inventories available: None

Comments: No se utiliza ninguno.

Medical equipment management unit: No

National level = 0

Regional level = 0

Hospital level = 0

Management software: No

Software and comments^λ: —

Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:Lists comments^λ: —

Lists available: No

Unit: —

Web site: —

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES OR SPECIFIC PROCEDURES: Lists available: For specific procedures

Web site - facilities: —

Web site - procedures: http://portal.mspas.gob.gt/images/files//docs_dgrvcs/DRCPPFA/Regulaciones/normativa%20tecnica/normativa%2037.pdf**NATIONAL LIST FOR DISEASES AND SITUATIONS:**

Lists available: No list available

Web site: —

Types:

Communicable diseases

Non-communicable diseases

Injuries

Public health emergency situations



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 548 | n/a | 548 | 3.543 |
| Health centre | 77 | n/a | 77 | 0.498 |
| District hospital | 43 | n/a | 43 | 0.278 |
| Provincial hospital | 5 | n/a | 5 | 0.032 |
| Regional hospital | 5 | n/a | 5 | 0.032 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | n/a | n/a | n/a | n/a |
| Computerized Tomography Scanner | n/a | n/a | n/a | n/a |
| Positron Emission Tomography Scanner | n/a | n/a | n/a | n/a |
| Nuclear medicine | n/a | n/a | n/a | n/a |
| Mammograph* | n/a | n/a | n/a | n/a |
| Linear accelerator | n/a | n/a | n/a | n/a |
| Telecobalt unit (Cobalt-60) | n/a | n/a | n/a | n/a |
| Radiotherapy | n/a | n/a | n/a | n/a |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: —

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|-------|---|-----|--------------------------------------|--------------|
| Population (000s)* | 800 | Life expectancy at birth (years) ^a | 63 | World Bank income group ^β | Lower-middle |
| Internet users (%) ^γ | 33.0% | Per capita total health expenditure (PPP Int \$) ^δ | 223 | GNI per capita (US\$) ^ε | 3'750 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: —

Name of principal institution: Food & Drug department

Web site: <http://www.health.gov.gy/index.php/programmes/administration/food-drug-department>



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: Regional Radiology

Web site: —

OTHER: Application/ user training

Unit/department: Regional Radiology

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: Yes

Web site: —

DONATIONS

Policy or guideline: No

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ: —



Inventory and maintenance

Type of inventories available: National functional inventory for medical equipment

Comments: Inventories for X-ray equipment.

Medical equipment management unit: Yes

National level = 1

Regional level = 0

Hospital level = 4

Management software: No

Software and comments^λ: one public corporation uses an assets software to carry out the same function.



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^δ:

Lists available: No

Unit: —

Web site: —

Lists comments^λ:

Lists available for communicable and non communicable diseases, injuries, and public health emergency situations.

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES OR SPECIFIC PROCEDURES^δ: Lists available: No list available

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS^δ:

Lists available: One or more

Web site: —

Types: Communicable diseases x Non-communicable diseases x Injuries x Public health emergency situations x



Healthcare facility

| | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 205 | n/a | 205 | 25.637 |
| Health centre | 118 | n/a | 118 | 14.757 |
| District hospital | 16 | n/a | 16 | 2.001 |
| Provincial hospital | 4 | 6 | 10 | 1.251 |
| Regional hospital | 1 | n/a | 1 | 0.125 |



Medical equipment

| | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | n/a | 1 | 1 | 1.251 |
| Computerized Tomography Scanner | n/a | 3 | 3 | 3.752 |
| Positron Emission Tomography Scanner | n/a | n/a | n/a | n/a |
| Nuclear medicine | n/a | n/a | n/a | n/a |
| Mammograph* | n/a | 3 | 3 | 69.977 |
| Linear accelerator | n/a | 1 | 1 | 1.251 |
| Telecobalt unit (Cobalt-60) | n/a | n/a | n/a | n/a |
| Radiotherapy | n/a | 1 | 1 | 1.251 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: —

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|--------|---|----|--------------------------------------|-----|
| Population (000s)* | 10'317 | Life expectancy at birth (years) ^a | 62 | World Bank income group ^β | Low |
| Internet users (%) ^γ | 10.6% | Per capita total health expenditure (PPP Int \$) ^δ | 84 | GNI per capita (US\$) ^ε | 810 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: No

Name of principal institution: —

Web site: —



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): No

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: No

Web site: —

DONATIONS

Policy or guideline: Yes

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: Yes, but not publically available

Web site: —

Medical device incorporation comments^λ: —



Inventory and maintenance

Type of inventories available: —

Comments: IL N'EXISTE PAS ENCORE UNE LISTE D'INVENTAIRE TECHNIQUE NATIONAL POUR LES EQUIPEMENTS MEDICAUX

Medical equipment management unit: Yes

National level = 1

Regional level = —

Hospital level = —

Management software: Yes

Software and comments^λ: GMAO



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:

Lists comments^λ: —

Lists available: No

Unit: —

Web site: —

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: No list available

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: —

Types:

Communicable diseases

Non-communicable diseases

Injuries

Public health emergency situations



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | n/a | n/a | n/a | n/a |
| Health centre | 10 | 20 | 30 | 0.291 |
| District hospital | 10 | 7 | 17 | 0.165 |
| Provincial hospital | n/a | 4 | 4 | 0.039 |
| Regional hospital | 4 | n/a | 4 | 0.039 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | n/a | n/a | n/a | n/a |
| Computerized Tomography Scanner | n/a | 3 | 3 | 0.291 |
| Positron Emission Tomography Scanner | n/a | n/a | n/a | n/a |
| Nuclear medicine | n/a | n/a | n/a | n/a |
| Mammograph* | 6 | 5 | 11 | 19.471 |
| Linear accelerator | n/a | n/a | n/a | n/a |
| Telecobalt unit (Cobalt-60) | n/a | n/a | n/a | n/a |
| Radiotherapy | n/a | n/a | n/a | n/a |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ:

Concerning the infrastructure section: les centres de santé sont dotés de 10 lits.

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|-------|---|-----|--------------------------------------|--------------|
| Population (000s)* | 8'098 | Life expectancy at birth (years) ^a | 74 | World Bank income group ^β | Lower-middle |
| Internet users (%) ^γ | 17.8% | Per capita total health expenditure (PPP Int \$) ^δ | 354 | GNI per capita (US\$) ^ε | 2'180 |



National policy on health technology

Health technology (medical device) national policy: Yes, and it is part of the National Health Program/Plan or Policy

Web site: —

Language(s): Español

MOH responsible for health technology policy implementation: Departamento de Hospitales.Dirección General de Sistemas y Servicios de Salud. El programa de Equipamiento tiene en proceso de elaboración la Política para la Secretaría de Salud



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Dirección General de Regulación Sanitaria

Web site: <http://www.dgrs.gob.hn>



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: Unidades de Mantenimiento de Hospitales y Regiones Sanitarias

Web site: —

OTHER: Development of technical specifications/Planificación se realiza unicamente para proyectos, elaboración de especificaciones por demanda.

Unit/department: Programa de Equipamiento. Dirección General de Sistemas y Servicios de Salud

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Nationally developed Use: For regulatory purposes and procurement

Nomenclature system name: Registry nomenclature Web site: <http://www.dgrs.gob.hn>



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: <http://www.honducompras.gob.hn/Info/Normativa.asp>

National level procurement: Yes

Web site: —

DONATIONS

Policy or guideline: Yes

Web site:<http://www.dgrs.gob.hn>

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ:

For procurement: Ley de Contratación del Estado, y Reglamento de Ley de Contratación del Estado. Cada uno de los los Programas de Salud dependientes de la Direccion realizan compras de DM para proveer a nivel nacional. El Programa de Equipamiento los elabora por demanda y por complejidad.



Inventory and maintenance

Type of inventories available: National inventory for medical equipment

Comments: El inventario es por Objeto de Gasto. Se remitirá en correo adjunto

Medical equipment management unit: Yes

National level = 1

Regional level = 20

Hospital level = 31

Management software: Yes

Software and comments^λ: Existe el SIAFI que es un sistema informatico para fines de presupuesto, el cual actualmente se encuentra en procesos de ampliación ya que permitirá la gestión del equipamiento en todas sus fases.



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:

Lists available: No

Unit: —

Web site: —

Lists comments^λ:

Lists guidelines are established in: instrumentos de inspeccion sanitaria para el licenciamiento de establecimientos de Salud.

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: For different healthcare facilities

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: —

| | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|--------|-----------------------|---------------------------|----------|------------------------------------|



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 1'424 | n/a | 1424 | 17.585 |
| Health centre | 59 | n/a | 59 | 0.729 |
| District hospital | 16 | n/a | 16 | 0.198 |
| Provincial hospital | 6 | n/a | 6 | 0.074 |
| Regional hospital | 7 | n/a | 7 | 0.086 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 0 | 9 | 9 | 1.111 |
| Computerized Tomography Scanner | 5 | 12 | 17 | 2.099 |
| Positron Emission Tomography Scanner | 0 | 0 | 0 | 0.000 |
| Nuclear medicine | 0 | 1 | 1 | 0.123 |
| Mammograph* | 7 | 13 | 20 | 50.867 |
| Linear accelerator | 0 | 2 | 2 | 0.247 |
| Telecobalt unit (Cobalt-60) | 2 | 2 | 4 | 0.494 |
| Radiotherapy | 2 | 4 | 6 | 0.741 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: —

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|-------|---|-----|--------------------------------------|--------------|
| Population (000s)* | 2'784 | Life expectancy at birth (years) ^a | 74 | World Bank income group ^β | Upper-middle |
| Internet users (%) ^γ | 37.8% | Per capita total health expenditure (PPP Int \$) ^δ | 461 | GNI per capita (US\$) ^ε | 5'220 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: No

Name of principal institution: —

Web site: —



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: Health Facilities Maintenance Unit

Web site: —

OTHER: —

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: Yes

Web site: —

DONATIONS

Policy or guideline: No

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: Yes, but not publically available

Web site: —

Medical device incorporation comments^λ:
Procurement carried out at the regional and hospital level.



Inventory and maintenance

Type of inventories available: National inventory only for high cost technologies (such as MRI, CT or PET scanners)

Comments: —

Medical equipment management unit: Yes

National level = —

Regional level = —

Hospital level = —

Management software: —

Software and comments^λ: —



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^δ

Lists comments^λ:

Lists available: No

Unit: —

Web site: —

Other lists other than for public health emergency situations, are not available by the moment.

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES OR SPECIFIC PROCEDURES: Lists available: No list available

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: One or more

Web site: —

| | | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|---|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations | x |
|--------|-----------------------|---------------------------|----------|------------------------------------|---|



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | n/a | n/a | n/a | n/a |
| Health centre | n/a | n/a | n/a | n/a |
| District hospital | 11 | n/a | 11 | 0.395 |
| Provincial hospital | 8 | n/a | 8 | 0.287 |
| Regional hospital | 2 | n/a | 2 | 0.072 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 2 | 2 | 4 | 1.437 |
| Computerized Tomography Scanner | 4 | n/a | 4 | 1.437 |
| Positron Emission Tomography Scanner | 0 | 0 | 0 | 0.000 |
| Nuclear medicine | n/a | n/a | n/a | n/a |
| Mammograph* | 5 | 6 | 11 | 51.272 |
| Linear accelerator | n/a | n/a | n/a | n/a |
| Telecobalt unit (Cobalt-60) | 2 | 1 | 3 | 1.078 |
| Radiotherapy | 2 | 1 | 3 | 1.078 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ:

Concerning HT national policy we provide the following doc.: Ritza O4.doc

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

Mexico



Country indicators

| | | | | | |
|---------------------------------|---------|---|------|--------------------------------------|--------------|
| Population (000s)* | 122'332 | Life expectancy at birth (years) ^a | 76 | World Bank income group ^β | Upper-middle |
| Internet users (%) ^γ | 43.5% | Per capita total health expenditure (PPP Int \$) ^δ | 1062 | GNI per capita (US\$) ^ε | 9'940 |



National policy on health technology

Health technology (medical device) national policy: Yes, and it is part of the National Health Program/Plan or Policy

Web site: —

Language(s): Spanish

MOH responsible for health technology policy implementation: Centro Nacional de Excelencia Tecnológica en Salud



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Comisión Federal para la protección contra riesgos sanitario (COFEPRIS)

Web site: <http://www.cofepris.gob.mx>



National health technology assessment unit

Unit/department: Centro Nacional de Excelencia Tecnológica en Salud

Web site: <http://www.cenetec.salud.gob.mx/>



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: Centro Nacional de Excelencia Tecnológica en Salud

Web site: <http://www.cenetec.salud.gob.mx/>

OTHER: Master Plan of Infrastructure

Unit/department: Dirección General de Planeación y Desarrollo en Salud

Web site: <http://www.dgplades.salud.gob.mx/>

OTHER: Planning of medical equipment allocation/National System of Health Information

Unit/department: Dirección General de Información en Salud

Web site: <http://www.dgis.salud.gob.mx/>



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Nationally developed Use: Not specified

Nomenclature system name: Catálogo y Cuadro Básico de Insumos para la Salud Web site: <http://www.csg.salud.gob.mx/index.html#>



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: http://www.cenetec.salud.gob.mx/interior/equipo_medico.html

National level procurement: No

Web site: —

DONATIONS

Policy or guideline: Yes

Web site: http://www.cenetec.salud.gob.mx/interior/equipo_medico.html

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: Yes

Web site: <http://www.cenetec.salud.gob.mx/interior/cet.html>

Medical device incorporation comments^λ:

There are some recommendations for this topic, but they are not policies. The specifications are only recommendations



Inventory and maintenance

Type of inventories available: National functional inventory for medical equipment

Comments: Subsistema de Información de Equipamiento, Recursos Humanos e Infraestructura para la Atención a la Salud (Subsystem of Equipment, Human Resources and Infraestructure in Health)

Medical equipment management unit: Yes

National level = 18

Regional level = 114

Hospital level = 467

Management software: Yes

Software and comments^λ: There are not only one, in general these are made in each one of the units for their particular needs.



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:

Lists comments^λ:

Lists available: Yes

Unit: Consejo de Salubridad General

Web site: http://www.csg.salud.gob.mx/interiores/cb_cat/cuadrobasico_cat.html

See: http://www.csg.salud.gob.mx/interiores/cb_cat/cuadrobasico_cat.html

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: For different healthcare facilities

Web site - facilities: http://www.cenetec.salud.gob.mx/interior/modelos_equip.html

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: One or more

Web site: —

Types:

| |
|-----------------------|
| Communicable diseases |
|-----------------------|

| |
|---------------------------|
| Non-communicable diseases |
|---------------------------|

| |
|----------|
| Injuries |
|----------|

| |
|------------------------------------|
| Public health emergency situations |
|------------------------------------|

x



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|--------|--------------------------------|
| Health post | 19'778 | 105'083 | 124861 | 102.067 |
| Health centre | n/a | n/a | n/a | n/a |
| District hospital | n/a | n/a | n/a | n/a |
| Provincial hospital | 1'117 | 3'111 | 4228 | 3.456 |
| Regional hospital | 69 | n/a | 69 | 0.056 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 49 | 124 | 173 | 1.414 |
| Computerized Tomography Scanner | 201 | 246 | 447 | 3.654 |
| Positron Emission Tomography Scanner | 6 | 8 | 14 | 0.114 |
| Nuclear medicine | 25 | 68 | 93 | 0.760 |
| Mammograph* | 314 | 366 | 680 | 74.469 |
| Linear accelerator | 38 | 21 | 59 | 0.482 |
| Telecobalt unit (Cobalt-60) | 32 | 13 | 45 | 0.368 |
| Radiotherapy | 32 | 34 | 66 | 0.540 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: —

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

Nicaragua



Country indicators

| | | | | | |
|---------------------------------|-------|---|-----|--------------------------------------|--------------|
| Population (000s)* | 6'080 | Life expectancy at birth (years) ^a | 73 | World Bank income group ^β | Lower-middle |
| Internet users (%) ^γ | 15.5% | Per capita total health expenditure (PPP Int \$) ^δ | 335 | GNI per capita (US\$) ^ε | 1'790 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Dirección General de Regulación Sanitaria

Web site: <http://www.minsa.gob.ni>



National health technology assessment unit

Unit/department: Dirección General de Extensión y Calidad en la Atención

Web site: <http://www.minsa.gob.ni>



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: Dirección de Infraestructura y Desarrollo Tecnológico

Web site: <http://www.minsa.gob.ni>

OTHER: HTA

Unit/department: Dirección General de Regulación Sanitaria

Web site: <http://www.minsa.gob.ni>

OTHER: Maintenance

Unit/department: Centro de Mantenimiento de Equipos Médicos

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on GMDN (Global Medical Device Nomenclature)

Use: For regulatory purposes

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: Yes

Web site: <http://www.minsa.gob.ni>

DONATIONS

Policy or guideline: Yes

Web site: <http://www.minsa.gob.ni/regulacion/donaciones.html>

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ:

Procurement department works as a team with the Health Services Department, the Sanitary Regulations Department and the Acquisition Unit of the Ministry of Health



Inventory and maintenance

Type of inventories available: National inventory for medical equipment

Comments: This inventory was carried out for our maintenance unit (CEMED). The last time was updated was 2009

Medical equipment management unit: Yes

National level = 1

Regional level = 0

Hospital level = 25

Management software: No

Software and comments^λ: —



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^α:

Lists available: No

Unit: —

Web site: —

Lists comments^λ:

The Ministry of Health does not have lists recommending health technology for communicable and non communicable diseases, injuries, and neither for public health emergency situations.

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: For different healthcare facilities and specific procedures

Web site - facilities: <http://www.minsa.gob.ni/regulacion/establecimientos/N-013-ManualHabilitacionEstablecimientos.pdf>

Web site - procedures: <http://www.minsa.gob.ni/>

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: —

| | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|--------|-----------------------|---------------------------|----------|------------------------------------|



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 890 | n/a | 890 | 14.637 |
| Health centre | 158 | n/a | 158 | 2.598 |
| District hospital | 26 | n/a | 26 | 0.428 |
| Provincial hospital | 26 | n/a | 26 | 0.428 |
| Regional hospital | 6 | n/a | 6 | 0.099 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 1 | n/a | 1 | 0.164 |
| Computerized Tomography Scanner | 3 | n/a | 3 | 0.493 |
| Positron Emission Tomography Scanner | 0 | n/a | 0 | 0.000 |
| Nuclear medicine | 1 | n/a | 1 | 0.164 |
| Mammograph* | n/a | n/a | n/a | n/a |
| Linear accelerator | 1 | n/a | 1 | 0.164 |
| Telecobalt unit (Cobalt-60) | 1 | n/a | 1 | 0.164 |
| Radiotherapy | 2 | n/a | 2 | 0.329 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^δ:

Our Ministry of Health is doing big efforts to normalize and to regulate the procurement of medical devices, but we do have need of training for our personnel in order to perform a better job. We also have limitations in providing maintenance to the equipments adquired.

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|-------|---|------|--------------------------------------|--------------|
| Population (000s)* | 3'864 | Life expectancy at birth (years) ^a | 77 | World Bank income group ^β | Upper-middle |
| Internet users (%) ^γ | 42.9% | Per capita total health expenditure (PPP Int \$) ^δ | 1260 | GNI per capita (US\$) ^ε | 10'700 |



National policy on health technology

Health technology (medical device) national policy: Yes, and it is part of the National Health Program/Plan or Policy

Web site: http://www.minsa.gob.pa/minsa2008/final_newpage/dispositivos_medicos.htm

Language(s): Español

MOH responsible for health technology policy implementation: Comision Nacional de Registro Nacional de Oferentes - Departamento de Investigación - Desarrollo Tecnológico en Salud y Comité Técnico Nacional Interinstitucional - Dirección Nacional de Farmacias y Drogas - Laboratorio Central de Referencia



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Departamento de Investigación y Desarrollo Tecnológico en Salud

Web site: http://www.minsa.gob.pa/minsa2008/final_newpage/dispositivos_medicos.htm



National health technology assessment unit

Unit/department: Dirección de provision

Web site: <http://190.34.154.88/ProvServWebApp/>



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: Comité Técnico Nacional Interinstitucional

Web site: <http://190.34.154.88/WFichasTecnicasApp/>

OTHER: Registration of medical devices

Unit/department: Comision Nacional de Oferentes

Web site: <http://190.34.154.88/WOfereentes/Index.aspx>

OTHER: Innovation and research

Unit/department: Departamento de Investigación y Desarrollo Tecnológico en Salud

Web site: <http://190.34.154.88/wcriterios/>



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Nationally developed Use: Not specified

Nomenclature system name: Se usa la nomenclatura del listado de fichas técnicas de Comité Técnico Nacional Intstitucional (Soon UMDNS) Web site: <http://www.minsa.gob.pa>



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: <http://190.34.154.88/WFichasTecnicasApp/>

National level procurement: Yes

Web site: <http://190.34.154.88/ProvServWebApp/>

DONATIONS

Policy or guideline: Yes

Web site: http://www.asamblea.gob.pa/APPS/LEGISPAN/PDF_NORMAS/1990/1995/1995_114_1172.PDF

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: Yes

Web site: <http://190.34.154.88/WFichasTecnicasApp/>

Medical device incorporation comments^λ:

La Caja de Seguro Social hace sus procesos de adquisición independiente del Ministerio de Salud pero sujeto al sistema de Fichas Técnicas Nacionales en cuyas confecciones participa también.



Inventory and maintenance

Type of inventories available: None

Comments: –

Medical equipment management unit: Yes

National level = 1

Regional level = 7

Hospital level = 0

Management software: Yes

Software and comments^λ: ECRI

Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^α:

Lists available: Yes

Unit: Comité Técnico Nacional Interinstitucional

Web site: <http://190.34.154.88/WFichasTecnicasApp/>Lists comments^λ:

You can find it at:

<http://190.34.154.88/WFichasTecnicasApp/>

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: For different healthcare facilities

Web site - facilities: <http://190.34.154.88/WFichasTecnicasApp/>

Web site - procedures: –

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: –

Types:

| | | | |
|-----------------------|---------------------------|----------|------------------------------------|
| Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|-----------------------|---------------------------|----------|------------------------------------|



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 480 | n/a | 480 | 12.422 |
| Health centre | 388 | n/a | 388 | 10.041 |
| District hospital | 15 | n/a | 15 | 0.388 |
| Provincial hospital | 9 | 4 | 13 | 0.336 |
| Regional hospital | 7 | n/a | 7 | 0.181 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 2 | 9 | 11 | 2.847 |
| Computerized Tomography Scanner | 28 | 9 | 37 | 9.575 |
| Positron Emission Tomography Scanner | 0 | 0 | 0 | 0.000 |
| Nuclear medicine | 3 | 5 | 8 | 2.070 |
| Mammograph* | 50 | 29 | 79 | 278.539 |
| Linear accelerator | 3 | 3 | 6 | 1.553 |
| Telecobalt unit (Cobalt-60) | 0 | 0 | 0 | 0.000 |
| Radiotherapy | 3 | 3 | 6 | 1.553 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: –

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

Paraguay



Country indicators

| | | | | | |
|---------------------------------|-------|---|-----|--------------------------------------|--------------|
| Population (000s)* | 6'802 | Life expectancy at birth (years) ^a | 75 | World Bank income group ^β | Lower-middle |
| Internet users (%) ^γ | 36.9% | Per capita total health expenditure (PPP Int \$) ^δ | 633 | GNI per capita (US\$) ^ε | 4'010 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: —

Name of principal institution: Direccion de Vigilancia Sanitaria del Ministerio de Salud Publica y Bienestar Social (MSPyBS)

Web site: <http://www.mspbs.gov.py/>



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: Direccion General

Web site: —

OTHER: Planning of medical equipment allocation

Unit/department: Direccion de desarrollo de servicios de salud

Web site: —

OTHER: Planning of medical equipment allocation/development technical specifications/application/user training

Unit/department: Direccion Biomedica

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: Yes

Web site: —

DONATIONS

Policy or guideline: No

Web site: —

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ:

Procurement guidelines: se inicio la elaboracion de directrices.



Inventory and maintenance

Type of inventories available: National inventory for medical equipment

Comments: —

Medical equipment management unit: Yes

National level = 1

Regional level = 10

Hospital level = 7

Management software: No

Software and comments^λ: —



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:

Lists comments^λ: —

Lists available: No

Unit: —

Web site: —

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES OR SPECIFIC PROCEDURES: Lists available: No list available

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: —

| | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|--------|-----------------------|---------------------------|----------|------------------------------------|



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 657 | n/a | 657 | 9.659 |
| Health centre | 118 | n/a | 118 | 1.735 |
| District hospital | 140 | n/a | 140 | 2.058 |
| Provincial hospital | 8 | n/a | 8 | 0.118 |
| Regional hospital | 17 | n/a | 17 | 0.250 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 0 | 2 | 2 | 0.294 |
| Computerized Tomography Scanner | 3 | 4 | 7 | 1.029 |
| Positron Emission Tomography Scanner | 0 | 0 | 0 | 0.000 |
| Nuclear medicine | 0 | n/a | 0 | 0.000 |
| Mammograph* | 3 | n/a | 3 | 7.327 |
| Linear accelerator | 1 | n/a | 1 | 0.147 |
| Telecobalt unit (Cobalt-60) | 1 | 2 | 3 | 0.441 |
| Radiotherapy | 2 | 2 | 4 | 0.588 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ:

Concerning HT national policy we provide the following doc.: DECRETO EJECUTIVO 468.pdf

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|--------|---|-----|--------------------------------------|--------------|
| Population (000s)* | 30'376 | Life expectancy at birth (years) ^a | 77 | World Bank income group ^β | Upper-middle |
| Internet users (%) ^γ | 39.2% | Per capita total health expenditure (PPP Int \$) ^δ | 555 | GNI per capita (US\$) ^ε | 6'270 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: <http://www.minsa.gob.pe>

Language(s): Spanish

MOH responsible for health technology policy implementation: National Authority for Pharmaceutical Products, Medical Devices and Sanitary Products - (DIGEMID) from the Ministry of Health



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: DIGEMID

Web site: <http://www.digemid.minsa.gob.pe>



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: —

Web site: —

OTHER: Medical Devices procedures

Unit/department: Unit of Medical Devices

Web site: —

OTHER: Acquisition

Unit/department: Direction of Acquisition and supply of Strategic Resources in Health

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Nationally developed Use: Not specified

Nomenclature system name: GMDN adapted to national needs (Ley N°29459-D.S and the D.S. N° 016-2011-SA) Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: <http://www.digemid.minsa.gob.pe/dispositivos medicos>

National level procurement: Yes

Web site: <http://www.dares.minsa.gob.pe>

DONATIONS

Policy or guideline: Yes

Web site: <http://www.digemid.minsa.gob.pe/Main.asp?Seccion=469>

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ: —



Inventory and maintenance

Type of inventories available: None

Comments: There are any kind of inventories for medical devices available in my country

Medical equipment management unit: No

National level = 0

Regional level = 0

Hospital level = 0

Management software: No

Software and comments^λ: –



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^δ:

Lists available: Yes

Unit: Agencia de Cooperacion Internacional

Web site: –

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES OR SPECIFIC PROCEDURES: Lists available: For different healthcare facilities and specific procedures

Web site - facilities: <ftp://ftp2.minsa.gob.pe/normaslegales/2011/RM369-2011-MINSA.PDF>

Web site - procedures: –

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: One or more

Web site: –

Types:

Communicable diseases x

Non-communicable diseases x

Injuries x

Public health emergency situations

Lists comments^λ:

We use international standards. Like ISO 13485; ISO 10993; CE Regulations. We have a list of strategic and support Pharmaceutical and Medical Devices Products used in Health care for a group of Sanitary interventions, IMDRF (GHITF). As well as lists for communicable and non communicable diseases, and injuries. There are protocolos of care at level of hospitals.



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | n/a | n/a | n/a | n/a |
| Health centre | n/a | n/a | n/a | n/a |
| District hospital | n/a | n/a | n/a | n/a |
| Provincial hospital | n/a | n/a | n/a | n/a |
| Regional hospital | n/a | n/a | n/a | n/a |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | n/a | n/a | n/a | n/a |
| Computerized Tomography Scanner | n/a | n/a | n/a | n/a |
| Positron Emission Tomography Scanner | n/a | n/a | n/a | n/a |
| Nuclear medicine | n/a | n/a | n/a | n/a |
| Mammograph* | n/a | n/a | n/a | n/a |
| Linear accelerator | n/a | n/a | n/a | n/a |
| Telecobalt unit (Cobalt-60) | n/a | n/a | n/a | n/a |
| Radiotherapy | n/a | n/a | n/a | n/a |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: –

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

Saint Kitts and Nevis



Country indicators

| | | | | | |
|---------------------------------|-------|---|------|--------------------------------------|--------|
| Population (000s)* | 54 | Life expectancy at birth (years) ^a | 74 | World Bank income group ^β | High |
| Internet users (%) ^γ | 80.0% | Per capita total health expenditure (PPP Int \$) ^δ | 1065 | GNI per capita (US\$) ^ε | 13'890 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: No

Name of principal institution: —

Web site: —



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): No

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: Yes

Web site: —

DONATIONS

Policy or guideline: No

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ:

Hospital management purchases devices directly from vendors.



Inventory and maintenance

Type of inventories available: None

Comments: –

Medical equipment management unit: Yes

National level = 0

Regional level = 0

Hospital level = 1

Management software: No

Software and comments^λ: –

Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^δ:Lists comments^λ: –

Lists available: No

Unit: –

Web site: –

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES OR SPECIFIC PROCEDURES: Lists available: No list available

Web site - facilities: –

Web site - procedures: –

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: –

Types:

| | | | |
|-----------------------|---------------------------|----------|------------------------------------|
| Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|-----------------------|---------------------------|----------|------------------------------------|



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | n/a | n/a | 0 | 0.000 |
| Health centre | 17 | n/a | 17 | 31.371 |
| District hospital | 2 | n/a | 2 | 3.691 |
| Provincial hospital | 2 | n/a | 2 | 3.691 |
| Regional hospital | n/a | n/a | 0 | 0.000 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 0 | 0 | 0 | 0.000 |
| Computerized Tomography Scanner | 1 | 0 | 1 | 18.453 |
| Positron Emission Tomography Scanner | 0 | 0 | 0 | 0.000 |
| Nuclear medicine | 0 | 0 | 0 | 0.000 |
| Mammograph* | 1 | 0 | 1 | 149.436 |
| Linear accelerator | 0 | 0 | 0 | 0.000 |
| Telecobalt unit (Cobalt-60) | 0 | 0 | 0 | 0.000 |
| Radiotherapy | 0 | 0 | 0 | 0.000 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: –

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|-------|---|-----|--------------------------------------|--------------|
| Population (000s)* | 182 | Life expectancy at birth (years) ^a | 75 | World Bank income group ^β | Upper-middle |
| Internet users (%) ^γ | 35.2% | Per capita total health expenditure (PPP Int \$) ^δ | 945 | GNI per capita (US\$) ^ε | 7'060 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: No

Name of principal institution: Not quite but we have a Bureau of standards who should be doing so

Web site: —



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): No

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: No

Web site: —

DONATIONS

Policy or guideline: No

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ:

The procurement at national level is not for medical equipment, but yes for pharmaceuticals



Inventory and maintenance

Type of inventories available: None

Comments: Medical equipment inventories of public hospitals exist. The functional status of such equipment is reflected in these lists. No PET scanners are available on island. CT and MRI available only in one private hospital facility.

Medical equipment management unit: Yes

National level = 1

Regional level = 0

Hospital level = 1

Management software: No

Software and comments^λ: –



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:

Lists comments^λ: –

Lists available: No

Unit: –

Web site: –

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: No list available

Web site - facilities: –

Web site - procedures: –

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: –

Types:

Communicable diseases

Non-communicable diseases

Injuries

Public health emergency situations



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 34 | n/a | 34 | 18.653 |
| Health centre | n/a | n/a | n/a | n/a |
| District hospital | n/a | n/a | n/a | n/a |
| Provincial hospital | n/a | n/a | n/a | n/a |
| Regional hospital | 2 | 1 | 3 | 1.646 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 1 | 1 | 2 | 10.973 |
| Computerized Tomography Scanner | 1 | 1 | 2 | 10.973 |
| Positron Emission Tomography Scanner | 0 | 0 | 0 | 0.000 |
| Nuclear medicine | 0 | 0 | 0 | 0.000 |
| Mammograph* | 2 | 0 | 2 | 131.062 |
| Linear accelerator | 0 | 0 | 0 | 0.000 |
| Telecobalt unit (Cobalt-60) | 0 | 0 | 0 | 0.000 |
| Radiotherapy | 0 | 0 | 0 | 0.000 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: –

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|-------|---|-----|--------------------------------------|--------------|
| Population (000s)* | 109 | Life expectancy at birth (years) ^a | 74 | World Bank income group ^β | Upper-middle |
| Internet users (%) ^γ | 52.0% | Per capita total health expenditure (PPP Int \$) ^δ | 573 | GNI per capita (US\$) ^ε | 6'460 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: No

Name of principal institution: —

Web site: —



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): No

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: Yes

Web site: —

DONATIONS

Policy or guideline: No

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ: —



Inventory and maintenance

Type of inventories available: None

Comments: No National Inventory exist

Medical equipment management unit: Yes

Management software: No

Software and comments^λ: —

National level = 0

Regional level = 0

Hospital level = 1



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:Lists comments^λ: —

Lists available: No

Unit: —

Web site: —

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES OR SPECIFIC PROCEDURES: Lists available: No list available

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: —

Types:

| | | | |
|-----------------------|---------------------------|----------|------------------------------------|
| Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|-----------------------|---------------------------|----------|------------------------------------|



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 39 | n/a | 39 | 35.658 |
| Health centre | 1 | n/a | 1 | 0.914 |
| District hospital | n/a | n/a | 0 | 0.000 |
| Provincial hospital | n/a | n/a | 0 | 0.000 |
| Regional hospital | n/a | n/a | 0 | 0.000 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 0 | 0 | 0 | 0.000 |
| Computerized Tomography Scanner | 0 | 0 | 0 | 0.000 |
| Positron Emission Tomography Scanner | 0 | 0 | 0 | 0.000 |
| Nuclear medicine | 0 | 0 | 0 | 0.000 |
| Mammograph* | 1 | 1 | 2 | 229.859 |
| Linear accelerator | 0 | 0 | 0 | 0.000 |
| Telecobalt unit (Cobalt-60) | 0 | 0 | 0 | 0.000 |
| Radiotherapy | 0 | 0 | 0 | 0.000 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: —

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|-------|---|-----|--------------------------------------|--------------|
| Population (000s)* | 539 | Life expectancy at birth (years) ^a | 77 | World Bank income group ^β | Upper-middle |
| Internet users (%) ^γ | 37.4% | Per capita total health expenditure (PPP Int \$) ^δ | 521 | GNI per capita (US\$) ^ε | 9'370 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: No

Name of principal institution: —

Web site: —



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): No

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: No

Web site: —

DONATIONS

Policy or guideline: No

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ: —



Inventory and maintenance

Type of inventories available: —

Comments: —

Medical equipment management unit: No

National level = —

Regional level = —

Hospital level = —

Management software: No

Software and comments^λ: —

Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^δ:Lists comments^λ: —

Lists available: No

Unit: —

Web site: —

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES OR SPECIFIC PROCEDURES: Lists available: No list available

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: —

Types:

| | | | |
|-----------------------|---------------------------|----------|------------------------------------|
| Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|-----------------------|---------------------------|----------|------------------------------------|



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 98 | 146 | 244 | 45.246 |
| Health centre | 6 | n/a | 6 | 1.113 |
| District hospital | 1 | n/a | 1 | 0.185 |
| Provincial hospital | n/a | n/a | 0 | 0.000 |
| Regional hospital | 1 | n/a | 1 | 0.185 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 1 | 1 | 2 | 3.709 |
| Computerized Tomography Scanner | 1 | 3 | 4 | 7.417 |
| Positron Emission Tomography Scanner | 0 | 0 | 0 | 0.000 |
| Nuclear medicine | 0 | 0 | 0 | 0.000 |
| Mammograph* | 1 | 3 | 4 | 93.596 |
| Linear accelerator | 2 | 0 | 2 | 3.709 |
| Telecobalt unit (Cobalt-60) | 0 | 0 | 0 | 0.000 |
| Radiotherapy | 2 | 0 | 2 | 3.709 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: —

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

Trinidad and Tobago



Country indicators

| | | | | | |
|---------------------------------|-------|---|------|--------------------------------------|--------|
| Population (000s)* | 1'341 | Life expectancy at birth (years) ^a | 70 | World Bank income group ^β | High |
| Internet users (%) ^γ | 63.8% | Per capita total health expenditure (PPP Int \$) ^δ | 1450 | GNI per capita (US\$) ^ε | 15'760 |



National policy on health technology

Health technology (medical device) national policy: Yes, but is not part of the National Health Program

Web site: —

Language(s): English

MOH responsible for health technology policy implementation: Health, Policy, Research and Planning Unit and the Project Management Unit



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Chemistry Food and Drug Division

Web site: <http://www.health.gov.tt>



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: Project Management Unit

Web site: —

OTHER: Planning of medical equipment allocation/development of technical specifications/application/user training

Unit/department: Biomedical Department, North Central Regional Health Authority

Web site: —

OTHER: Planning of medical equipment allocation/development of technical specifications/maintenance/application/user training

Unit/department: Biomedical Dept, North West Regional Health Authority

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Nationally developed Use: For procurement

Nomenclature system name: TMA Systems Maintenance Management Software (the nomenclature of medical devices are generally developed by the respective Regional Health Authorities for procurement purposes) Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: —

National level procurement: No

Web site: —

DONATIONS

Policy or guideline: Yes

Web site: —

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: Yes

Web site: —

Medical device incorporation comments^λ:

There are guidelines based on RHAs internal policies and procedures on the procurement process and in particular the need for development of specifications. The MoH is presently moving towards standardising policies and procedures for all technical areas which would include the procurement of medical devices. Technical specifications are developed as part of all equipment procurement for public open tender. In general there are recommended technical specifications used by each RHA for



Inventory and maintenance

Type of inventories available: National inventory only for high cost technologies for Diagnostic Imaging

Comments: Inventories of other medical devices exist at each respective RHA

Medical equipment management unit: Yes

National level = 5

Regional level = 5

Hospital level = —

Management software: Yes

Software and comments^λ: TMA systems



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^δ

Lists available: Yes

Unit: MoH

Web site: —

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: For different healthcare facilities and specific procedures

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: One or more

Web site: —

Lists comments^λ:

Standards developed by American Institute of Architects and American Hospital Association. The medical equipment requirements for specific procedures are done by the respective inhouse Hospital Biomedical Department and the clinicians. The American Hospital Association guidelines are used as a reference. The Ministry has also established requirements

Types:

Communicable diseases

Non-communicable diseases

x

Injuries

Public health emergency situations



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 105 | n/a | 105 | 7.829 |
| Health centre | 4 | n/a | 4 | 0.298 |
| District hospital | n/a | n/a | n/a | n/a |
| Provincial hospital | n/a | n/a | n/a | n/a |
| Regional hospital | n/a | n/a | n/a | n/a |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 4 | n/a | 4 | 2.983 |
| Computerized Tomography Scanner | 4 | n/a | 4 | 2.983 |
| Positron Emission Tomography Scanner | 0 | n/a | 0 | 0.000 |
| Nuclear medicine | 3 | n/a | 3 | 2.237 |
| Mammograph* | 5 | n/a | 5 | 35.217 |
| Linear accelerator | 0 | 2 | 2 | 1.491 |
| Telecobalt unit (Cobalt-60) | 2 | 0 | 2 | 1.491 |
| Radiotherapy | 2 | 2 | 4 | 2.983 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ:

It is noted that a number of medical devices systems exist at the respective RHA level. The MoH is currently working towards standardising these and in particular with respect to the procurement guidelines for medical devices.

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

United States of America



Country indicators

| | | | | | |
|---------------------------------|---------|---|------|--------------------------------------|--------|
| Population (000s)* | 320'051 | Life expectancy at birth (years) ^a | 79 | World Bank income group ^β | High |
| Internet users (%) ^γ | 84.2% | Per capita total health expenditure (PPP Int \$) ^δ | 8895 | GNI per capita (US\$) ^ε | 53'470 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: U.S. Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH)

Web site: <http://www.fda.gov/MedicalDevices/default.htm>



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): No

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Nationally developed Use: Not specified

Nomenclature system name: 1. Product code - 2. Problem code Nomenclature. Web site: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051637.htm>



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: No

Web site: —

DONATIONS

Policy or guideline: No

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ: —



Inventory and maintenance

Type of inventories available: None

Comments: —

Medical equipment management unit: —

National level = 0

Regional level = 0

Hospital level = 0

Management software: —

Software and comments^λ: —

Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^δ:Lists comments^λ: —

Lists available: No

Unit: —

Web site: —

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES OR SPECIFIC PROCEDURES: Lists available: —

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: —

Types:

Communicable diseases

Non-communicable diseases

Injuries

Public health emergency situations



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | n/a | n/a | n/a | n/a |
| Health centre | n/a | n/a | n/a | n/a |
| District hospital | n/a | n/a | n/a | n/a |
| Provincial hospital | n/a | n/a | n/a | n/a |
| Regional hospital | n/a | n/a | n/a | n/a |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | n/a | n/a | n/a | n/a |
| Computerized Tomography Scanner | n/a | n/a | n/a | n/a |
| Positron Emission Tomography Scanner | n/a | n/a | n/a | n/a |
| Nuclear medicine | n/a | n/a | n/a | n/a |
| Mammograph* | n/a | n/a | n/a | n/a |
| Linear accelerator | n/a | n/a | n/a | n/a |
| Telecobalt unit (Cobalt-60) | n/a | n/a | n/a | n/a |
| Radiotherapy | n/a | n/a | n/a | n/a |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ:

Concerning HT national policy we provide the following doc.: Biomedical Procedures final.zip. Unfortunately, we are only able to respond to numeric country statistics. As is often the case, they are too much difficulty for Federal States to answer, furthermore is largely irrelevant for a system like ours that is so based on private sector.

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|-------|---|------|--------------------------------------|--------|
| Population (000s)* | 3'407 | Life expectancy at birth (years) ^a | 77 | World Bank income group ^β | High |
| Internet users (%) ^γ | 58.1% | Per capita total health expenditure (PPP Int \$) ^δ | 1438 | GNI per capita (US\$) ^ε | 15'180 |



National policy on health technology

Health technology (medical device) national policy: Yes, and it is part of the National Health Program/Plan or Policy

Web site: —

Language(s): Español

MOH responsible for health technology policy implementation: Departamento de Evaluación de Tecnología



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Ministerio de Salud Pública - Departamento de Evaluación de Tecnología

Web site: <http://www.msp.gub.uy>



National health technology assessment unit

Unit/department: Departamento de Evaluación de Tecnología

Web site: —



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: —

Web site: —

OTHER: Planning of medical equipment allocation

Unit/department: Departamento de Evaluación de Tecnología

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on UMDNS (Universal Medical Device Nomenclature System) Use: For procurement

Nomenclature system name: — Web site: <http://www.msp.gub.uy>



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: —

National level procurement: Yes

Web site: <http://uca.mef.gub.uy/portal/web/guest/institucional> AND <http://www.cocemi.com.uy/>

DONATIONS

Policy or guideline: Yes

Web site: <http://www.msp.gub.uy>

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ:

Procurement: Artículo 6º de la Ley N°18211 Sistema Nacional Integrado de Salud.

UCA: Un mecanismo para los prestadores públicos
COCEMI: Un mecanismo para algunos prestadores privados



Inventory and maintenance

Type of inventories available: Inventario funcional de equipo médico a escala nacional

Comments: Realizado en 2008. Actualizado en 2010 para Tomógrafos y Equipos de Resonancia Magnética. El detalle de la información individual no se encuentra disponible aun en formato electrónico.

Medical equipment management unit: Yes

National level = 1

Regional level = –

Hospital level = –

Management software: –

Software and comments^λ: –



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:

Lists available: Yes

Unit: Departamento de Evaluación de Tecnología

Web site: –

Lists comments^λ:

Las listas no se encuentran disponible públicamente aun.

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: For different healthcare facilities

Web site - facilities: –

Web site - procedures: –

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: –

| | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|--------|-----------------------|---------------------------|----------|------------------------------------|



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 600 | n/a | 600 | 17.610 |
| Health centre | 40 | n/a | 40 | 1.174 |
| District hospital | n/a | n/a | n/a | n/a |
| Provincial hospital | 120 | n/a | 120 | 3.522 |
| Regional hospital | 14 | n/a | 14 | 0.411 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 2 | 8 | 10 | 2.935 |
| Computerized Tomography Scanner | 11 | 33 | 44 | 12.914 |
| Positron Emission Tomography Scanner | 1 | 0 | 1 | 0.294 |
| Nuclear medicine | 4 | 6 | 10 | 2.935 |
| Mammograph* | 30 | 32 | 62 | 172.417 |
| Linear accelerator | 5 | 5 | 10 | 2.935 |
| Telecobalt unit (Cobalt-60) | 1 | 2 | 3 | 0.881 |
| Radiotherapy | 6 | 7 | 13 | 3.816 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: –

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

4.4 Eastern Mediterranean Region facts and country profiles

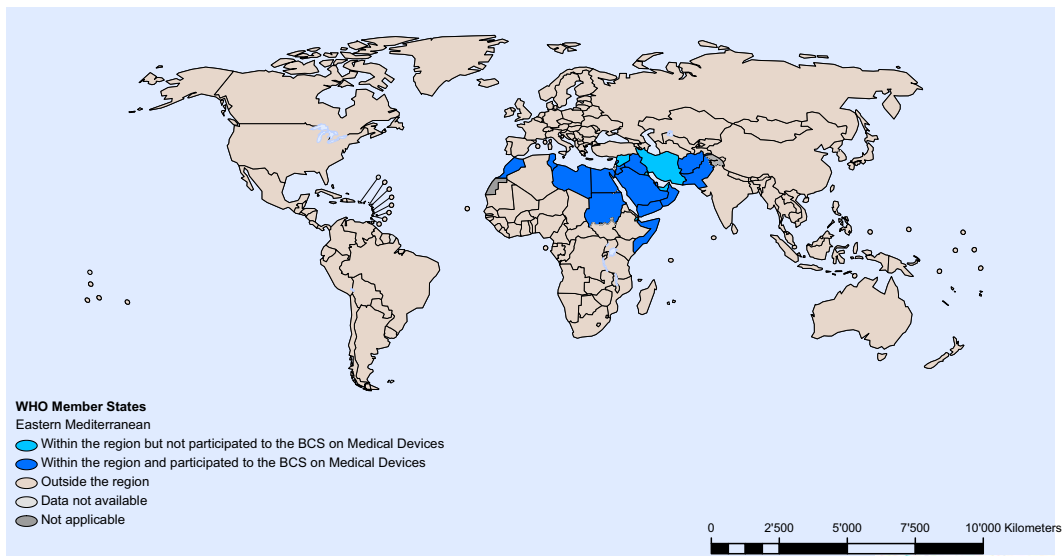


Fig. 4.4-1. Baseline Country Survey on Medical Devices Eastern Mediterranean Region participation

Participation: The Eastern Mediterranean Region's survey participation was 71% (15/21). Participating countries are shown in Fig. 4.4-1.

National policy on health technology: 60% of the respondent EMR states (9/15) have a Health Technology policy, however for more than the half of them the HT policy is not part of the national health programme.

Regulatory agency:²³ 71% of the respondent EMR states (10/14) have a regulatory authority responsible for medical devices.

National health technology assessment unit:²⁴ 62.5% of the respondent countries (5/8) have a national agency/unit/committee that produces Health Technology Assessment (HTA) reports for the Ministry of Health.

National health technology management units: 87% of the respondent EMR states (13/15) have a national unit which technically manages medical devices. Of these countries, 77% (10/13) have a national unit in charge of technical specifications development for procurement process, as well as a unit in charge of planning of medical devices allocation, and a support user/training application of medical devices (Fig. 4.4-2).

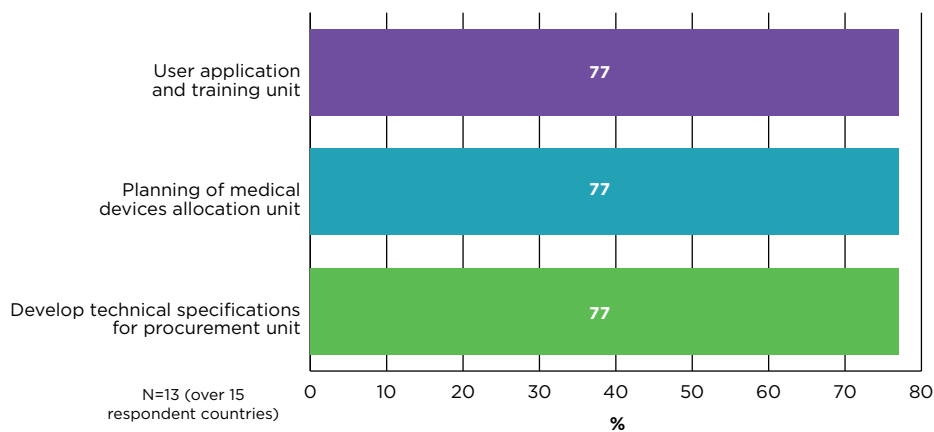


Fig. 4.4-2. Proportion of EMR countries having different types of health technology units (percentages taken from countries that have at least one health technology management national unit)



Medical device nomenclature system: 66% of the respondent EMR states (10/15) have an official nomenclature system for medical devices. The most used type of nomenclature is UMDNS with 50% of the countries with an official nomenclature (Fig. 4.4-3).

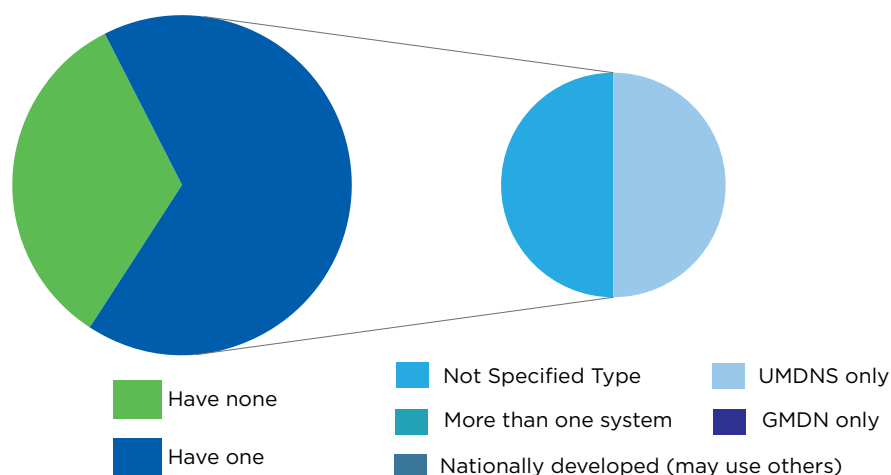


Fig. 4.4-3. Proportion of EMR countries with an official nomenclature system for medical devices and their corresponding type (percentages taken from all respondent countries)

Medical device incorporation: 60% of the respondent EMR states (9/15) have national guidelines, policies or recommendations on the procurement of medical devices. A total of 73% of the respondent states (11/15) carried out the procurement of medical devices at national level, and only 7% of the respondent states (1/14) do not have recommended technical specifications of medical devices to support procurement or donations.

Inventory and maintenance: 92% of the respondent EMR states (11/12) have an available inventory for medical devices. From those countries 82% (9/11) have a national inventory for medical equipment.

Lists of medical devices: 85% of the respondent EMR states (11/13) have national standards or recommended lists of medical devices for different types of healthcare facilities. A total of 54% of the respondent states (7/13) have national list(s) of recommended medical devices for specific procedures, and 43% of the respondent states (6/14) have national list(s) of recommended medical devices for high burden diseases or injuries or health emergency situations.

Healthcare facilities: 83% of the respondent EMR countries have at least one health post per 100 000 population, and 56% of the respondent countries have a least one health centre per 100 000 population. However, the regional density of health posts and health centres per 100 000 population is the lowest of the six regions (see Fig 4.4-4).

| Healthcare facility | Have at least one per 100,000 pop. (%) | Number of responding countries | Regional Density per 100,000 pop. |
|--|--|--------------------------------|-----------------------------------|
| Health posts | 83% | 12 | 4.71 |
| Health centre | 56% | 9 | 1.21 |
| Distric/Rural hospitals | 36% | 11 | 0.55 |
| Regional/ Specialized/ Teaching and Research hospitals | 0% | 12 | 0.11 |

Fig 4.4-4. Proportion of EMR countries and regional densities regarding existence of healthcare facility units (percentages taken from all respondent countries) .

Medical equipment: More than 60% of the respondent countries have a least one MRI, CT, Gamma Camera and mammograph per million population. The regional density of medical high technology equipment (per million population) in this region is one of the lowest of the six regions (see Table 4.4-5).

| Medical Equipment | Have at least one unit per 1,000,000 pop. (%) | Number of responding countries | Regional density per 1,000,000 pop. |
|--|---|--------------------------------|-------------------------------------|
| Magnetic Resonance Imaging (MRI) | 62% | 13 | 0.80 |
| Computed Tomography (CT Scanner) | 85% | 13 | 1.93 |
| Positron Emission Tomography (PET Scanner) | 9% | 11 | 0.04 |
| Gamma Camera or Nuclear Medicine | 25% | 12 | 0.17 |
| *Mammographs | 92% | 12 | 1.04 |
| Radiotherapy Unit: Linear Accelerator (LA) | 8% | 13 | 0.13 |
| Radiotherapy Unit:Telecobalt Unit (TU) | 8% | 13 | 0.09 |
| Radiotherapy Unit (LA+TU) | 15% | 13 | 0.22 |

* Mammographs density is per 100,000 females aged between 50 and 69 years old, and the regional density per million females of the same age

Fig. 4.4-5. Proportion of EMR countries and regional densities regarding high technology equipment (percentages taken from all respondent countries)



List of country profiles for WHO Eastern Mediterranean Region

| | | | |
|-------------|-----|--------------|-----|
| Afghanistan | 258 | Pakistan | 274 |
| Egypt | 260 | Qatar | 276 |
| Iraq | 262 | Saudi Arabia | 278 |
| Jordan | 264 | Somalia | 280 |
| Lebanon | 266 | Sudan | 282 |
| Libya | 268 | Tunisia | 284 |
| Morocco | 270 | Yemen | 286 |
| Oman | 272 | | |

Afghanistan



Country indicators

| | | | | | |
|---------------------------------|--------|---|----|--------------------------------------|-----|
| Population (000s)* | 30'552 | Life expectancy at birth (years) ^a | 60 | World Bank income group ^β | Low |
| Internet users (%) ^γ | 5.9% | Per capita total health expenditure (PPP Int \$) ^δ | 47 | GNI per capita (US\$) ^ε | 690 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: No

Name of principal institution: General Directorate Pharmaceutical Affairs/MoPH

Web site: <http://moph.gov.af/en>



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: —

Web site: —

OTHER: Planning of medical equipment allocation/Application/user training

Unit/department: Radiology, MoPH

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: No

Web site: —

DONATIONS

Policy or guideline: No

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: Yes, but not publically available

Web site: —

Medical device incorporation comments^λ: —



Inventory and maintenance

Type of inventories available: National inventory for medical equipment

Comments: —

Medical equipment management unit: Yes

National level = 1

Regional level = 0

Hospital level = —

Management software: No

Software and comments^λ: —



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:

Lists comments^λ: —

Lists available: Yes, but it is only a recommendation

Unit: —

Web site: —

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES OR SPECIFIC PROCEDURES: Lists available: No list available

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: —

| | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|--------|-----------------------|---------------------------|----------|------------------------------------|



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 901 | n/a | 901 | 2.949 |
| Health centre | 374 | n/a | 374 | 1.224 |
| District hospital | 56 | n/a | 56 | 0.183 |
| Provincial hospital | 30 | n/a | 30 | 0.098 |
| Regional hospital | 26 | n/a | 26 | 0.085 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 1 | 2 | 3 | 0.098 |
| Computerized Tomography Scanner | 1 | 5 | 6 | 0.196 |
| Positron Emission Tomography Scanner | 0 | 0 | 0 | 0.000 |
| Nuclear medicine | 0 | 0 | 0 | 0.000 |
| Mammograph* | 0 | 0 | 0 | 0.000 |
| Linear accelerator | 0 | 0 | 0 | 0.000 |
| Telecobalt unit (Cobalt-60) | 0 | 0 | 0 | 0.000 |
| Radiotherapy | 0 | 0 | 0 | 0.000 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ:

Concerning HT national policy we provide the following doc.: ley-18211-dec-5-2007 SNIS.pdf

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|--------|---|-----|--------------------------------------|--------------|
| Population (000s)* | 82'056 | Life expectancy at birth (years) ^a | 71 | World Bank income group ^β | Lower-middle |
| Internet users (%) ^γ | 49.6% | Per capita total health expenditure (PPP Int \$) ^δ | 323 | GNI per capita (US\$) ^ε | 3'140 |



National policy on health technology

Health technology (medical device) national policy: Yes, and it is part of the National Health Program/Plan or Policy

Web site: <http://10.0.0.115/mohweb/login.aspx>

Language(s): Arabic and English

MOH responsible for health technology policy implementation: There Administration medical devices, but not available with limited hardware, but is limited to the knowledge of the geographical unit of health information GIS Aantrz National Health Information



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: —

Name of principal institution: The Medical Device Safety Department (MDS), within the Central Administration of Pharmaceutical Affairs (CAPA), is a separate entity slated with monitoring the medical device market in Egypt.

Web site: http://www.eda.mohp.gov.eg/Services/Reg_MedDevice.aspx?Main=Services&Serviceid=2&Submain=serv8



National health technology assessment unit

Unit/department: The management of hospitals

Web site: www.mohealth.gov.eg



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: Department of Radiology

Web site: www.mohealth.gov.eg

OTHER: HTA/Application/user training

Unit/department: Quality Management

Web site: —

OTHER: Development of technical specifications for procurement purposes/application/training

Unit/department: Management of medical devices

Web site: www.mohealth.gov.eg



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Nationally developed Use: Not specified

Nomenclature system name: Database of geographical information system health Web site: <http://10.0.0.115/MOHWeb/Default2.aspx>



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: —

National level procurement: Yes

Web site: —

DONATIONS

Policy or guideline: Yes

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: Yes

Web site: —

Medical device incorporation comments^λ:

Management of medical equipment and hospital management. Curative medicine sector and management of medical devices



Inventory and maintenance

Type of inventories available: National inventory for medical equipment

Comments: —

Medical equipment management unit: Yes

National level = —

Regional level = —

Hospital level = —

Management software: Yes

Software and comments^λ: Database of geographical information system health



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^δ:

Lists available: No

Unit: —

Web site: —

Lists comments^λ:

Concerning lists of healthcare facilities, they were counted by the sector ministry and therapeutic medicine National Information Center Ministry

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: For different healthcare facilities and specific procedures

Web site - facilities: —

Web site - procedures: www.mohealth.gov.eg

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: One or more

Web site: <http://www.mohealth.gov.eg>

Types:

| | | | | | | | |
|-----------------------|---|---------------------------|--|----------|---|------------------------------------|--|
| Communicable diseases | x | Non-communicable diseases | | Injuries | x | Public health emergency situations | |
|-----------------------|---|---------------------------|--|----------|---|------------------------------------|--|



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 314 | n/a | 314 | 0.383 |
| Health centre | 208 | n/a | 208 | 0.253 |
| District hospital | 407 | n/a | 407 | 0.496 |
| Provincial hospital | n/a | n/a | n/a | n/a |
| Regional hospital | 99 | n/a | 99 | 0.121 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | n/a | n/a | n/a | n/a |
| Computerized Tomography Scanner | n/a | n/a | n/a | n/a |
| Positron Emission Tomography Scanner | n/a | n/a | n/a | n/a |
| Nuclear medicine | n/a | n/a | n/a | n/a |
| Mammograph* | n/a | n/a | n/a | n/a |
| Linear accelerator | n/a | n/a | n/a | n/a |
| Telecobalt unit (Cobalt-60) | n/a | n/a | n/a | n/a |
| Radiotherapy | n/a | n/a | n/a | n/a |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ:

Concerning Infrastructure Section: The proposed names are not totally compatible with ours. Thus the number of units is under the Ministry of Health only and is not confined to Tfsalia to the private sector in 2010.

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|--------|---|-----|--------------------------------------|--------------|
| Population (000s)* | 33'765 | Life expectancy at birth (years) ^a | 70 | World Bank income group ^β | Upper-middle |
| Internet users (%) ^γ | 9.2% | Per capita total health expenditure (PPP Int \$) ^δ | 149 | GNI per capita (US\$) ^ε | 6'720 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: The activities of medical equipment program is executed between different directorates / entities at MOH Iraq. There is no single entity fully responsible for medical equipment program (assessment, planning, acquisition, maintenance, etc). Efforts were made to promote the management of medical devices and therefore WHO facilitated a technical meeting during July 2008 and out of the recommendations a committee was formed to look into the issue of management of medical equipment and the Minister of Health agreed to establish a department of medical equipment within the Directorate of Technical Affairs



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: The State Company for Provision of Medicines and Medical Appliances (KIMADIA)

Web site: <http://www.kimadia-iraq.com>



National health technology assessment unit

Unit/department: Directorate of Technical Affairs

Web site: <http://www.techmoh.net>



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: Department of Medical Equipment Management / Directorate of Technical Affairs

Web site: —

OTHER: Maintenance/Management/Application/user training

Unit/department: State Company for Provision of Medicines and Medical Appliances (KIMADIA)

Web site: —

OTHER: Implementation on projects of biomedical equipment with the World Bank and WHO/Application/user training

Unit/department: Directorate of Projects and Engineering Services

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: —

National level procurement: Yes

Web site: <http://www.kimadia-iraq.com>

DONATIONS

Policy or guideline: No

Web site: —

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: Yes, but not publically available

Web site: —

Medical device incorporation comments^λ:

The company provides storage and distribution and marketing of medicines and supplies for all Iraq where it is the sole importer of the public sector as well as developing the basic rules for setting the prices for each class of drugs, chemicals and medical supplies to ensure the right price to the citizens and pharmacies and the relevant authorities. Works as well as the allocation of quantities of medicine (drugs and emergency life-saving drugs) as well as the



Inventory and maintenance

Type of inventories available: National inventory for medical equipment

Comments: 1- MOH at Central level keeps updated records on monthly basis for the functional status of the high cost technologies. 2- WHO is supporting the procurement of 3 CMMS (from GE - Asset Plus) for three Central Maintenance Repair shops in Baghdad, Erbil and AL-Muthanna Provinces. 3- Inventories for 6 provinces out of 18 is completed and 6 provinces will be supported to carry out a functional inventory for their medical equipment during the current biennium 2010/11.

Medical equipment management unit: Yes

National level = 1

Regional level = 19

Hospital level = 0

Management software: Yes

Software and comments^λ: MS Excel is been used at the hospitals were inventory was carried out



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:

Lists available: Yes, but it is only a recommendation

Unit: Technical Affairs (Department of Medical Equipment Management and Needs Assessment)

Web site: —

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES OR SPECIFIC PROCEDURES: Lists available: For different healthcare facilities

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: —

Types:

| |
|-----------------------|
| Communicable diseases |
|-----------------------|

| |
|---------------------------|
| Non-communicable diseases |
|---------------------------|

| |
|----------|
| Injuries |
|----------|

| |
|------------------------------------|
| Public health emergency situations |
|------------------------------------|

Lists comments^λ:

The standards and lists goes back to 2006 and prepared by department of needs assessment / Directorate of Technical Affairs. We have announces the lists of medical equipments on annual basis



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 2'331 | n/a | 2331 | 6.904 |
| Health centre | n/a | n/a | n/a | n/a |
| District hospital | n/a | n/a | n/a | n/a |
| Provincial hospital | 168 | 92 | 260 | 0.770 |
| Regional hospital | 61 | n/a | 61 | 0.181 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 55 | n/a | 55 | 1.629 |
| Computerized Tomography Scanner | 75 | n/a | 75 | 2.221 |
| Positron Emission Tomography Scanner | 0 | n/a | 0 | 0.000 |
| Nuclear medicine | 5 | n/a | 5 | 0.148 |
| Mammograph* | 49 | n/a | 49 | 35.432 |
| Linear accelerator | 4 | n/a | 4 | 0.118 |
| Telecobalt unit (Cobalt-60) | 2 | n/a | 2 | 0.059 |
| Radiotherapy | 6 | n/a | 6 | 0.178 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ:

Data was obtained from the annual report for 2010 issued by the Department of Planning and Human Resource Development at MoH Iraq.

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|-------|---|-----|--------------------------------------|--------------|
| Population (000s)* | 7'274 | Life expectancy at birth (years) ^a | 74 | World Bank income group ^β | Upper-middle |
| Internet users (%) ^γ | 44.2% | Per capita total health expenditure (PPP Int \$) ^δ | 483 | GNI per capita (US\$) ^ε | 4'950 |



National policy on health technology

Health technology (medical device) national policy: Yes, but is not part of the National Health Program

Web site: http://www.moh.gov.jo/MOH/Files/National_Health/Health%20Strategic%20.pdf

Language(s): Arabic

MOH responsible for health technology policy implementation: Directorat of Biomedical Engineering



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Jordan Food & Drug Administration

Web site: <http://www.jfda.jo/en/default/>



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: Directorat of Biomedical Engineering

Web site: <http://dbe.gov.jo>

OTHER: Planning of medical equipment allocation/Application/user training

Unit/department: Directorat of Biomedical Engineering

Web site: <http://dbe.gov.jo>

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on UMDNS (Universal Medical Device Nomenclature System) Use: Not specified

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: <http://gsd.gov.jo>

National level procurement: No

Web site: —

DONATIONS

Policy or guideline: No

Web site: —

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: Yes, but not publically available

Web site: —

Medical device incorporation comments^λ:

The procurement done at national level by MoH. Some manufacturers have guidelines and technical specifications such as: ECRI, AAMI, HTM, Manufacturers,...



Inventory and maintenance

Type of inventories available: National functional inventory for medical equipment

Comments: –

Medical equipment management unit: Yes

National level = 1

Regional level = 0

Hospital level = 0

Management software: Yes

Software and comments^λ: CMMS



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^δ:

Lists available: Yes

Unit: Directorate of Biomedical Engineering / Department of Studies & Projects

Web site: –

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES OR SPECIFIC PROCEDURES^δ: Lists available: For different healthcare facilities

Web site - facilities: –

Web site - procedures: –

NATIONAL LIST FOR DISEASES AND SITUATIONS^δ:

Lists available: No list available

Web site: –

Types:

Communicable diseases

Non-communicable diseases

Injuries

Public health emergency situations

Lists comments^λ:

We have standards lists of recommended medical equipment for hospitals and healthcare centers



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 1'400 | n/a | 1400 | 19.247 |
| Health centre | n/a | n/a | n/a | n/a |
| District hospital | 43 | 60 | 103 | 1.416 |
| Provincial hospital | 10 | 20 | 30 | 0.412 |
| Regional hospital | 5 | 3 | 8 | 0.110 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 10 | 5 | 15 | 2.062 |
| Computerized Tomography Scanner | 30 | 10 | 40 | 5.499 |
| Positron Emission Tomography Scanner | 1 | 1 | 2 | 0.275 |
| Nuclear medicine | 4 | 3 | 7 | 0.962 |
| Mammograph* | 35 | 7 | 42 | 129.073 |
| Linear accelerator | 4 | 0 | 4 | 0.550 |
| Telecobalt unit (Cobalt-60) | 2 | 0 | 2 | 0.275 |
| Radiotherapy | 6 | 0 | 6 | 0.825 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: –

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

Lebanon



Country indicators

| | | | | | |
|---------------------------------|-------|---|-----|--------------------------------------|--------------|
| Population (000s)* | 4'822 | Life expectancy at birth (years) ^a | 80 | World Bank income group ^β | Upper-middle |
| Internet users (%) ^γ | 70.5% | Per capita total health expenditure (PPP Int \$) ^δ | 979 | GNI per capita (US\$) ^ε | 9'870 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: National Council for Atomic Energy

Web site: <http://www.cnrs.edu.lb/energycommission.html>



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: Projects & Health Programs

Web site: —

OTHER: Planning of medical equipment allocation

Unit/department: Projects & Health Programs

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: No

Web site: —

DONATIONS

Policy or guideline: No

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: Yes, but not publically available

Web site: —

Medical device incorporation comments^λ:

The procurement of medical equipment for public hospitals is done by the Council for Development and Reconstruction in coordination with the Ministry of Public Health. a procurement procedure and bidding documents are used and adapted according to the specific project and considering the government rules for procurement. No guidelines exist in the private sector that is dominating the health sector (80% of beds are private).



Inventory and maintenance

Type of inventories available: National inventory only for high cost technologies (such as MRI, CT or PET scanners)
 Comments: the Ministry of Health has acquired a GIS licence in order to establish a database including the available high cost technologies

Medical equipment management unit: Yes

National level = 0

Regional level = 0

Hospital level = 0

Management software: —

Software and comments^λ: —



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:

Lists comments^λ: —

Lists available: No

Unit: —

Web site: —

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: For different healthcare facilities

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: —

Types:

| |
|-----------------------|
| Communicable diseases |
|-----------------------|

| |
|---------------------------|
| Non-communicable diseases |
|---------------------------|

| |
|----------|
| Injuries |
|----------|

| |
|------------------------------------|
| Public health emergency situations |
|------------------------------------|



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 36 | 82 | 118 | 2.447 |
| Health centre | 3 | n/a | 3 | 0.062 |
| District hospital | 21 | 16 | 37 | 0.767 |
| Provincial hospital | 5 | 75 | 80 | 1.659 |
| Regional hospital | 1 | 31 | 32 | 0.664 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 1 | 39 | 40 | 8.295 |
| Computerized Tomography Scanner | 16 | 105 | 121 | 25.093 |
| Positron Emission Tomography Scanner | 0 | 6 | 6 | 1.244 |
| Nuclear medicine | 1 | n/a | 1 | 0.207 |
| Mammograph* | 19 | 112 | 131 | 370.230 |
| Linear accelerator | 2 | 4 | 6 | 1.244 |
| Telecobalt unit (Cobalt-60) | 0 | 3 | 3 | 0.622 |
| Radiotherapy | 2 | 7 | 9 | 1.866 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: —

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|-------|---|-----|--------------------------------------|--------------|
| Population (000s)* | 6'202 | Life expectancy at birth (years) ^a | 75 | World Bank income group ^β | Upper-middle |
| Internet users (%) ^γ | 16.5% | Per capita total health expenditure (PPP Int \$) ^δ | 439 | GNI per capita (US\$) ^ε | |



National policy on health technology

Health technology (medical device) national policy: Yes, and it is part of the National Health Program/Plan or Policy

Web site: —

Language(s): Arabic

MOH responsible for health technology policy implementation: Pharmacy and Medical Devices Department



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Pharmacy Management, Equipment, Supplies and Medical Supplies Ministry of Health

Web site: <http://www.health.gov.ly>



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: —

Web site: —

OTHER: Management of medical equipment (each province has an specific unit)

Unit/department: Pharmacy and Medical Equipment Administration

Web site: <http://www.health.gov.ly>

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Nationally developed Use: For regulatory purposes and procurement

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: Yes

Web site: —

DONATIONS

Policy or guideline: No

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ:

As regarding to technical specifications of medical devices we depend mainly on the technical committees. Consist of experts in medicine, pharmacy and biomedical engineer. These committees set up decrees issued by Secretariat of Health.



Inventory and maintenance

Type of inventories available: National inventory for medical equipment

Comments: Last version 2006

Medical equipment management unit: —

National level = 1

Regional level = 23

Hospital level = 1

Management software: No

Software and comments^λ: —



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^δ:

Lists available: Yes, but it is only a recommendation

Unit: —

Web site: —

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES OR SPECIFIC PROCEDURES^δ: Lists available: For different healthcare facilities and specific procedures

Web site - facilities: —

Web site - procedures:

NATIONAL LIST FOR DISEASES AND SITUATIONS^δ:

Lists available: No list available

Web site: —

Types:

Communicable diseases

Non-communicable diseases

Injuries

Public health emergency situations

Lists comments^λ:

There are national standards lists but are not written. There are lists for Sundries Hospital consumable-Diagnostics Laboratory 37/3.

We do not have any available lists for communicable and non-communicable diseases, injuries, and public health emergency situations.



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 1'387 | 427 | 1814 | 29.251 |
| Health centre | 37 | 67 | 104 | 1.677 |
| District hospital | 32 | 67 | 99 | 1.596 |
| Provincial hospital | 34 | n/a | 34 | 0.548 |
| Regional hospital | 31 | n/a | 31 | 0.500 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 20 | 12 | 32 | 5.160 |
| Computerized Tomography Scanner | 40 | 20 | 60 | 9.675 |
| Positron Emission Tomography Scanner | 1 | 0 | 1 | 0.161 |
| Nuclear medicine | 2 | 0 | 2 | 0.323 |
| Mammograph* | n/a | n/a | n/a | n/a |
| Linear accelerator | 1 | 0 | 1 | 0.161 |
| Telecobalt unit (Cobalt-60) | 5 | 0 | 5 | 0.806 |
| Radiotherapy | 6 | 0 | 6 | 0.968 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ:

This is the first time for us to participate in this survey. Our standards and policies are under development and/or being updated. Many issues in this survey are available but not still documented.

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|--------|---|-----|--------------------------------------|--------------|
| Population (000s)* | 33'008 | Life expectancy at birth (years) ^a | 71 | World Bank income group ^β | Lower-middle |
| Internet users (%) ^γ | 56.0% | Per capita total health expenditure (PPP Int \$) ^δ | 340 | GNI per capita (US\$) ^ε | 3'020 |



National policy on health technology

Health technology (medical device) national policy: Yes, but is not part of the National Health Program

Web site: —

Language(s): Français

MOH responsible for health technology policy implementation: Direction de Equipements et de la Maintenance, Ministère de la Santé



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: No

Name of principal institution: —

Web site: —



National health technology assessment unit

Unit/department: DEM

Web site: www.sante.gov.ma



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: DELM

Web site: —

OTHER: Planning of medical equipment allocation/Technical Specifications/Application/user training

Unit/department: DEM

Web site: —

OTHER: Planning of medical equipment allocation/ development of technical specifications

Unit/department: DHSA

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on UMDNS (Universal Medical Device Nomenclature System) Use: Not specified

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: Yes

Web site: —

DONATIONS

Policy or guideline: No

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: Yes, but not publically available

Web site: —

Medical device incorporation comments^λ:

Un projet de mise en place d'une stratégie Nationale en matière de gestion des T.S est en cours. Les spécifications techniques sont établies selon les besoins des utilisateurs (grands projets de CHUs) et standardisées pour chaque type d'établissement de soins.



Inventory and maintenance

Type of inventories available: National inventory for medical equipment

Comments: La majorité des inventaires des régions sont sur support papier et non encore informatisé. L'alimentation de la base de données du progiciel de gestion des D.M est en cours.

Medical equipment management unit: Yes

National level = 1

Regional level = 16

Hospital level = 70

Management software: Yes

Software and comments^λ: Up Manager Praxis



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:

Lists available: Yes, but it is only a recommendation

Unit: —

Web site: —

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: For different healthcare facilities and specific procedures

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: One or more

Web site: —

Types:

| | |
|-----------------------|---|
| Communicable diseases | x |
|-----------------------|---|

| | |
|---------------------------|---|
| Non-communicable diseases | x |
|---------------------------|---|

| | |
|----------|--|
| Injuries | |
|----------|--|

| | |
|------------------------------------|---|
| Public health emergency situations | x |
|------------------------------------|---|

Lists comments^λ:

Des listes standardisées de D.M pour différents établissements de soins sont établies au niveau de la DEM. Concernant "Non-communicable diseases and injuries" des listes sont établies au niveau de la DEM. La DELM prend en charge "Communicable and non communicable diseases" aussi. Une procédure d'enregistrement des D.M est établie au niveau de la DMP.



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | n/a | n/a | n/a | n/a |
| Health centre | n/a | n/a | n/a | n/a |
| District hospital | n/a | n/a | n/a | n/a |
| Provincial hospital | n/a | n/a | n/a | n/a |
| Regional hospital | n/a | n/a | n/a | n/a |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 12 | n/a | 12 | 0.364 |
| Computerized Tomography Scanner | 40 | n/a | 40 | 1.212 |
| Positron Emission Tomography Scanner | 0 | n/a | 0 | 0.000 |
| Nuclear medicine | n/a | n/a | n/a | n/a |
| Mammograph* | 44 | n/a | 44 | 18.456 |
| Linear accelerator | 11 | n/a | 11 | 0.333 |
| Telecobalt unit (Cobalt-60) | 2 | n/a | 2 | 0.061 |
| Radiotherapy | 13 | n/a | 13 | 0.394 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ:

Concerning HT national policy we provide the following doc.: National_Medicine_policy_2010_Libya.doc

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|-------|---|-----|--------------------------------------|--------|
| Population (000s)* | 3'632 | Life expectancy at birth (years) ^a | 76 | World Bank income group ^β | High |
| Internet users (%) ^γ | 66.5% | Per capita total health expenditure (PPP Int \$) ^δ | 810 | GNI per capita (US\$) ^ε | 25'150 |



National policy on health technology

Health technology (medical device) national policy: Yes, but is not part of the National Health Program

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Directorate General of Medical Supply

Web site: <http://www.moh.gov.om/en/>



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: Directorate of Medical Technologies

Web site: —

OTHER: Planning of medical equipment allocation/Application/user training

Unit/department: Directorate of Medical Technologies

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Nationally developed Use: Not specified

Nomenclature system name: Based on UMDNS and adapted to national needs. Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: —

National level procurement: Yes

Web site: —

DONATIONS

Policy or guideline: Yes

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: Yes, but not publically available

Web site: —

Medical device incorporation comments^λ:

Procurement guidelines available at Directorate of Medical Technologies.



Inventory and maintenance

Type of inventories available: National inventory for medical equipment

Comments: Available at Directorate of Medical Technologies.

Medical equipment management unit: Yes

National level = 1

Regional level = 11

Hospital level = 3

Management software: Yes

Software and comments^λ: Al Shifa (Not for all functions)



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^δ:

Lists available: Yes, but it is only a recommendation

Unit: Directorate of Medical Technologies

Web site: –

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES OR SPECIFIC PROCEDURES^δ: Lists available: For different healthcare facilities and specific procedures

Web site - facilities: –

Web site - procedures: –

NATIONAL LIST FOR DISEASES AND SITUATIONS^δ:

Lists available: One or more

Web site: –

Types:

| | | | | | | | |
|-----------------------|--|---------------------------|---|----------|---|------------------------------------|--|
| Communicable diseases | | Non-communicable diseases | x | Injuries | x | Public health emergency situations | |
|-----------------------|--|---------------------------|---|----------|---|------------------------------------|--|

Lists comments^λ:

Standard list for various health facilities available at Directorate of Medical Technologies. Medical devices for specific procedures, whenever required, are prepared or modified based on the requirement from end users. We have lists for Non-communicable diseases, and injuries.



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 101 | n/a | 101 | 2.780 |
| Health centre | 74 | n/a | 74 | 2.037 |
| District hospital | 35 | n/a | 35 | 0.964 |
| Provincial hospital | 10 | n/a | 10 | 0.275 |
| Regional hospital | 4 | n/a | 4 | 0.110 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 8 | 8 | 16 | 4.405 |
| Computerized Tomography Scanner | 18 | 7 | 25 | 6.882 |
| Positron Emission Tomography Scanner | 0 | 0 | 0 | 0.000 |
| Nuclear medicine | 4 | n/a | 4 | 1.101 |
| Mammograph* | 11 | 4 | 15 | 149.751 |
| Linear accelerator | 2 | 0 | 2 | 0.551 |
| Telecobalt unit (Cobalt-60) | 0 | 0 | 0 | 0.000 |
| Radiotherapy | 2 | 0 | 2 | 0.551 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: –

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

Pakistan



Country indicators

| | | | | | |
|---------------------------------|---------|---|----|--------------------------------------|--------------|
| Population (000s)* | 182'143 | Life expectancy at birth (years) ^a | 65 | World Bank income group ^β | Lower-middle |
| Internet users (%) ^γ | 10.9% | Per capita total health expenditure (PPP Int \$) ^δ | 77 | GNI per capita (US\$) ^ε | 1'360 |



National policy on health technology

Health technology (medical device) national policy: Yes, and it is part of the National Health Program/Plan or Policy

Web site: <http://www.pc.gov.pk/Policies/Health.doc>

Language(s): English

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Pakistan nuclear regulatory authority (PNRA) does partially for some medical devices, otherwise no authority

Web site: <http://www.pnra.org/>



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): No

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: <http://www.ppra.org.pk>

National level procurement: Yes

Web site: —

DONATIONS

Policy or guideline: No

Web site: —

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: Yes

Web site: <http://www.sindhhealth.gov.pk/pprasindh.gov.pk>

Medical device incorporation comments^λ:

Procurement service rules 2003,KPK,issued by finance dept. procurement carries out at provincial level identified by SPRA etc. There is a National inventory for medical equipment.



Inventory and maintenance

Type of inventories available: —

Comments: Previously maintained national inventory but now at province/region level it is in pipeline

Medical equipment management unit: Yes

National level = 2

Regional level = 6

Hospital level = 10

Management software: No

Software and comments^λ: —



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^δ:

Lists available: Yes, but it is only a recommendation

Unit: —

Web site: —

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES OR SPECIFIC PROCEDURES^δ: Lists available: No list available

Web site - facilities: —

Web site - procedures: www.ppra.org.pk

NATIONAL LIST FOR DISEASES AND SITUATIONS^δ:

Lists available: One or more

Web site: —

Types: Communicable diseases Non-communicable diseases Injuries Public health emergency situations

Lists comments^λ:

Provinces develop their own list of equipments on the basis of need of health facilities and available funds and according to PVMS available. We have lists for communicable diseases, and public health emergency situations. WHOP Pakistan share such lists with ministry of health at time of emergency



Healthcare facility

| | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 5'350 | 80 | 5430 | 2.981 |
| Health centre | 1'508 | n/a | 1508 | 0.828 |
| District hospital | 600 | 36 | 636 | 0.349 |
| Provincial hospital | 100 | 50 | 150 | 0.082 |
| Regional hospital | 60 | 120 | 180 | 0.099 |



Medical equipment

| | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 20 | 20 | 40 | 0.220 |
| Computerized Tomography Scanner | 26 | 35 | 61 | 0.335 |
| Positron Emission Tomography Scanner | 4 | 1 | 5 | 0.027 |
| Nuclear medicine | 6 | 1 | 7 | 0.038 |
| Mammograph* | 12 | 3 | 15 | 1.612 |
| Linear accelerator | 7 | 1 | 8 | 0.044 |
| Telecobalt unit (Cobalt-60) | 6 | 1 | 7 | 0.038 |
| Radiotherapy | 13 | 2 | 15 | 0.082 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ:

After 18th ammendment and devolution of MoH, no person or authority is able to provide information, WHO as convening body of health systems in Pakistan collected the information separately from all regions/provinces then the information was compiled by WHO focal person of health technologies

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|-------|---|------|--------------------------------------|--------|
| Population (000s)* | 2'169 | Life expectancy at birth (years) ^a | 79 | World Bank income group ^β | High |
| Internet users (%) ^γ | 85.3% | Per capita total health expenditure (PPP Int \$) ^δ | 1805 | GNI per capita (US\$) ^ε | 86'790 |



National policy on health technology

Health technology (medical device) national policy: Yes, but is not part of the National Health Program

Web site: <http://hmc.org.qa>

Language(s): English

MOH responsible for health technology policy implementation: Bio-Medical Engineering Department



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Medical Device Registration Unit, Pharmacy & Drug Control, Supreme Council of Health

Web site: <http://www.sch.gov.qa/home-en>



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: Biomedical Engineering Dept

Web site: <http://hmc.org.qa>

OTHER: Planning of medical equipment allocation/HTA/maintenance/technical specifications/application/user training

Unit/department: Biomedical Engineering Dept

Web site: <http://hmc.org.qa>

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on UMDNS (Universal Medical Device Nomenclature System) Use: Not specified

Nomenclature system name: ECRI or relevant Web site: <http://www.ECRI.org>



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: —

National level procurement: Yes

Web site: <http://www.hmc.org.qa/en/>

DONATIONS

Policy or guideline: Yes

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: Yes, but not publically available

Web site: —

Medical device incorporation comments^λ:

Specification compliance both on safety and clinical requisites, regularly updated. HMC Materials Management and Tender committee takes over the procurement activities of Medical and Non-Medical Equipment/ items for HMC hospitals, and for ministry upon request, as deem necessary. Specification of equipment formulated in cooperation with enuser prepared by Bio-eng



Inventory and maintenance

Type of inventories available: National functional inventory for medical equipment

Comments: Maintained GE AssetPlus for functional inventory of Medical equipment for HMC hospitals and Public Health Care Centers

Medical equipment management unit: Yes

National level = 1

Regional level = –

Hospital level = 4

Management software: Yes

Software and comments^λ: AssetPlus by GE



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:

Lists available: Yes, but it is only a recommendation

Unit: Bio-Medical Engineering Department

Web site: –

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: For different healthcare facilities and specific procedures

Web site - facilities: –

Web site - procedures: –

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: –

Types:

| |
|-----------------------|
| Communicable diseases |
|-----------------------|

| |
|---------------------------|
| Non-communicable diseases |
|---------------------------|

| |
|----------|
| Injuries |
|----------|

| |
|------------------------------------|
| Public health emergency situations |
|------------------------------------|

Lists comments^λ:

There are functional inventory of medical devices for procurement and/ or reimbursement in HMC hospitals. HMC disciplines occupies functional inventory of medical devices for prompt delivery of patient care services. Emergency preparedness policy reference.



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | n/a | n/a | n/a | n/a |
| Health centre | n/a | n/a | n/a | n/a |
| District hospital | n/a | n/a | n/a | n/a |
| Provincial hospital | n/a | n/a | n/a | n/a |
| Regional hospital | n/a | n/a | n/a | n/a |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 10 | 10 | 20 | 9.222 |
| Computerized Tomography Scanner | 10 | 8 | 18 | 8.300 |
| Positron Emission Tomography Scanner | 1 | 0 | 1 | 0.461 |
| Nuclear medicine | 4 | 0 | 4 | 1.844 |
| Mammograph* | 5 | 4 | 9 | 225.096 |
| Linear accelerator | 2 | 0 | 2 | 0.922 |
| Telecobalt unit (Cobalt-60) | 0 | 0 | 0 | 0.000 |
| Radiotherapy | 2 | 0 | 2 | 0.922 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ:

Concerning HT national policy we provide the following doc.: <http://www.pc.gov.pk/Policies/Health.doc>. List of accredited HMC hospitals: Hamad General Hospital, Women's Hospital, Rumailah Hospital, Al Amal Hospital, and Al Khor Hospital. Emergency Medical Services (EMS), Pediatric Emergency, Trauma Centers, Orthopedic Center, Dental and...

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|--------|---|------|--------------------------------------|--------|
| Population (000s)* | 28'829 | Life expectancy at birth (years) ^a | 76 | World Bank income group ^β | High |
| Internet users (%) ^γ | 60.5% | Per capita total health expenditure (PPP Int \$) ^δ | 1004 | GNI per capita (US\$) ^ε | 26'260 |



National policy on health technology

Health technology (medical device) national policy: Yes, but is not part of the National Health Program

Web site: <http://www.sfda.gov.sa> & <http://www.saso.org.sa>

Language(s): English

MOH responsible for health technology policy implementation: General Supplies and Equipment Directorate



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Directorates of Supplies and Equipment; and Maintenance.

Web site: <http://www.sfda.gov.sa/ar/Pages/default.aspx>



National health technology assessment unit

Unit/department: ICT

Web site: www.moh.gov.sa



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: Supplies and Equipment Directorate

Web site: —

OTHER: Planning of medical equipment allocation/development of technical specifications

Unit/department: Maintenance Directorate

Web site: —

OTHER: Planning of medical equipment allocation/maintenance

Unit/department: Supplies and Equipment Directorate

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Nationally developed Use: For regulatory purposes and procurement

Nomenclature system name: National Unified Procurement Company for Medical Supplies (NUPCO). Web site: <http://www.nupco.com>



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: <http://www.nupco.com>

National level procurement: Yes

Web site: <http://www.nupco.com>

DONATIONS

Policy or guideline: Yes

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: Yes

Web site: —

Medical device incorporation comments^λ:

National Unified Procurement Company for Medical Supplies (NUPCO)



Inventory and maintenance

Type of inventories available: National inventory only for high cost technologies (such as MRI, CT or PET scanners), National inventory for medical equipment

Comments: For every hospital and health centre there is a maintenance-specialized company contracted to make inventory and perform necessary maintenance activities for all medical devices within the facility.

Medical equipment management unit: Yes

National level = 0

Regional level = 0

Hospital level = 0

Management software: Yes

Software and comments^λ: Bank Maintenance.



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:

Lists available: Yes, but it is only a recommendation

Unit: National Unified Procurement Company for Medical Supplies (NUPCO) & Saudi Food and Drug Administration (SFDA)

Web site: —

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: For different healthcare facilities and specific procedures

Web site - facilities: —

Web site - procedures: www.sfda.gov.sa

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: One or more

Web site: <http://www.moh.gov.sa>

Types: Communicable diseases x Non-communicable diseases x Injuries x Public health emergency situations x

Lists comments^λ:

Specification and procurement department. We have lists available for communicable and non-communicable diseases, injuries, and public health emergency situations.



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | n/a | n/a | 0 | 0.000 |
| Health centre | n/a | n/a | 0 | 0.000 |
| District hospital | 61 | n/a | 61 | 0.212 |
| Provincial hospital | 235 | n/a | 235 | 0.815 |
| Regional hospital | 4 | n/a | 4 | 0.014 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 28 | n/a | 28 | 0.971 |
| Computerized Tomography Scanner | 110 | n/a | 110 | 3.816 |
| Positron Emission Tomography Scanner | 0 | n/a | 0 | 0.000 |
| Nuclear medicine | 11 | n/a | 11 | 0.382 |
| Mammograph* | 50 | n/a | 50 | 40.619 |
| Linear accelerator | 3 | n/a | 3 | 0.104 |
| Telecobalt unit (Cobalt-60) | 0 | n/a | 0 | 0.000 |
| Radiotherapy | 3 | n/a | 3 | 0.104 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ:

Concerning HT national policy we provide the following doc.: Medical Eqpt Management Plan (Corporate) April 2011 (2).doc

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|--------|---|----|--------------------------------------|-----|
| Population (000s)* | 10'496 | Life expectancy at birth (years) ^a | 53 | World Bank income group ^β | Low |
| Internet users (%) ^γ | 1.5% | Per capita total health expenditure (PPP Int \$) ^δ | 0 | GNI per capita (US\$) ^ε | |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: No

Name of principal institution: —

Web site: —



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): No

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on UMDNS (Universal Medical Device Nomenclature System) Use: Not specified

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: No

Web site: —

DONATIONS

Policy or guideline: Yes

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: —

Web site: —

Medical device incorporation comments^λ: —



Inventory and maintenance

Type of inventories available: —

Comments: —

Medical equipment management unit: —

National level = —

Regional level = —

Hospital level = —

Management software: —

Software and comments^λ: —

Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:Lists comments^λ: —

Lists available: No

Unit: —

Web site: —

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES OR SPECIFIC PROCEDURES: Lists available: —

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: —

Web site: —

Types:

| | | | |
|-----------------------|---------------------------|----------|------------------------------------|
| Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|-----------------------|---------------------------|----------|------------------------------------|



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | n/a | n/a | n/a | n/a |
| Health centre | n/a | n/a | n/a | n/a |
| District hospital | n/a | n/a | n/a | n/a |
| Provincial hospital | n/a | n/a | n/a | n/a |
| Regional hospital | n/a | n/a | n/a | n/a |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | n/a | n/a | n/a | n/a |
| Computerized Tomography Scanner | n/a | n/a | n/a | n/a |
| Positron Emission Tomography Scanner | n/a | n/a | n/a | n/a |
| Nuclear medicine | n/a | n/a | n/a | n/a |
| Mammograph* | n/a | n/a | n/a | n/a |
| Linear accelerator | n/a | n/a | n/a | n/a |
| Telecobalt unit (Cobalt-60) | n/a | n/a | n/a | n/a |
| Radiotherapy | n/a | n/a | n/a | n/a |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: —

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

Sudan



Country indicators

| | | | | | |
|---------------------------------|--------|---|-----|--------------------------------------|--------------|
| Population (000s)* | 37'964 | Life expectancy at birth (years) ^a | 63 | World Bank income group ^β | Lower-middle |
| Internet users (%) ^γ | 22.7% | Per capita total health expenditure (PPP Int \$) ^δ | 159 | GNI per capita (US\$) ^ε | 1'550 |



National policy on health technology

Health technology (medical device) national policy: Yes

Web site: —

Language(s): Arabic and English

MOH responsible for health technology policy implementation: Health Development Unit



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: National Medicine and Poison Board

Web site: <http://www.nmpb.gov.sd/>



National health technology assessment unit

Unit/department: National Health Technology Management Unit

Web site: —



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: National Health Technology Management Unit

Web site: —

OTHER: Planning of medical equipment allocation/Application/user training

Unit/department: Medical Engineering Unit/ Curative Medicine department

Web site: —

OTHER: Planning of medical equipment allocation/Application/user training

Unit/department: National Nuclear Medicine Hospital

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on UMDNS (Universal Medical Device Nomenclature System) Use: For procurement

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: Yes

Web site: —

DONATIONS

Policy or guideline: Yes

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: Yes, but not publically available

Web site: —

Medical device incorporation comments^λ: —



Inventory and maintenance

Type of inventories available: National inventory only for high cost technologies (such as MRI, CT or PET scanners)

Comments: –

Medical equipment management unit: Yes

National level = 1

Regional level = 7

Hospital level = 26

Management software: No

Software and comments^λ: –



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^δ:

Lists available: No

Unit: –

Web site: –

Lists comments^λ:

We do not have any available lists for communicable and non communicable diseases.

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES OR SPECIFIC PROCEDURES^δ: Lists available: For different healthcare facilities

Web site - facilities: <http://www.fmoh.gov.sd/English/index.php>

Web site - procedures: –

NATIONAL LIST FOR DISEASES AND SITUATIONS^δ:

Lists available: One or more

Web site: <http://www.fmoh.gov.sd/English/index.php>

| | | | | | | |
|--------|-----------------------|---|---------------------------|---|----------|------------------------------------|
| Types: | Communicable diseases | x | Non-communicable diseases | x | Injuries | Public health emergency situations |
|--------|-----------------------|---|---------------------------|---|----------|------------------------------------|



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 4'088 | n/a | 4088 | 10.768 |
| Health centre | 1'398 | n/a | 1398 | 3.682 |
| District hospital | 242 | n/a | 242 | 0.637 |
| Provincial hospital | n/a | 256 | 256 | 0.674 |
| Regional hospital | 13 | n/a | 13 | 0.034 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 5 | 7 | 12 | 0.316 |
| Computerized Tomography Scanner | 22 | 21 | 43 | 1.133 |
| Positron Emission Tomography Scanner | n/a | n/a | n/a | n/a |
| Nuclear medicine | 4 | 1 | 5 | 0.132 |
| Mammograph* | 8 | 12 | 20 | 12.183 |
| Linear accelerator | 3 | 0 | 3 | 0.079 |
| Telecobalt unit (Cobalt-60) | 4 | 0 | 4 | 0.105 |
| Radiotherapy | 7 | 0 | 7 | 0.184 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: –

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|--------|---|-----|--------------------------------------|--------------|
| Population (000s)* | 10'997 | Life expectancy at birth (years) ^a | 76 | World Bank income group ^β | Upper-middle |
| Internet users (%) ^γ | 43.8% | Per capita total health expenditure (PPP Int \$) ^δ | 686 | GNI per capita (US\$) ^ε | 4'200 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Ministry of health

Web site: <http://www.santetunisie.rns.tn/index.html>



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: Centre des etudes techniques et de maintenance biomédicale et hospitaliere

Web site: <http://www.santetunisie.tn>

OTHER: coordination des contrôles et vigilance des materieux

Unit/department: Agence nationale de controle sanitaire et de l'environnemental des produits

Web site: <http://www.santetunisie.tn>

OTHER: Elaboration des normes techniques et certification des produits

Unit/department: Institut national de la normalisation et de la propriete industrielle

Web site: <http://www.innorpi.tn>



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Nationally developed Use: Not specified

Nomenclature system name: Nomenclature du centre national de l'expertise hospitalière Français Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: —

National level procurement: Yes

Web site: <http://www.santetunisie.rns.tn/msp/msp.html>

DONATIONS

Policy or guideline: No

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: Yes, but not publically available

Web site: —

Medical device incorporation comments^λ:

L'achat des dispositifs médicaux obéit en plus des des procédures réglementaires (Règlement des marchés publics) d'unepart et passe par des commissions techniques spécialisés(commissions d'elaboration des cahiers des clauses techniques particulieres,fiches techniques ,commissions de sélection, des commissions de réception provisoire et définitifs du matériel fiches techniques. Il n'ya pas de fiches techniques standard mais elles sont préparés au cas par cas en fonction du besoin(caractéristiques opérationnelles



Inventory and maintenance

Type of inventories available: —

Comments: Conformément au manuel des procédures de gestion de la maintenance chaque établissement de santé est dans l'obligation de tenir un inventaire technique des équipements et des infrastructures techniques, remplir la fiche d'identification et une fiche de santé (maintenance) par appareil. Un applicatif informatique dédiée a été développée à cet effet.

Medical equipment management unit: Yes

National level = 1

Regional level = 3

Hospital level = 59

Management software: Yes

Software and comments^λ: G.M.B.H développé en local par le cetembh et le centre informatique du msp



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:

Lists available: No

Unit: —

Web site: —

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: —

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: —

| | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|--------|-----------------------|---------------------------|----------|------------------------------------|

Lists comments^λ:

L'acquisition et la mise en service des équipements lourds sont soumis à l'autorisation préalable du MoH pour les secteurs publique et privé et ce conformément aux critères et normes fixés par les arrêtés sus-indiqués. Arrêté. Une manière générale la liste de matériel découle de l'activité préconisée sans liste préétablie. Seules les produits non conformes aux spécifications techniques fixés



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 2'058 | n/a | 2058 | 18.715 |
| Health centre | n/a | n/a | n/a | n/a |
| District hospital | 115 | 16 | 131 | 1.191 |
| Provincial hospital | 35 | 60 | 95 | 0.864 |
| Regional hospital | 30 | n/a | 30 | 0.273 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 9 | 13 | 22 | 2.001 |
| Computerized Tomography Scanner | 32 | 66 | 98 | 8.912 |
| Positron Emission Tomography Scanner | n/a | n/a | n/a | n/a |
| Nuclear medicine | 7 | 6 | 13 | 1.182 |
| Mammograph* | 21 | n/a | 21 | 22.576 |
| Linear accelerator | 3 | 4 | 7 | 0.637 |
| Telecobalt unit (Cobalt-60) | 4 | 7 | 11 | 1.000 |
| Radiotherapy | 7 | 11 | 18 | 1.637 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ:

La structure publique de santé en Tunisie est composé de : établissements publics de santé(CHU,H. Spécialisés) dans les sièges de faculté de médecine des hôpitaux régionaux des hôpitaux de circonscription des groupements de santé de base des centres de santé de base et des centres régionaux de médecine scolaire et universitaire en plus des trois hôpitaux...

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|--------|---|-----|--------------------------------------|--------------|
| Population (000s)* | 24'407 | Life expectancy at birth (years) ^a | 64 | World Bank income group ^β | Lower-middle |
| Internet users (%) ^γ | 20.0% | Per capita total health expenditure (PPP Int \$) ^δ | 118 | GNI per capita (US\$) ^ε | 1'330 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: No

Name of principal institution: Ministry of industry & The Supreme board for Drugs & Medical Appliance

Web site: www.sbd-ye.org www.moit.gov.ye



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: Health Policy Unit

Web site: <http://www.sbd-ye.org/>

OTHER: Supervision/Maintenance/Operation/Needs Assessment/development of technical specifications/application/user training

Unit/department: The General Directorate of Medical Equipment and maintenance

Web site: —

OTHER: Planning of medical equipment allocation

Unit/department: Public administration Department of Planning

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: www.htb.gov.ye

National level procurement: Yes

Web site: —

DONATIONS

Policy or guideline: Yes

Web site: www.mophp-ye.org

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: Yes, but not publically available

Web site: —

Medical device incorporation comments^λ:

There are many Procurements carry in national level but Non-uniform standards by : the health Governorate Office , local governorates authority, general hospitals authority, police health service , and army health service and there are procurements carried in out the national level like Unicef or UNFPA ,Emro, etc.



Inventory and maintenance

Type of inventories available: None

Comments: We recommended MOPH to do complete database for medical equipment

Medical equipment management unit: Yes

National level = 1

Regional level = 6

Hospital level = 15

Management software: No

Software and comments^λ: —



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^δ

Lists available: No

Unit: Eng-Mohammed Al Maswary and Eng- faisal Mujamal

Web site: —

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES OR SPECIFIC PROCEDURES^δ: Lists available: For different healthcare facilities

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS^δ:

Lists available: No list available

Web site: —

Types:

Communicable diseases

Non-communicable diseases

Injuries

Public health emergency situations

Lists comments^λ:

National Standards of lists: ECRI,NHS www.pasa.nhs.uk/cep and individual efforts. We need financial support and cooperation, technical support to put national standards or lists of recommended medical devices for specific procedures. We need guidelines for that also technical support and cooperation to do that with WHO



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 2'774 | n/a | 2774 | 11.365 |
| Health centre | 739 | 420 | 1159 | 4.749 |
| District hospital | 182 | 321 | 503 | 2.061 |
| Provincial hospital | 53 | 167 | 220 | 0.901 |
| Regional hospital | 2 | n/a | 2 | 0.008 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 7 | 21 | 28 | 1.147 |
| Computerized Tomography Scanner | 31 | 57 | 88 | 3.605 |
| Positron Emission Tomography Scanner | 0 | 0 | 0 | 0.000 |
| Nuclear medicine | 2 | 1 | 3 | 0.123 |
| Mammograph* | 8 | 10 | 18 | 17.624 |
| Linear accelerator | 1 | 0 | 1 | 0.041 |
| Telecobalt unit (Cobalt-60) | 2 | 0 | 2 | 0.082 |
| Radiotherapy | 3 | 0 | 3 | 0.123 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ:

There was deficiency about maintenance and calibrations of medical devices

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

4.5 European Region facts and country profiles

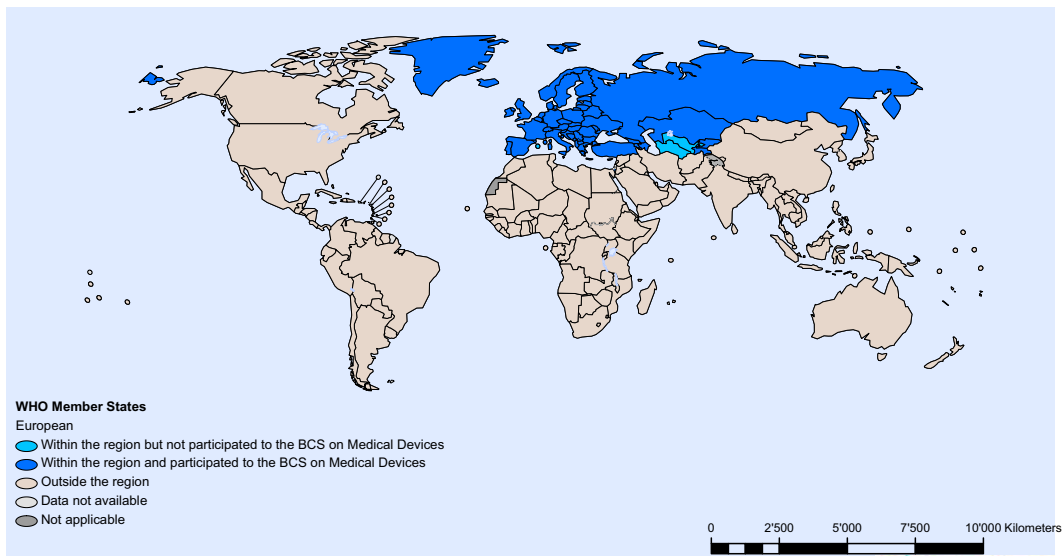


Fig. 4.5-1. Baseline Country Survey on Medical Devices European Region participation

Participation: European Region's survey participation was 94% (50/53). Participating countries are shown in Fig. 4.5-1.

National policy on health technology: 60% of the respondent EUR states (29/48) have a Health Technology policy, and for around 80% of them the HT policy is part of the national health programme.

Regulatory agency:²³ 89% of the EUR Member States (47/53) have a regulatory authority responsible for medical devices.

National health technology assessment unit:²⁴ 81% of the respondent countries (30/37) have a national agency/unit/committee that produces Health Technology Assessment (HTA) reports for the Ministry of Health.

National health technology management units: 82% of the respondent EUR states (40/49) have a national unit which technically manages medical devices. Of these countries, 50% (20/40) have a national unit in charge of technical specifications development for procurement process; 68% (27/40) have a unit in charge of planning of medical devices allocation, and 33% (13/40) have a unit to support user/training application of medical devices (Fig. 4.5-2).

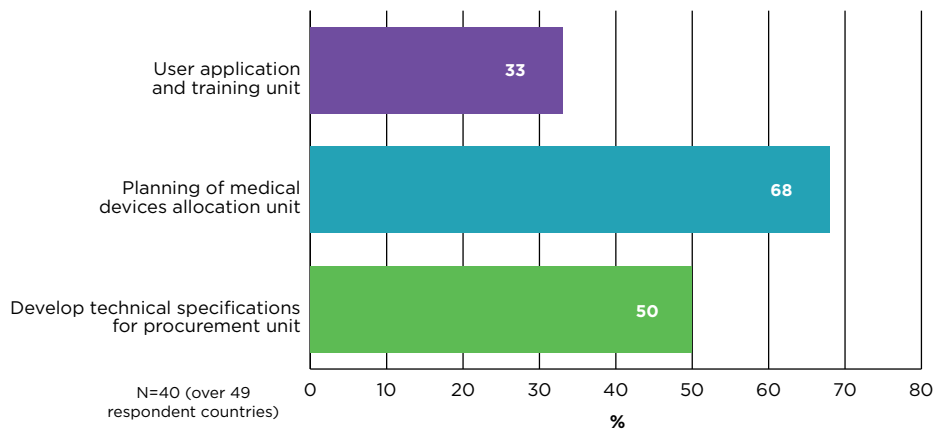


Fig. 4.5-2. Proportion of countries having different types of health technology units (percentages taken from countries that have at least one health technology management national unit)



Medical device nomenclature system: 74% of the respondent EUR states (37/50) have an official nomenclature system for medical devices. The most used type of nomenclature is GMDN only and nationally developed one, both of these account to 35% of the countries with an official nomenclature respectively (Fig. 4.5-3).

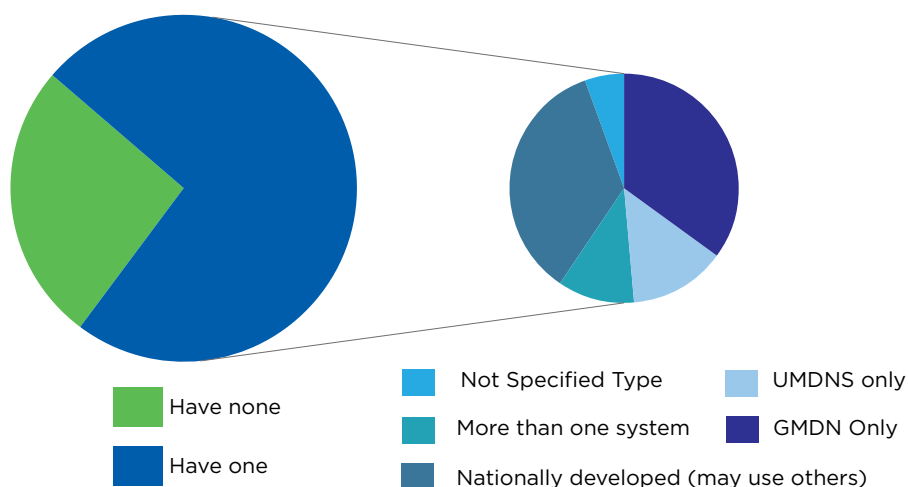


Fig. 4.5-3. Proportion of countries with official nomenclature system for medical devices and their corresponding type (percentages taken from all respondent countries)

Medical device incorporation: 45% of the respondent EUR states (22/49) have national guidelines, policies or recommendations on the procurement of medical devices. A total of 55% of the respondent states (27/49) carried out the procurement of medical devices at national level; however 58% of the respondent states (28/48) do not have recommended technical specifications of medical devices to support procurement or donations.

Inventory and maintenance: 63% of the respondent EUR states (27/43) have an available inventory for medical devices. From those countries, 56% (15/27) have a national inventory for medical equipment.

Lists of medical devices: 55% of the respondent EUR states (23/42) have national standards or recommended list(s) of medical devices for different types of healthcare facilities. In total, 63% of the respondent states (27/43) have national list(s) of recommended medical devices for specific procedures, and 47% of the respondent states (21/45) have national list(s) of recommended medical devices for high burden diseases or injuries or health emergency situations.

Healthcare facilities: 32% of the respondent EUR countries have at least one provincial hospital per 100 000 population, and 6% of the respondent countries have at least one specialized/ teaching and research hospital per 100 000 population. Furthermore, the regional density of provincial hospitals and regional/specialized/teaching and research hospitals per 100 000 population is one the highest of the six WHO regions (see Fig 4.5-4).

| Healthcare facility | Have at least one per 100,000 pop. (%) | Number of responding countries | Regional Density per 100,000 pop. |
|--|--|--------------------------------|-----------------------------------|
| Health posts | 88% | 26 | 23.20 |
| Health centre | 60% | 25 | 2.03 |
| Distric/Rural hospitals | 37% | 30 | 0.96 |
| Regional/ Specialized/ Teaching and Research hospitals | 6% | 35 | 0.32 |

Fig. 4.5-4. Proportion of EUR countries and regional densities regarding existence of healthcare facility units (percentages taken from all respondent countries)

Medical equipment: The regional density of the surveyed high technology medical equipment is one of the highest in the world, especially for gamma camera and radiotherapy units per million population (Fig. 4.5-5).

| Medical Equipment | Have at least one unit per 1,00,000 pop. (%) | Number of responding countries | Regional density per 1,000,000 pop. |
|--|--|--------------------------------|-------------------------------------|
| Magnetic Resonance Imaging (MRI) | 89% | 38 | 6.74 |
| Computed Tomography (CT Scanner) | 97% | 37 | 12.42 |
| Positron Emission Tomography (PET Scanner) | 20% | 35 | 0.75 |
| Gamma Camera or Nuclear Medicine | 79% | 34 | 4.76 |
| *Mammographs | 100% | 33 | 15.00 |
| Radiotherapy Unit: Linear Accelerator (LA) | 72% | 36 | 2.53 |
| Radiotherapy Unit:Telecobalt Unit (TU) | 13% | 32 | 0.56 |
| Radiotherapy Unit (LA+TU) | 86% | 36 | 3.06 |

* Mammographs density is per 100,000 females aged between 50 and 69 years old, and the regional density per million females of the same age

Fig. 4.5-5. Proportion of EUR countries and regional densities regarding high technology equipment (percentages taken from all respondent countries)



List of country profiles for the WHO European Region

| | | | |
|------------------------|-----|--|-----|
| Albania | 294 | Lithuania | 346 |
| Armenia | 296 | Luxembourg | 348 |
| Austria | 298 | Macedonia, The former Yugoslav Republic of | 350 |
| Azerbaijan | 300 | Malta | 352 |
| Belarus | 302 | Monaco | 354 |
| Belgium | 304 | Montenegro | 356 |
| Bosnia and Herzegovina | 306 | Netherlands | 358 |
| Bulgaria | 308 | Norway | 360 |
| Croatia | 310 | Poland | 362 |
| Cyprus | 312 | Portugal | 364 |
| Czech Republic | 314 | Moldova, Republic of | 366 |
| Denmark | 316 | Romania | 368 |
| Estonia | 318 | Russian Federation | 370 |
| Finland | 320 | San Marino | 372 |
| France | 322 | Serbia | 374 |
| Georgia | 324 | Slovakia | 376 |
| Germany | 326 | Slovenia | 378 |
| Greece | 328 | Spain | 380 |
| Hungary | 330 | Sweden | 382 |
| Iceland | 332 | Switzerland | 384 |
| Ireland | 334 | Tajikistan | 386 |
| Israel | 336 | Turkey | 388 |
| Italy | 338 | Ukraine | 390 |
| Kazakhstan | 340 | United Kingdom of Great Britain and Northern Ireland | 392 |
| Kyrgyzstan | 342 | | |
| Latvia | 344 | | |



Country indicators

| | | | | | |
|---------------------------------|-------|---|-----|--------------------------------------|--------------|
| Population (000s)* | 3'173 | Life expectancy at birth (years) ^a | 74 | World Bank income group ^β | Upper-middle |
| Internet users (%) ^γ | 60.1% | Per capita total health expenditure (PPP Int \$) ^δ | 541 | GNI per capita (US\$) ^ε | 4'710 |



National policy on health technology

Health technology (medical device) national policy: Yes, and it is part of the National Health Program/Plan or Policy

Web site: <http://www.moh.gov.al/>

Language(s): English and Albanian

MOH responsible for health technology policy implementation: Unit for the Management of Medical Devices



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: National Agency for Drugs and Medical Devices (AKBPM)

Web site: <http://akbpm.gov.al/>



National health technology assessment unit

Unit/department: Unit for medical systems

Web site: —



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: Unit for Medical Systems

Web site: —

OTHER: Planning of medical equipment allocation/Application/user training

Unit/department: Unit for Medical Systems

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Nationally developed Use: For inventory

Nomenclature system name: CIVAB Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: —

National level procurement: Yes

Web site: —

DONATIONS

Policy or guideline: Yes

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ:

Exists the National Policy for management of medical devices in Albania. Procurement of medical devices at national levels is done partially



Inventory and maintenance

Type of inventories available: National inventory for medical equipment

Comments: The inventory system is called CLINGO. The National Biomedical Centre manages the system. Each hospital(13 regional hospitals are involved) is in charge of adding their own data. Doesn't cover all the hospitals and other public health institutions. Not able to upload because of the system restrictions

Medical equipment management unit: Yes

National level = 1

Regional level = 4

Hospital level = 8

Management software: Yes

Software and comments^λ: Clingo. Used only for inventory.



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:

Lists comments^λ: –

Lists available: No

Unit: –

Web site: –

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES OR SPECIFIC PROCEDURES: Lists available: No list available

Web site - facilities: –

Web site - procedures: –

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: –

| | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|--------|-----------------------|---------------------------|----------|------------------------------------|



Healthcare facility

| | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 415 | n/a | 415 | 13.078 |
| Health centre | n/a | n/a | n/a | n/a |
| District hospital | 23 | n/a | 23 | 0.725 |
| Provincial hospital | 11 | n/a | 11 | 0.347 |
| Regional hospital | 5 | 4 | 9 | 0.284 |



Medical equipment

| | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 1 | 4 | 5 | 1.576 |
| Computerized Tomography Scanner | 5 | 12 | 17 | 5.357 |
| Positron Emission Tomography Scanner | 0 | 0 | 0 | 0.000 |
| Nuclear medicine | 0 | 0 | 0 | 0.000 |
| Mammograph* | 6 | 12 | 18 | 54.400 |
| Linear accelerator | 0 | 0 | 0 | 0.000 |
| Telecobalt unit (Cobalt-60) | 1 | 0 | 1 | 0.315 |
| Radiotherapy | 1 | 0 | 1 | 0.315 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: –

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|-------|---|-----|--------------------------------------|--------------|
| Population (000s)* | 2'977 | Life expectancy at birth (years) ^a | 71 | World Bank income group ^β | Lower-middle |
| Internet users (%) ^γ | 46.3% | Per capita total health expenditure (PPP Int \$) ^δ | 299 | GNI per capita (US\$) ^ε | 3'800 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: MoH

Web site: <http://moh.am>



National health technology assessment unit

Unit/department: HPIU

Web site: <http://healthpiu.am>



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: HPIU

Web site: <http://healthpiu.am>

OTHER: Planning of medical equipment allocation

Unit/department: HPIU

Web site: <http://healthpiu.am>

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: Yes

Web site: <http://www.spyur.am/en/companies/public-procurement-agency/70054>

DONATIONS

Policy or guideline: No

Web site: —

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: Yes

Web site: —

Medical device incorporation comments^λ:

Technical specifications developed by the HPIU biomedical engineer in cooperation with international consultants



Inventory and maintenance

Type of inventories available: —

Comments: —

Medical equipment management unit: Yes

National level = —

Regional level = —

Hospital level = —

Management software: No

Software and comments^λ: —

Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^α:

Lists available: No

Unit: —

Web site: —

Lists comments^λ:

Government Decree #1936-N on Technical and Professional Requirements for Licensing of Health Care Facilities

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: For different healthcare facilities

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: —

| | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|--------|-----------------------|---------------------------|----------|------------------------------------|



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 238 | n/a | 238 | 7.996 |
| Health centre | 16 | n/a | 16 | 0.538 |
| District hospital | 54 | n/a | 54 | 1.814 |
| Provincial hospital | 30 | 17 | 47 | 1.579 |
| Regional hospital | 14 | 5 | 19 | 0.638 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 6 | 1 | 7 | 2.352 |
| Computerized Tomography Scanner | 7 | 2 | 9 | 3.024 |
| Positron Emission Tomography Scanner | 0 | 0 | 0 | 0.000 |
| Nuclear medicine | 4 | 0 | 4 | 1.344 |
| Mammograph* | 5 | 2 | 7 | 22.496 |
| Linear accelerator | 1 | 0 | 1 | 0.336 |
| Telecobalt unit (Cobalt-60) | 3 | 0 | 3 | 1.008 |
| Radiotherapy | 4 | 0 | 4 | 1.344 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ:

Concerning HT national policy we provide the following doc.: http://www.who.int/medical_devices/survey_resources/health_technology_national_policy_albania.pdf

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

Austria



Country indicators

| | | | | | |
|---------------------------------|-------|---|------|--------------------------------------|--------|
| Population (000s)* | 8'495 | Life expectancy at birth (years) ^a | 81 | World Bank income group ^β | High |
| Internet users (%) ^γ | 80.6% | Per capita total health expenditure (PPP Int \$) ^δ | 5065 | GNI per capita (US\$) ^ε | 50'430 |



National policy on health technology

Health technology (medical device) national policy: Yes, and it is part of the National Health Program/Plan or Policy

Web site: <http://www.bmg.gv.at/cms/site/thema.html?channel=CH0952>

Language(s): German

MOH responsible for health technology policy implementation: III/3



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Austrian Medicines and Medical Devices Agency

Web site: <http://www.basg.gv.at/en/medical-devices/>



National health technology assessment unit

Unit/department: GÖG/BIQG

Web site: <http://www.goeg.at/de/BIQG.html>



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: —

Web site: —

OTHER: Planning of medical equipment allocation

Unit/department: III/3

Web site: <http://www.bmg.gv.at>

OTHER: Regulation

Unit/department: I/C

Web site: <http://www.bmg.gv.at>



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on UMDNS (Universal Medical Device Nomenclature System) Use: For regulatory purposes

Nomenclature system name: — Web site: <http://www.goeg.at/de/Medizinprodukte-Register>



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: <http://www.hauptverband.at/>

National level procurement: No

Web site: —

DONATIONS

Policy or guideline: Yes

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: Yes, but not publically available

Web site: —

Medical device incorporation comments^λ:

Procurement done with internal guidelines of the Hauptverband, insurance funds, hospitals, Bundesbeschaffungs GmbH etc.



Inventory and maintenance

Type of inventories available: National inventory only for high cost technologies (such as MRI, CT or PET scanners)

Comments: Implementation of the national Plan for high cost technologies "Großgeräteplan"

Medical equipment management unit: Yes

National level = 1

Regional level = 9

Hospital level = 242

Management software: Yes

Software and comments^λ: Various software for maintenance and inspection of medical devices in hospital (for example MTECS, Visual FM, SAP etc.)



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:

Lists available: Yes

Unit: Hauptverband der österreichischen Sozialversicherungsträger

Web site: —

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: For different healthcare facilities and specific procedures

Web site - facilities: <http://www.bmg.gv.at/cms/site/standard.html?channel=CHO716&doc=CMS1136983382893>

Web site - procedures: <http://www.bmg.gv.at/cms/site/standard.html?channel=CHO716&doc=CMS1136983382893>

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: —

Types:

| | | | |
|-----------------------|---------------------------|----------|------------------------------------|
| Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|-----------------------|---------------------------|----------|------------------------------------|

Lists comments^λ:

Osterreichischer Strukturplan Gesundheit (upmentioned link) and various guidelines of the medical societies, internal guidelines of the hospitals, etc.



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | n/a | n/a | n/a | n/a |
| Health centre | n/a | n/a | n/a | n/a |
| District hospital | n/a | n/a | n/a | n/a |
| Provincial hospital | n/a | n/a | n/a | n/a |
| Regional hospital | n/a | n/a | n/a | n/a |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 141 | n/a | 141 | 16.598 |
| Computerized Tomography Scanner | 242 | n/a | 242 | 28.487 |
| Positron Emission Tomography Scanner | 23 | n/a | 23 | 2.707 |
| Nuclear medicine | n/a | n/a | n/a | n/a |
| Mammograph* | n/a | n/a | n/a | n/a |
| Linear accelerator | 46 | n/a | 46 | 5.415 |
| Telecobalt unit (Cobalt-60) | n/a | n/a | n/a | n/a |
| Radiotherapy | 46 | n/a | 46 | 5.415 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: —

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

Azerbaijan



Country indicators

| | | | | | |
|---------------------------------|-------|---|-----|--------------------------------------|--------------|
| Population (000s)* | 9'413 | Life expectancy at birth (years) ^a | 72 | World Bank income group ^β | Upper-middle |
| Internet users (%) ^γ | 58.7% | Per capita total health expenditure (PPP Int \$) ^δ | 572 | GNI per capita (US\$) ^ε | 7'350 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: Health Organizaiton Department



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: —

Name of principal institution: CSEEA Analytical Expertise Centre

Web site: <http://www.pharma.az/>



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: Innovation and supply centre

Web site: —

OTHER: Planning of medical equipment allocation/Applicarion/User Training

Unit/department: Innovation and supply centre

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: Yes

Web site: —

DONATIONS

Policy or guideline: Yes

Web site: whqlibdoc.who.int/publications/2011/9789241501408_eng.pdf

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ:
Procurement guidelines under development



Inventory and maintenance

Type of inventories available: National inventory for medical equipment

Comments: –

Medical equipment management unit: No

National level = 0

Regional level = 0

Hospital level = 0

Management software: No

Software and comments^λ: –



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:

Lists comments^λ: –

Lists available: Yes, but it is only a recommendation

Unit: Medical Technical Department of the Innovation and supply centre

Web site: Available upon request

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: –

Web site - facilities: –

Web site - procedures: –

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: –

Web site: –

| | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|--------|-----------------------|---------------------------|----------|------------------------------------|



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | n/a | n/a | n/a | n/a |
| Health centre | 700 | n/a | 700 | 7.436 |
| District hospital | 500 | n/a | 500 | 5.312 |
| Provincial hospital | 200 | n/a | 200 | 2.125 |
| Regional hospital | 50 | n/a | 50 | 0.531 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 5 | n/a | 5 | 0.531 |
| Computerized Tomography Scanner | 10 | n/a | 10 | 1.062 |
| Positron Emission Tomography Scanner | 2 | n/a | 2 | 0.212 |
| Nuclear medicine | n/a | n/a | n/a | n/a |
| Mammograph* | 25 | n/a | 25 | 30.714 |
| Linear accelerator | 15 | n/a | 15 | 1.593 |
| Telecobalt unit (Cobalt-60) | n/a | n/a | n/a | n/a |
| Radiotherapy | 15 | n/a | 15 | 1.593 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: –

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

Belarus



Country indicators

| | | | | | |
|---------------------------------|-------|---|-----|--------------------------------------|--------------|
| Population (000s)* | 9'357 | Life expectancy at birth (years) ^a | 72 | World Bank income group ^β | Upper-middle |
| Internet users (%) ^γ | 54.2% | Per capita total health expenditure (PPP Int \$) ^δ | 790 | GNI per capita (US\$) ^ε | 6'730 |



National policy on health technology

Health technology (medical device) national policy: Yes, and it is part of the National Health Program/Plan or Policy

Web site: <http://pravo.by/webnpa/text.asp?start=1&RN=C20301276>

Language(s): Russian

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Department of Medical Equipment, Logistical Support, and Construction, Ministry of Health

Web site: http://minzdrav.gov.by/en/static/about/central_device/dept_medEquipmentOffice



National health technology assessment unit

Unit/department: BELCMT

Web site: <http://www.belcmt.by>



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: Department of Medical Technology, MoH

Web site: <http://minzdrav.by/>

OTHER: Application/ user training

Unit/department: IP

Web site: <http://www.belmt.by/>

OTHER: Application/ user training

Unit/department: HT Public Institution

Web site: <http://www.belcmt.by/>



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Nationally developed Use: Not specified

Nomenclature system name: State register of medical equipment and medical supplies of Belarus

Web site: <http://www.rceth.by/mfindr.htm>



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: <http://pravo.by/>

National level procurement: Yes

Web site: <http://www.belmt.by/>

DONATIONS

Policy or guideline: Yes

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: Yes

Web site: <http://icetrade.by/>

Medical device incorporation comments^λ:

Public procurement of medical devices and their specifications for each procurement procedure can be found in our website



Inventory and maintenance

Type of inventories available: National inventory for medical equipment

Comments: Go to web site and find the document titled mfindr.htm

Medical equipment management unit: Yes

National level = 2

Regional level = 7

Hospital level = 118

Management software: Yes

Software and comments^λ: translation



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^α

Lists available: Yes

Unit: Department of Medical Technology of the MoH

Web site: <http://www.pravo.by/>

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: For different healthcare facilities and specific procedures

Web site - facilities: http://minzdrav.by/med/ibp/ibp_list.php?prg=5&lst_p=6

Web site - procedures: http://minzdrav.by/med/article/sprav_sod1.php?prg=5&prn=%CF%F0%EE%F2%EE%EA%EE%EB%FB+%28%F1%F2%EO%ED%E4%EO%F0%F2%FB%29+%EE%E1%F1%EB%E5%E4%EE%E2%EO%ED%E8%FF+%E8+%EB%E5%F7%E5%ED%E8%FF+%E1%EE%EB%FC%ED%FB%F5

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: One or more

Web site: http://minzdrav.by/med/article/sprav_sod1.php?prg=5&prn=%CF%F0%EE%F2%EE%EA%EE%EB%FB+%28%F1%F2%EO%ED%E4%EO%F0%F2%FB%29+%EE%E1%F1%EB%E5%E4%EE%E2%EO%ED%E8%FF+%E8+%EB%E5%F7%E5%ED%E8%FF+%E1%EE%EB%FC%ED%FB%F5

Types:

Communicable diseases x

Non-communicable diseases x

Injuries x

Public health emergency situations x

Lists comments^λ:

Lists available for communicable and non communicable diseases, injuries, and public health emergency situations: Documents: n° 2007 " <http://www.pravo.by/webnpa/text.asp?RN=C20701722> AND N° 458 and <http://www.pravo.by/webnpa/text.asp?RN=P30900458>



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 1'437 | n/a | 1437 | 15.358 |
| Health centre | 268 | n/a | 268 | 2.864 |
| District hospital | 385 | n/a | 385 | 4.115 |
| Provincial hospital | 261 | n/a | 261 | 2.789 |
| Regional hospital | 51 | n/a | 51 | 0.545 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 24 | n/a | 24 | 2.565 |
| Computerized Tomography Scanner | 58 | n/a | 58 | 6.199 |
| Positron Emission Tomography Scanner | 0 | n/a | 0 | 0.000 |
| Nuclear medicine | 24 | n/a | 24 | 2.565 |
| Mammograph* | 23 | n/a | 23 | 17.482 |
| Linear accelerator | 6 | n/a | 6 | 0.641 |
| Telecobalt unit (Cobalt-60) | 23 | n/a | 23 | 2.458 |
| Radiotherapy | 29 | n/a | 29 | 3.099 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments: –

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

Belgium



Country indicators

| | | | | | |
|---------------------------------|--------|---|------|--------------------------------------|--------|
| Population (000s)* | 11'104 | Life expectancy at birth (years) ^a | 80 | World Bank income group ^β | High |
| Internet users (%) ^γ | 82.2% | Per capita total health expenditure (PPP Int \$) ^δ | 4320 | GNI per capita (US\$) ^ε | 46'290 |



National policy on health technology

Health technology (medical device) national policy: Yes, and it is part of the National Health Program/Plan or Policy

Web site: http://www.fagg-afmps.be/fr/humain/produits_de_sante/dispositifs_medicaux/legislation/index.jsp; http://www.iph.fgov.be/ClinBiol/bckb33/activities/competent_authority/_dowR14_11_2001dispositifsmedicauxIVD.pdf ; http://www.iph.fgov.be/ClinBiol/bckb33/activities/licence/_down/03_12_1999.pdf

Language(s): Français et Néerlandais

MOH responsible for health technology policy implementation: Agence Fédérale des Médicaments et des Produits de Santé pour les dispositifs médicaux et les dispositifs médicaux implantables actifs et l'Institut Scientifique de Santé Publique - Section de Biologie clinique pour les dispositifs médicaux de diagnostic in vitro



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Agence Fédérale des Médicaments et des Produits de Santé

Web site: <http://www.fagg-afmps.be>



National health technology assessment unit

Unit/department: Health Care Knowledge Center (KCE)

Web site: <https://kce.fgov.be/>



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on GMDN (Global Medical Device Nomenclature)

Use: For regulatory purposes

Nomenclature system name: — Web site: <http://www.gmdnagency.org/>



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: <http://www.fagg-afmps.be/fr/> and <http://www.iph.fgov.be>

National level procurement: No

Web site: —

DONATIONS

Policy or guideline: No

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: Yes

Web site: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:131:0017:0030:fr:PDF>

Medical device incorporation comments^λ:

Dans chaque Arrêté royal d'application se trouvent des exigences par rapport à la distribution et/ou la délivrance des dispositifs médicaux (docs: coord_tcm291-26685.pdf and tcm291-27069.pdf).

Décision de la Commission 2002/364/EC portant spécifications techniques communes des dispositifs médicaux de diagnostic in vitro



Inventory and maintenance

Type of inventories available: None

Comments: —

Medical equipment management unit: —

National level = 0

Regional level = 0

Hospital level = 0

Management software: —

Software and comments^λ: —

Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^δ

Lists available: Yes, but it is only a recommendation

Unit: Institut National d'Assurance Maladie Invalidité - INAMI

Web site: —

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: —

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: —

Lists comments^λ:

Ces listes existent indirectement par le remboursement de certains dispositifs médicaux et/ou le remboursement de certains tests cliniques effectués. Les dispositifs médicaux implantables et invasifs à long terme doivent se trouver dans ce listing de l'INAMI pour pouvoir être facturés par l'hôpital aux patients. La liste est disponible sur internet via le lien suivant: <https://www.riziv.>

| | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|--------|-----------------------|---------------------------|----------|------------------------------------|



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | n/a | n/a | n/a | n/a |
| Health centre | n/a | n/a | n/a | n/a |
| District hospital | n/a | n/a | n/a | n/a |
| Provincial hospital | n/a | n/a | n/a | n/a |
| Regional hospital | n/a | n/a | n/a | n/a |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | n/a | n/a | n/a | n/a |
| Computerized Tomography Scanner | n/a | n/a | n/a | n/a |
| Positron Emission Tomography Scanner | n/a | n/a | n/a | n/a |
| Nuclear medicine | n/a | n/a | n/a | n/a |
| Mammograph [*] | n/a | n/a | n/a | n/a |
| Linear accelerator | n/a | n/a | n/a | n/a |
| Telecobalt unit (Cobalt-60) | n/a | n/a | n/a | n/a |
| Radiotherapy | n/a | n/a | n/a | n/a |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ:

L'AFCN est en train de réviser les inventaires des dispositifs médicaux émettant des rayonnements ionisants présents en Belgique. Cet inventaire provient en partie de données fournies par les Organismes Agréés (AV Controlatom, TechniTest, ...). COCIR (European Coordination Committee of the Radiological, Electromedical and Medical IT Industries) peut également fournir des informations utiles (internationales, y compris pour la Belgique - données 2008 : http://www.cocir.org/uploads/documents/-609-new_members_ws_-_del_3_-_cocir_age_profiile_17_june_2009.pdf) sur les dispositifs...

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

Bosnia and Herzegovina



Country indicators

| | | | | | |
|---------------------------------|-------|---|-----|--------------------------------------|--------------|
| Population (000s)* | 3'829 | Life expectancy at birth (years) ^a | 77 | World Bank income group ^β | Upper-middle |
| Internet users (%) ^γ | 67.9% | Per capita total health expenditure (PPP Int \$) ^δ | 928 | GNI per capita (US\$) ^ε | 4'780 |



National policy on health technology

Health technology (medical device) national policy: Yes, and it is part of the National Health Program/Plan or Policy

Web site: <http://www.met.gov.ba/propisi/?id=55> AND http://www.almbih.gov.ba/regulativa/bih/en/medicinal_products_and_medical_devices_act.pdf

Language(s): Local language and English

MOH responsible for health technology policy implementation: Health Sector



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Agency for medical products and medical devices; Institute for standardization of Bosnia and Herzegovina

Web site: <http://www.almbih.gov.ba/>; http://www.bas.gov.ba/tc/?national_committee_id=6



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: —

Web site: —

OTHER: Planning of medical equipment allocation/regulations

Unit/department: Agency for medical products and medical devices

Web site: <http://www.almbih.gov.ba/>

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: http://www.almbih.gov.ba/regulativa/bih/en/medicinal_products_and_medical_devices_act.pdf

National level procurement: Yes

Web site: —

DONATIONS

Policy or guideline: Yes

Web site: —

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ:

Responsible authority in both entities. MoH of Republika Srpska is responsible for the procurement of high cost technologies while the health care institutions can provide procurement of other medical equipment.



Inventory and maintenance

Type of inventories available: National inventory only for high cost technologies (such as MRI, CT or PET scanners), National inventory for medical equipment

Comments: –

Medical equipment management unit: No

National level = 0

Regional level = 0

Hospital level = 0

Management software: No

Software and comments^λ: –



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:

Lists available: Yes

Unit: –

Web site: <http://www.almbih.gov.ba/ms/RegMS.pdf>

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: For different healthcare facilities and specific procedures

Web site - facilities: http://www.almbih.gov.ba/regulativa/bih/en/medicinal_products_and_medical_devices_act.pdf

Web site - procedures: <http://www.almbih.gov.ba/ms/RegMS.pdf>; http://www.bas.gov.ba/tc/?national_committee_id=6

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: One or more

Web site: –

Types: Communicable diseases x Non-communicable diseases x Injuries x Public health emergency situations x

Lists comments^λ:

There are the lists of medical devices for procurement regarding the each general hospital as well as clinical centres (situation analysis of health care institutions). At the primary health care level, there is a list of medical equipments that is necessary for family medicine. As well as lists for communicable and non communicable diseases, injuries, and public



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 133 | 1'477 | 1610 | 42.044 |
| Health centre | n/a | n/a | 0 | 0.000 |
| District hospital | 1 | n/a | 1 | 0.026 |
| Provincial hospital | 33 | n/a | 33 | 0.862 |
| Regional hospital | 5 | n/a | 5 | 0.131 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 16 | 5 | 21 | 5.484 |
| Computerized Tomography Scanner | 44 | 19 | 63 | 16.452 |
| Positron Emission Tomography Scanner | 1 | 0 | 1 | 0.261 |
| Nuclear medicine | 6 | 0 | 6 | 1.567 |
| Mammograph* | 64 | 24 | 88 | 182.720 |
| Linear accelerator | 6 | 3 | 9 | 2.350 |
| Telecobalt unit (Cobalt-60) | 2 | 0 | 2 | 0.522 |
| Radiotherapy | 8 | 3 | 11 | 2.873 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: –

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

Bulgaria



Country indicators

| | | | | | |
|---------------------------------|-------|---|------|--------------------------------------|--------------|
| Population (000s)* | 7'223 | Life expectancy at birth (years) ^a | 74 | World Bank income group ^β | Upper-middle |
| Internet users (%) ^γ | 53.1% | Per capita total health expenditure (PPP Int \$) ^δ | 1177 | GNI per capita (US\$) ^ε | 7'360 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Bulgarian Drug Agency (BDA)

Web site: <http://en.bda.bg/>



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): No

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on more than one system Use: Not specified

Nomenclature system name: UMDNS and GMND Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: <http://www.mh.government.bg/>

National level procurement: Yes

Web site: <http://www.mh.government.bg/>

DONATIONS

Policy or guideline: No

Web site: —

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ:

Only for the devices which are supplied through a centralized procedure accomplished by the MoH.



Inventory and maintenance

Type of inventories available: None

Comments: –

Medical equipment management unit: –

National level = 0

Regional level = 0

Hospital level = 0

Management software: –

Software and comments^λ: –

Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:Lists comments^λ: –

Lists available: Yes

Unit: National Health Insurance Fund

Web site: –

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES**OR SPECIFIC PROCEDURES:** Lists available: No list available

Web site - facilities: –

Web site - procedures: –

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: –

| | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|--------|-----------------------|---------------------------|----------|------------------------------------|



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | n/a | n/a | n/a | n/a |
| Health centre | n/a | n/a | n/a | n/a |
| District hospital | n/a | n/a | n/a | n/a |
| Provincial hospital | n/a | n/a | n/a | n/a |
| Regional hospital | n/a | n/a | n/a | n/a |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | n/a | n/a | n/a | n/a |
| Computerized Tomography Scanner | n/a | n/a | n/a | n/a |
| Positron Emission Tomography Scanner | n/a | n/a | n/a | n/a |
| Nuclear medicine | n/a | n/a | n/a | n/a |
| Mammograph* | n/a | n/a | n/a | n/a |
| Linear accelerator | n/a | n/a | n/a | n/a |
| Telecobalt unit (Cobalt-60) | n/a | n/a | n/a | n/a |
| Radiotherapy | n/a | n/a | n/a | n/a |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: –

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|-------|---|------|--------------------------------------|--------|
| Population (000s)* | 4'290 | Life expectancy at birth (years) ^a | 78 | World Bank income group ^β | High |
| Internet users (%) ^γ | 66.7% | Per capita total health expenditure (PPP Int \$) ^δ | 1410 | GNI per capita (US\$) ^ε | 13'430 |



National policy on health technology

Health technology (medical device) national policy: Yes, and it is part of the National Health Program/Plan or Policy

Web site: http://narodne-novine.nn.hr/clanci/sluzbeni/2006_06_72_1719.html

Language(s): Croatian

MOH responsible for health technology policy implementation: By „Act on Quality Health Care“, 10 October 2007 (<http://narodne-novine.nn.hr/clanci/sluzbeni/329378.html>) the Agency for Quality and Accreditation in Health (<http://www.aaz.hr/>) was established as a legal, public, independent, non-profit institution. Founder of the Agency is the Republic of Croatia; by law, Agency shall provide, among other services on quality and accreditation in health care, health technology assessment and a database related to HTA.



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Agency for Medical Products and Medical Devices, Subunit for Medical Devices

Web site: <http://www.almp.hr>



National health technology assessment unit

Unit/department: Agency for Quality and Accreditation in Health

Web site: <http://www.aaz.hr>



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: Directorate of Medical Affairs

Web site: <http://www.mzss.hr>

OTHER: Planning of medical equipment allocation

Unit/department: Directorate for Financial Affairs

Web site: <http://www.mzss.hr>

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: <http://narodne-novine.nn.hr>

National level procurement: Yes

Web site: <http://www.zdravlje.hr/>

DONATIONS

Policy or guideline: Yes

Web site: http://narodne-novine.nn.hr/clanci/sluzbeni/2009_12_151_3696.html

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^Λ:

Ministry of Health and Social Welfare currently conducts joined procurement of several groups of medical devices for more than 20 hospitals in the Republic of Croatia.

Procurement procedure is managed by the expert divisions within the Ministry in collaboration with all hospitals included in the Procurement Plan and top medical experts for every group of the equipment (see: [clanci/sluzbeni/2007_10_110_3225.html](http://narodne-novine.nn.hr/clanci/sluzbeni/2007_10_110_3225.html) and [clanci/sluzbeni/2008_10_125_3562.html](http://narodne-novine.nn.hr/clanci/sluzbeni/2008_10_125_3562.html)). Due to



Inventory and maintenance

Type of inventories available: None

Comments: The Ministry of Health and Social Welfare has an informal nacional internal inventory for medical devices in all public health institutions. This inventory is used mainly for analytical puposes and planning strategies within the Ministry. In 2008 Croatian National Institute of Public Health, as part of a pilot project under EUROSTAT guidelines, made an inventory of 10 most-expensive medical devices (MRI, Computed Tomography, Linear Accelerator...)

Medical equipment management unit: No

National level = 0

Regional level = 0

Hospital level = 0

Management software: No

Software and comments^λ: —



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^α:

Lists available: No

Unit: —

Web site: —

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: For different healthcare facilities and specific procedures

Web site - facilities: http://narodne-novine.nn.hr/clanci/sluzbeni/2004_07_90_1694.html,
http://narodne-novine.nn.hr/clanci/sluzbeni/2008_04_38_1318.html

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: One or more

Web site: http://www.mzss.hr/hr/ministarstvo/strategije_i_planovi/nacionalni_plan_pripripremljenosti_za_pandemiju_gripe

Types: Communicable diseases x Non-communicable diseases Injuries Public health emergency situations x

Lists comments^λ:

In 2007. MoH and Social Welfare issued Ordinance on the organization and work procedures of the Ministry of Health and Social Welfare's Crisis Headquarters (http://narodne-novine.nn.hr/clanci/sluzbeni/2007_05_46_1563.html) which determines organization scheme and work procedure of the MoH and Social Welfare's Crisis Headquarters as well as actions of other health



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 36 | n/a | 36 | 0.839 |
| Health centre | 13 | n/a | 13 | 0.303 |
| District hospital | 22 | n/a | 22 | 0.513 |
| Provincial hospital | 29 | n/a | 29 | 0.676 |
| Regional hospital | 15 | n/a | 15 | 0.350 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 15 | 16 | 31 | 7.227 |
| Computerized Tomography Scanner | 49 | 15 | 64 | 14.919 |
| Positron Emission Tomography Scanner | 0 | 2 | 2 | 0.466 |
| Nuclear medicine | 26 | 0 | 26 | 6.061 |
| Mammograph* | 84 | 40 | 124 | 206.539 |
| Linear accelerator | 10 | 0 | 10 | 2.331 |
| Telecobalt unit (Cobalt-60) | 3 | 0 | 3 | 0.699 |
| Radiotherapy | 13 | 0 | 13 | 3.031 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: —

* UNPD as of 1 July 2012 (2013 update)

^α WHO 2012 data

^β WB 2014 classification

^γ WB 2013 data (2014 update)

^δ WHO 2012 data

^ε WB 2013 (2014 update)

n/a not applicable

^λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|-------|---|------|--------------------------------------|--------|
| Population (000s)* | 1'141 | Life expectancy at birth (years) ^a | 82 | World Bank income group ^β | High |
| Internet users (%) ^γ | 65.5% | Per capita total health expenditure (PPP Int \$) ^δ | 2266 | GNI per capita (US\$) ^ε | 25'210 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Cyprus Medical Devices Competent Authority

Web site: <http://cymda.eu/>



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): No

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on more than one system Use: Not specified

Nomenclature system name: GMDN and UMDNS. Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: —

National level procurement: Yes

Web site: —

DONATIONS

Policy or guideline: Yes

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ:
Procurement guidelines apply to the Public Sector only



Inventory and maintenance

Type of inventories available: None

Comments: —

Medical equipment management unit: Yes

National level = 0

Regional level = 0

Hospital level = 0

Management software: No

Software and comments^λ: —

Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:Lists comments^λ: —

Lists available: No

Unit: —

Web site: —

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES**OR SPECIFIC PROCEDURES:** Lists available: No list available

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: —

| | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|--------|-----------------------|---------------------------|----------|------------------------------------|



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | n/a | n/a | n/a | n/a |
| Health centre | 38 | n/a | 38 | 3.330 |
| District hospital | n/a | n/a | n/a | n/a |
| Provincial hospital | 6 | 73 | 79 | 6.923 |
| Regional hospital | 2 | 5 | 7 | 0.613 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 1 | 15 | 16 | 14.021 |
| Computerized Tomography Scanner | 5 | 24 | 29 | 25.413 |
| Positron Emission Tomography Scanner | 0 | 0 | 0 | 0.000 |
| Nuclear medicine | 4 | 6 | 10 | 8.763 |
| Mammograph* | 9 | 31 | 40 | 329.641 |
| Linear accelerator | 0 | 3 | 3 | 2.629 |
| Telecobalt unit (Cobalt-60) | 0 | 0 | 0 | 0.000 |
| Radiotherapy | 0 | 3 | 3 | 2.629 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: —

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

Czech Republic



Country indicators

| | | | | | |
|---------------------------------|--------|---|------|--------------------------------------|--------|
| Population (000s)* | 10'702 | Life expectancy at birth (years) ^a | 78 | World Bank income group ^β | High |
| Internet users (%) ^γ | 74.1% | Per capita total health expenditure (PPP Int \$) ^δ | 2046 | GNI per capita (US\$) ^ε | 18'950 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Ministry of Health State Institute for Drug Control

Web site: <http://www.sukl.eu/>



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): No

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on UMDNS (Universal Medical Device Nomenclature System) Use: Not specified

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: No

Web site: —

DONATIONS

Policy or guideline: No

Web site: —

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ: —



Inventory and maintenance

Type of inventories available: None

Comments: –

Medical equipment management unit: Yes

National level = 0

Regional level = 0

Hospital level = 0

Management software: Yes

Software and comments^λ: –

Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^α

Lists comments^λ: –

Lists available: Yes

Unit: VZP CR (General Health Insurance Company)

Web site: http://www.vzp.cz/cms/internet/cz/Lekari/Ciselniky/PZT_740.pdf

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: No list available

Web site - facilities: –

Web site - procedures: –

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: –

| | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|--------|-----------------------|---------------------------|----------|------------------------------------|



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 177 | 23'886 | 24063 | 224.842 |
| Health centre | n/a | 17 | 17 | 0.159 |
| District hospital | 11 | 32 | 43 | 0.402 |
| Provincial hospital | 22 | 46 | 68 | 0.635 |
| Regional hospital | 21 | 6 | 27 | 0.252 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 31 | 21 | 52 | 4.859 |
| Computerized Tomography Scanner | 67 | 72 | 139 | 12.988 |
| Positron Emission Tomography Scanner | 6 | 0 | 6 | 0.561 |
| Nuclear medicine | 68 | 53 | 121 | 11.306 |
| Mammograph* | 44 | 95 | 139 | 96.988 |
| Linear accelerator | 23 | 14 | 37 | 3.457 |
| Telecobalt unit (Cobalt-60) | 10 | 5 | 15 | 1.402 |
| Radiotherapy | 33 | 19 | 52 | 4.859 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: –

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|-------|---|------|--------------------------------------|--------|
| Population (000s)* | 5'619 | Life expectancy at birth (years) ^a | 80 | World Bank income group ^β | High |
| Internet users (%) ^γ | 94.6% | Per capita total health expenditure (PPP Int \$) ^δ | 4720 | GNI per capita (US\$) ^ε | 61'680 |



National policy on health technology

Health technology (medical device) national policy: Yes, but is not part of the National Health Program

Web site: —

Language(s): Danish

MOH responsible for health technology policy implementation: Lægemiddelstyrelsen / Danish Medicines Agency



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Lægemiddelstyrelsen / Danish Medicines Agency

Web site: <http://www.dkma.dk> & www.medicaldevices.dk



National health technology assessment unit

Unit/department: Danish Health and Medicines Authority

Web site: www.sst.dk



National health technology management units

National health technology unit(s): No

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on GMDN (Global Medical Device Nomenclature)

Use: Not specified

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: No

Web site: —

DONATIONS

Policy or guideline: No

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ: —



Inventory and maintenance

Type of inventories available: National inventory for medical equipment

Comments: National Institute of Radiation Protection is in charge. Inventory covers all x-ray equipment, equipment for nuclear medicine and radiation therapy

Medical equipment management unit: Yes

National level = 0

Regional level = 0

Hospital level = 39

Management software: Yes

Software and comments^λ: Several systems: MEDUSA, MERIDA, QAMAP, REMEDY and more



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:

Lists available: No

Unit: —

Web site: —

Lists comments^λ:

There are some more general plans, but no specific medical devices recommended.

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: No list available

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: —

| | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|--------|-----------------------|---------------------------|----------|------------------------------------|



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 3'753 | 128 | 3881 | 69.068 |
| Health centre | n/a | 251 | 251 | 4.467 |
| District hospital | 29 | n/a | 29 | 0.516 |
| Provincial hospital | 23 | n/a | 23 | 0.409 |
| Regional hospital | 5 | n/a | 5 | 0.089 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 56 | 21 | 77 | 13.703 |
| Computerized Tomography Scanner | 125 | 9 | 134 | 23.847 |
| Positron Emission Tomography Scanner | 32 | 1 | 33 | 5.873 |
| Nuclear medicine | 83 | 0 | 83 | 14.771 |
| Mammograph* | 74 | 25 | 99 | 138.443 |
| Linear accelerator | 54 | 0 | 54 | 9.610 |
| Telecobalt unit (Cobalt-60) | 0 | 0 | 0 | 0.000 |
| Radiotherapy | 54 | 0 | 54 | 9.610 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ:

The National Board of Health is issuing some Health Technology Assessments, including but not limited to medical devices. Only a minority of technologies are handled, so this is regarded as being outside the scope of Policy section.

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|-------|---|------|--------------------------------------|--------|
| Population (000s)* | 1'287 | Life expectancy at birth (years) ^a | 77 | World Bank income group ^β | High |
| Internet users (%) ^γ | 80.0% | Per capita total health expenditure (PPP Int \$) ^δ | 1385 | GNI per capita (US\$) ^ε | 17'690 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Health Board, Medical Devices Department

Web site: <http://www.terviseamet.ee/en.html>



National health technology assessment unit

Unit/department: University of Tartu, Department of Public Health

Web site: <http://www.arth.ut.ee/en/health-technology-assessment>



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: —

Web site: —

OTHER: Health Technology Management

Unit/department: Department of Public Health, University of Tartu

Web site: <http://www.arth.ut.ee/>

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Nationally developed Use: Not specified

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: No

Web site: —

DONATIONS

Policy or guideline: No

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ:

Procurement of medical devices is regulated by law, as all other commodities: public procurement law (see <https://www.riigiteataja.ee/ert/act.jsp?id=13191371>)



Inventory and maintenance

Type of inventories available: None

Comments: –

Medical equipment management unit: Yes

National level = 0

Regional level = 0

Hospital level = 0

Management software: No

Software and comments^λ: –

Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^δ

Lists available: Yes

Unit: –

Web site: <https://www.riigiteataja.ee/ert/>

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: For different healthcare facilities and specific proceduresWeb site - facilities: <https://www.riigiteataja.ee/ert/act.jsp?id=13252715>Web site - procedures: <https://www.riigiteataja.ee/ert/act.jsp?id=13252715>

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: –

Types:

| | | | |
|-----------------------|---------------------------|----------|------------------------------------|
| Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|-----------------------|---------------------------|----------|------------------------------------|

Lists comments^λ:Recommended medical devices for specific procedures are described in diagnostic (and treatment) guidelines, what are composed and/or approved by specialists organizations. The list about reimbursed medical devices, used in outpatient conditions, is available on website <https://www.riigiteataja.ee/ert/act.jsp?id=13284086>. Medical devices used inpatient conditions

Healthcare facility

| | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 485 | n/a | 485 | 37.677 |
| Health centre | n/a | n/a | n/a | n/a |
| District hospital | 18 | n/a | 18 | 1.398 |
| Provincial hospital | 4 | n/a | 4 | 0.311 |
| Regional hospital | 3 | n/a | 3 | 0.233 |



Medical equipment

| | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 11 | 0 | 11 | 8.545 |
| Computerized Tomography Scanner | 20 | 0 | 20 | 15.537 |
| Positron Emission Tomography Scanner | 1 | 0 | 1 | 0.777 |
| Nuclear medicine | 3 | 0 | 3 | 2.331 |
| Mammograph [*] | n/a | n/a | n/a | n/a |
| Linear accelerator | 3 | 0 | 3 | 2.331 |
| Telecobalt unit (Cobalt-60) | n/a | n/a | n/a | n/a |
| Radiotherapy | 3 | 0 | 3 | 2.331 |

^{*} Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: –

^{*} UNPD as of 1 July 2012 (2013 update)^α WHO 2012 data^β WB 2014 classification^γ WB 2013 data (2014 update)^δ WHO 2012 data^ε WB 2013 (2014 update)

n/a not applicable

^λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

Finland



Country indicators

| | | | | | |
|---------------------------------|-------|---|------|--------------------------------------|--------|
| Population (000s)* | 5'426 | Life expectancy at birth (years) ^a | 81 | World Bank income group ^β | High |
| Internet users (%) ^γ | 91.5% | Per capita total health expenditure (PPP Int \$) ^δ | 3545 | GNI per capita (US\$) ^ε | 48'820 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: National Supervisory Authority for Welfare and Health

Web site: <http://www.valvira.fi>



National health technology assessment unit

Unit/department: Finohta - Finnish Office for Health Technology Assessment

Web site: <http://finohta.stakes.fi>



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on GMDN (Global Medical Device Nomenclature)

Use: Not specified

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: No

Web site: —

DONATIONS

Policy or guideline: No

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ: —



Inventory and maintenance

Type of inventories available: National inventory for medical equipment

Comments: –

Medical equipment management unit: No

National level = 0

Regional level = 0

Hospital level = 0

Management software: No

Software and comments^λ: –

Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:Lists comments^λ: –

Lists available: No

Unit: –

Web site: –

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES OR SPECIFIC PROCEDURES: Lists available: No list available

Web site - facilities: –

Web site - procedures: –

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: –

| | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|--------|-----------------------|---------------------------|----------|------------------------------------|



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | n/a | 2'200 | 2200 | 40.543 |
| Health centre | 194 | n/a | 194 | 3.575 |
| District hospital | 23 | n/a | 23 | 0.424 |
| Provincial hospital | 17 | 30 | 47 | 0.866 |
| Regional hospital | 5 | n/a | 5 | 0.092 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 86 | n/a | 86 | 15.849 |
| Computerized Tomography Scanner | 109 | n/a | 109 | 20.087 |
| Positron Emission Tomography Scanner | 8 | n/a | 8 | 1.474 |
| Nuclear medicine | 45 | n/a | 45 | 8.293 |
| Mammograph* | 169 | n/a | 169 | 223.200 |
| Linear accelerator | 40 | n/a | 40 | 7.371 |
| Telecobalt unit (Cobalt-60) | 0 | n/a | 0 | 0.000 |
| Radiotherapy | 40 | n/a | 40 | 7.371 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: –

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

France



Country indicators

| | | | | | |
|---------------------------------|--------|---|------|--------------------------------------|--------|
| Population (000s)* | 64'291 | Life expectancy at birth (years) ^a | 82 | World Bank income group ^β | High |
| Internet users (%) ^γ | 81.9% | Per capita total health expenditure (PPP Int \$) ^δ | 4260 | GNI per capita (US\$) ^ε | 43'460 |



National policy on health technology

Health technology (medical device) national policy: Yes, and it is part of the National Health Program/Plan or Policy

Web site: <http://www.sante-sports.gouv.fr/les-dispositifs-medicaux.html>

Language(s): Français

MOH responsible for health technology policy implementation: Direction Générale de la Santé et Direction Générale de l'Offre de Soins



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Agence nationale de sécurité du médicament et des produits de santé

Web site: <http://ansm.sante.fr/>



National health technology assessment unit

Unit/department: Haute Autorité de Santé

Web site: <http://www.has-sante.fr>



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: —

Web site: —

OTHER:

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on GMDN (Global Medical Device Nomenclature)

Use: For regulatory purposes

Nomenclature system name: — Web site: http://www.legifrance.gouv.fr/affichCode.do;jsessionid=3DA99E555F0AB933E0B91227088DB46C.tpdjo04v_3?idSectionTA=LEGISCTA000006190738&cidTexte=LEGITEXT000006072665&dateTexte=20100330



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: No

Web site: —

DONATIONS

Policy or guideline: No

Web site: —

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: Yes

Web site: <http://www.ameli.fr/professionnels-de-sante/fournisseurs-de-biens-medicaux/exercer-au-quotidien/liste-des-produits-et-prestations-lpp/liste-des-produits-et-prestations-lpp/consultation-et-telechargement-de-la-lpp.php>

Medical device incorporation comments^λ: —



Inventory and maintenance

Type of inventories available: —

Comments: —

Medical equipment management unit: Yes

National level = —

Regional level = —

Hospital level = —

Management software: —

Software and comments^λ: —



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^δ

Lists available: Yes

Unit: Ministère chargé de la santé et de la sécurité sociale

Web site: —

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES OR SPECIFIC PROCEDURES: Lists available: For different healthcare facilities and specific procedures

Web site - facilities: <http://www.ameli.fr/professionnels-de-sante/fournisseurs-de-biens-medicaux/exercer-au-quotidien/liste-des-produits-et-prestations-lpp/liste-des-produits-et-prestations-lpp/consultation-et-telechargement-de-la-lpp.php>

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: —

Types:

| |
|-----------------------|
| Communicable diseases |
|-----------------------|

| |
|---------------------------|
| Non-communicable diseases |
|---------------------------|

| |
|----------|
| Injuries |
|----------|

| |
|------------------------------------|
| Public health emergency situations |
|------------------------------------|

Lists comments^λ:

La liste des dispositifs médicaux et prestations pris en charge par l'assurance maladie est accessible à l'adresse suivante:<http://www.ameli.fr/professionnels-de-sante/fournisseurs-de-biens-medicaux/exercer-au-quotidien/liste-des-produits-et-prestations-lpp/liste-des-produits-et-prestations-lpp/consultation-et-telechargement-de-la-lpp.php>



Healthcare facility

| | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | n/a | n/a | n/a | n/a |
| Health centre | n/a | n/a | n/a | n/a |
| District hospital | n/a | n/a | n/a | n/a |
| Provincial hospital | n/a | n/a | n/a | n/a |
| Regional hospital | n/a | n/a | n/a | n/a |



Medical equipment

| | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 325 | 326 | 651 | 10.126 |
| Computerized Tomography Scanner | n/a | n/a | n/a | n/a |
| Positron Emission Tomography Scanner | n/a | n/a | n/a | n/a |
| Nuclear medicine | n/a | n/a | n/a | n/a |
| Mammograph* | n/a | n/a | n/a | n/a |
| Linear accelerator | n/a | n/a | n/a | n/a |
| Telecobalt unit (Cobalt-60) | n/a | n/a | n/a | n/a |
| Radiotherapy | n/a | n/a | n/a | n/a |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ:

Dans cette enquête, nous avons mentionnées la HAS et l'ANSM qui sont deux agences qui sont chargées:

HAS: Agence d'évaluation des dispositifs médicaux, ANSM : Agence nationale de sécurité du médicament qui est chargée de la sécurité sanitaire des dispositifs médicaux

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|-------|---|-----|--------------------------------------|--------------|
| Population (000s)* | 4'341 | Life expectancy at birth (years) ^a | 74 | World Bank income group ^β | Lower-middle |
| Internet users (%) ^γ | 43.1% | Per capita total health expenditure (PPP Int \$) ^δ | 561 | GNI per capita (US\$) ^ε | 3'570 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: State Regulation Agency for Medical Activities, Ministry of Labour, Health and Social Affairs

Web site: <http://rama.moh.gov.ge>



National health technology assessment unit

Unit/department: State Regulation Agency for Medical Activities

Web site: www.rama.moh.gov.ge



National health technology management units

National health technology unit(s): No

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: Yes

Web site: <http://www.moh.gov.ge>

DONATIONS

Policy or guideline: No

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ: —



Inventory and maintenance

Type of inventories available: National inventory only for high cost technologies (such as MRI, CT or PET scanners)

Comments: Nuclear and Radiation Safety Service, Ministry of Environment and Natural Resources

Medical equipment management unit: Yes

National level = 0

Regional level = 0

Hospital level = –

Management software: No

Software and comments^λ: –



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^α:

Lists available: No

Unit: –

Web site: –

Lists comments^λ:

Standards for lists: Governmental decree #153, 2007. Lists available for communicable and non communicable diseases

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: No list available

Web site - facilities: –

Web site - procedures: –

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: One or more

Web site: <http://www.moh.gov.ge>

| | | | | | | | | |
|--------|-----------------------|---|---------------------------|--|----------|--|------------------------------------|---|
| Types: | Communicable diseases | x | Non-communicable diseases | | Injuries | | Public health emergency situations | x |
|--------|-----------------------|---|---------------------------|--|----------|--|------------------------------------|---|



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 498 | 101 | 599 | 13.799 |
| Health centre | n/a | n/a | n/a | n/a |
| District hospital | n/a | n/a | n/a | n/a |
| Provincial hospital | n/a | n/a | n/a | n/a |
| Regional hospital | 93 | 3 | 96 | 2.212 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 0 | n/a | 0 | 0.000 |
| Computerized Tomography Scanner | 0 | 38 | 38 | 8.754 |
| Positron Emission Tomography Scanner | 0 | 0 | 0 | 0.000 |
| Nuclear medicine | 0 | 3 | 3 | 0.691 |
| Mammograph* | 0 | 23 | 23 | 40.743 |
| Linear accelerator | 0 | 3 | 3 | 0.691 |
| Telecobalt unit (Cobalt-60) | 0 | 3 | 3 | 0.691 |
| Radiotherapy | 0 | 6 | 6 | 1.382 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: –

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

Germany



Country indicators

| | | | | | |
|---------------------------------|--------|---|------|--------------------------------------|--------|
| Population (000s)* | 82'727 | Life expectancy at birth (years) ^a | 81 | World Bank income group ^β | High |
| Internet users (%) ^γ | 84.0% | Per capita total health expenditure (PPP Int \$) ^δ | 4617 | GNI per capita (US\$) ^ε | 47'270 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Federal Ministry of Health (BMG) - Unit Medical Devices

Web site: <http://www.bmg.bund.de>



National health technology assessment unit

Unit/department: DAHTA-DIMDI

Web site: <http://www.dimdi.de/static/de/hta/dahta/>



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: n/a

Web site: —

OTHER: —

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on UMDNS (Universal Medical Device Nomenclature System) Use: Not specified

Nomenclature system name: — Web site: <http://www.dimdi.de>



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: —

Web site: —

DONATIONS

Policy or guideline: No

Web site: —

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: —

Web site: —

Medical device incorporation comments^λ: —



Inventory and maintenance

Type of inventories available: None

Comments: —

Medical equipment management unit: Yes

National level = 0

Regional level = 0

Hospital level = 0

Management software: —

Software and comments^λ: —

Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:Lists comments^λ: —

Lists available: No

Unit: —

Web site: —

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES**OR SPECIFIC PROCEDURES:** Lists available: —

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: —

Types:

| | | | |
|-----------------------|---------------------------|----------|------------------------------------|
| Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|-----------------------|---------------------------|----------|------------------------------------|



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | n/a | n/a | n/a | n/a |
| Health centre | n/a | n/a | n/a | n/a |
| District hospital | n/a | n/a | n/a | n/a |
| Provincial hospital | n/a | n/a | n/a | n/a |
| Regional hospital | n/a | n/a | n/a | n/a |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | n/a | n/a | n/a | n/a |
| Computerized Tomography Scanner | n/a | n/a | n/a | n/a |
| Positron Emission Tomography Scanner | n/a | n/a | n/a | n/a |
| Nuclear medicine | n/a | n/a | n/a | n/a |
| Mammograph* | n/a | n/a | n/a | n/a |
| Linear accelerator | n/a | n/a | n/a | n/a |
| Telecobalt unit (Cobalt-60) | n/a | n/a | n/a | n/a |
| Radiotherapy | n/a | n/a | n/a | n/a |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ:

Germany do not complete the whole survey because of their federal system, which will imply to make the whole survey in their 16 states. Regarding the regulations section: they follow the EU system other matters are state competent.

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|--------|---|------|--------------------------------------|--------|
| Population (000s)* | 11'128 | Life expectancy at birth (years) ^a | 81 | World Bank income group ^β | High |
| Internet users (%) ^γ | 59.9% | Per capita total health expenditure (PPP Int \$) ^δ | 2347 | GNI per capita (US\$) ^ε | 22'690 |



National policy on health technology

Health technology (medical device) national policy: Yes, but is not part of the National Health Program

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: National Organization for Medicines

Web site: www.eof.gr



National health technology assessment unit

Unit/department: National Evaluation Center of Quality and Technology in Health-EKAPTY

Web site: www.ekapty.gr



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: National Evaluation Center of Quality and Technology in Health-EKAPTY

Web site: www.ekapty.gr

OTHER: Procurement

Unit/department: Health Procurement Committee

Web site: <http://www.moh.gov.gr/articles/epitroph-promhtheiwn-ygeias>

OTHER: Management of Medical Devices

Unit/department: Ministry of Health, Directorate General for Health Services

Web site: www.moh.gov.gr



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on GMDN (Global Medical Device Nomenclature)

Use: Not specified

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: —

National level procurement: No

Web site: —

DONATIONS

Policy or guideline: Yes

Web site: www.eof.gr

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: Yes

Web site: <http://specs.ekevyl.gr/>

Medical device incorporation comments^λ:

EU Directive for public procurement and national specific legislation for health procurement (law 3580/2007). A part of procurement of medical devices is carried out at the national level, by the Health Procurement Committee.



Inventory and maintenance

Type of inventories available: National inventory only for high cost technologies (such as MRI, CT or PET scanners)

Comments: Greek Atomic Energy Commission (www.eeae.gr)

Medical equipment management unit: Yes

National level = —

Regional level = —

Hospital level = —

Management software: Yes

Software and comments^λ: "Praxis" developed by INBIT, is a specific one. Also are used other, asset management, software.



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:

Lists comments^λ: —

Lists available: No

Unit: —

Web site: —

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: No list available

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: —

Web site: —

| | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|--------|-----------------------|---------------------------|----------|------------------------------------|



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | n/a | n/a | n/a | n/a |
| Health centre | n/a | n/a | n/a | n/a |
| District hospital | n/a | n/a | n/a | n/a |
| Provincial hospital | n/a | n/a | n/a | n/a |
| Regional hospital | n/a | n/a | n/a | n/a |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 32 | 213 | 245 | 22.017 |
| Computerized Tomography Scanner | 120 | 249 | 369 | 33.160 |
| Positron Emission Tomography Scanner | 2 | 3 | 5 | 0.449 |
| Nuclear medicine | 50 | 110 | 160 | 14.378 |
| Mammograph* | 135 | 483 | 618 | 438.350 |
| Linear accelerator | 25 | 14 | 39 | 3.505 |
| Telecobalt unit (Cobalt-60) | 8 | 1 | 9 | 0.809 |
| Radiotherapy | 33 | 15 | 48 | 4.313 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: —

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

Hungary



Country indicators

| | | | | | |
|---------------------------------|-------|---|------|--------------------------------------|--------------|
| Population (000s)* | 9'955 | Life expectancy at birth (years) ^a | 75 | World Bank income group ^β | Upper-middle |
| Internet users (%) ^γ | 72.6% | Per capita total health expenditure (PPP Int \$) ^δ | 1729 | GNI per capita (US\$) ^ε | 13'260 |



National policy on health technology

Health technology (medical device) national policy: Yes, and it is part of the National Health Program/Plan or Policy

Web site: <http://www.eum.hu/biztonsag-partnerseg/biztonsag-partnerseg-pdf-080717>

Language(s): Hungarian

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Office of Health Authorisation and Administrative Procedures - Authority for Medical Devices

Web site: http://www.eekh.hu/en/index.php?option=com_content&task=blogcategory&id=14&Itemid=28



National health technology assessment unit

Unit/department: National Institute for Strategic Health Research - Office of Health Technology Assessment

Web site: <http://www.eski.hu/> www.ogyei.gov.hu



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: National Health Insurance Fund - Departement of Benefits In kind

Web site: <http://www.oep.hu>

OTHER: —

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Nationally developed Use: Not specified

Nomenclature system name: ORKI-kód (ORKI CODING) Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=99300009.NM

National level procurement: Yes

Web site: <http://www.oep.hu>

DONATIONS

Policy or guideline: No

Web site: —

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ:

For procurement guidelines see the "Decree of the Minister of Welfare (No. 9/1993 NM) on the specific aspects of financing of healthcare insurance services.

In respect of certain medical devices procured at national level over a certain amount, procurement is carried out by the Central Services Directorate General of the Prime Minister's Office. In the remaining cases hospitals procure medical devices subject to itemized accounting (see first list in the file uploaded under question 3.4.1, but with exception of pacemakers, heart valves, cochlear implants)



Inventory and maintenance

Type of inventories available: National inventory only for high cost technologies (such as MRI, CT or PET scanners)

Comments: Under high cost we mean amounts exceeding EUR 400. Unfortunately the catastro is not a public registry. Access is ensured only for data providers, manufacturers and conformity assessment bodies.

Medical equipment management unit: No

National level = 0

Regional level = 0

Hospital level = 0

Management software: Yes

Software and comments^λ: Most of the public institutions use the software CT-EcoSTAT



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:

Lists available: Yes

Unit: National Health Insurance Fund / Central Services Directorate General of the Prime Minister's Office, respectively

Web site: —

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES OR SPECIFIC PROCEDURES: Lists available: For different healthcare facilities and specific procedures

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: One or more

Web site: http://www.antsz.hu/portal/down/kulso/aktualis/ujinfluenza/7_sz_melleklet_20090810.pdf http://www.antsz.hu/portal/down/kulso/aktualis/ujinfluenza/4_sz_melleklet_20090810.pdf http://www.antsz.hu/portal/down/kulso/aktualis/ujinfluenza/8_sz_melleklet_20090810.pdf

Types: Communicable diseases Non-communicable diseases Injuries Public health emergency situations

Lists comments^λ:

The uploaded ministerial decree lays down the minimum requirements for the provision of healthcare services. The criteria are equally specified for healthcare facilities (1.2.1) and the specific procedures. This is why we have uploaded the document only once (available in Hungarian). The assigned URLs contain protocols for pandemic situation according to the National



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 577 | n/a | 577 | 5.796 |
| Health centre | 11 | n/a | 11 | 0.110 |
| District hospital | 74 | n/a | 74 | 0.743 |
| Provincial hospital | 17 | n/a | 17 | 0.171 |
| Regional hospital | 11 | n/a | 11 | 0.110 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 13 | 1 | 14 | 1.406 |
| Computerized Tomography Scanner | 62 | 4 | 66 | 6.630 |
| Positron Emission Tomography Scanner | 3 | 3 | 6 | 0.603 |
| Nuclear medicine | 102 | 0 | 102 | 10.246 |
| Mammograph* | 99 | 43 | 142 | 103.554 |
| Linear accelerator | 11 | 0 | 11 | 1.105 |
| Telecobalt unit (Cobalt-60) | 6 | 1 | 7 | 0.703 |
| Radiotherapy | 17 | 1 | 18 | 1.808 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ:

Concerning HT policies: "Safety and Partnership Program" - a health program adopted by the Hungarian government on 9 July 2008 - the acceptance of medical devices and health technologies into the social insurance scheme was defined in...

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|-------|---|------|--------------------------------------|--------|
| Population (000s)* | 330 | Life expectancy at birth (years) ^a | 82 | World Bank income group ^β | High |
| Internet users (%) ^γ | 96.5% | Per capita total health expenditure (PPP Int \$) ^δ | 3436 | GNI per capita (US\$) ^ε | 46'400 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Directorate of Health

Web site: <http://www.landlaeknir.is/>



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): No

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: No

Web site: —

DONATIONS

Policy or guideline: No

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ: —



Inventory and maintenance

Type of inventories available: None

Comments: –

Medical equipment management unit: Yes

National level = 0

Regional level = 0

Hospital level = 1

Management software: Yes

Software and comments^λ: It is an institutional equipment, hospital private

Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^α:

Lists available: No

Unit: –

Web site: –

Lists comments^λ:

Only CE market Medical Devices are approved.

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: No list available

Web site - facilities: –

Web site - procedures: –

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: –

| | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|--------|-----------------------|---------------------------|----------|------------------------------------|



Healthcare facility

| | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 57 | n/a | 57 | 17.297 |
| Health centre | 6 | n/a | 6 | 1.821 |
| District hospital | 7 | n/a | 7 | 2.124 |
| Provincial hospital | 3 | n/a | 3 | 0.910 |
| Regional hospital | 2 | n/a | 2 | 0.607 |



Medical equipment

| | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 3 | 4 | 7 | 21.242 |
| Computerized Tomography Scanner | 9 | 4 | 13 | 39.450 |
| Positron Emission Tomography Scanner | 0 | 0 | 0 | 0.000 |
| Nuclear medicine | 3 | 1 | 4 | 12.138 |
| Mammograph* | 0 | 5 | 5 | 139.012 |
| Linear accelerator | 2 | 0 | 2 | 6.069 |
| Telecobalt unit (Cobalt-60) | 0 | 0 | 0 | 0.000 |
| Radiotherapy | 2 | 0 | 2 | 6.069 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: –

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|-------|---|------|--------------------------------------|--------|
| Population (000s)* | 4'627 | Life expectancy at birth (years) ^a | 81 | World Bank income group ^β | High |
| Internet users (%) ^γ | 78.2% | Per capita total health expenditure (PPP Int \$) ^δ | 3529 | GNI per capita (US\$) ^ε | 43'110 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Irish Medicines Board

Web site: <http://www.imb.ie>



National health technology assessment unit

Unit/department: Health Information and Quality Authority

Web site: <http://www.hiqa.ie/>



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: HSE/Procurement, Portfolio & Category Management

Web site: <http://www.hse.ie>

OTHER: —

Unit/department: —

Web site: —

OTHER: Medical Equipment Management Policy

Unit/department: Health Service Executive

Web site: <http://www.hse.ie>



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on GMDN (Global Medical Device Nomenclature)

Use: Not specified

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: <http://www.hse.ie/eng/>

National level procurement: Yes

Web site: <http://www.hse.ie/eng/about/Procurement/Contactus/>

DONATIONS

Policy or guideline: Yes

Web site: <http://www.hse.ie>

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: Yes, but not publically available

Web site: —

Medical device incorporation comments^λ:

Portfolio & Category Management approach involves development of medical devices/equipment procurement strategies at national level and facilitating regional and local decision making consistent with these strategies and accompanying procedures. Go to website and search for: [services/Publications/corporate/procurementpolicy.pdf](#)



Inventory and maintenance

Type of inventories available: —

Comments: No national inventories available to date. Inventories of medical equipment (including functional inventories) are maintained at a local level. Often there are separate asset management and medical equipment management inventories. There is now an initiative to compile this data into regional/national inventories in the near future.

Medical equipment management unit: Yes

National level = 1

Regional level = 4

Hospital level = 25

Management software: Yes

Software and comments^λ: No common software - a variety of systems including HEX, SAP, MS Access are employed



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^α:

Lists available: Yes

Unit: There is a list in operation for Primary Care Reimbursement.

Web site: —

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES OR SPECIFIC PROCEDURES^β: Lists available: For different healthcare facilities

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS^γ:

Lists available: One or more

Web site: —

Types:

| | | | |
|-----------------------|---------------------------|----------|------------------------------------|
| Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|-----------------------|---------------------------|----------|------------------------------------|

 x

Lists comments^λ:

Hospital Equipping System has an inventory of standard rooms e.g. Emergency Department Resuscitation Room with schedule of associated equipment required to operate. There are also several National Framework Agreement contracts for the supply of medical devices/equipment. List of reimbursable devices from PCRS available at www.pcrs.ie -> online services -> list of reimbursable



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | n/a | n/a | n/a | n/a |
| Health centre | n/a | n/a | n/a | n/a |
| District hospital | n/a | n/a | n/a | n/a |
| Provincial hospital | n/a | n/a | n/a | n/a |
| Regional hospital | n/a | n/a | n/a | n/a |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 9 | n/a | 9 | 1.945 |
| Computerized Tomography Scanner | 21 | n/a | 21 | 4.538 |
| Positron Emission Tomography Scanner | 2 | n/a | 2 | 0.432 |
| Nuclear medicine | 14 | n/a | 14 | 3.026 |
| Mammograph* | 11 | n/a | 11 | 23.195 |
| Linear accelerator | 17 | n/a | 17 | 3.674 |
| Telecobalt unit (Cobalt-60) | 1 | n/a | 1 | 0.216 |
| Radiotherapy | 18 | n/a | 18 | 3.890 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^δ:

Concerning infrastructure section: the breakdown of infrastructures does not match to our public sector.

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|-------|---|------|--------------------------------------|--------|
| Population (000s)* | 7'733 | Life expectancy at birth (years) ^a | 82 | World Bank income group ^β | High |
| Internet users (%) ^γ | 70.8% | Per capita total health expenditure (PPP Int \$) ^δ | 2239 | GNI per capita (US\$) ^ε | 33'930 |



National policy on health technology

Health technology (medical device) national policy: Yes, and it is part of the National Health Program/Plan or Policy

Web site: —

Language(s): Hebrew

MOH responsible for health technology policy implementation: Medical Device department within the Medical Technology Administration



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: medical device department

Web site: <http://www.health.gov.il/English/Pages/HomePage.aspx>



National health technology assessment unit

Unit/department: Medical devices dept.

Web site: —



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: —

Web site: —

OTHER: Planning of medical equipment allocation/HTA

Unit/department: Medical Technology Administration

Web site: —

OTHER: HTA

Unit/department: Division of medical technology

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on UMDNS (Universal Medical Device Nomenclature System) Use: Not specified

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: No

Web site: —

DONATIONS

Policy or guideline: No

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: Yes

Web site: —

Medical device incorporation comments^λ:

Technical specifications available only in hardcopy.



Inventory and maintenance

Type of inventories available: National inventory only for high cost technologies (such as MRI, CT or PET scanners)

Comments: —

Medical equipment management unit: Yes

National level = 0

Regional level = 0

Hospital level = 0

Management software: Yes

Software and comments^λ: locally developed



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^δ

Lists comments^λ:

Lists available: Yes

Standards and lists are in the Israeli legislation. List for procurement/reimbursement It is part of the National Insurance Law

Unit: Medical Technology Administration

Web site: —

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: For different healthcare facilities and specific procedures

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: —

| | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|--------|-----------------------|---------------------------|----------|------------------------------------|



Healthcare facility

| | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | n/a | n/a | n/a | n/a |
| Health centre | n/a | 1 | 1 | 0.013 |
| District hospital | n/a | n/a | n/a | n/a |
| Provincial hospital | 28 | 9 | 37 | 0.478 |
| Regional hospital | 6 | n/a | 6 | 0.078 |



Medical equipment

| | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 9 | 1 | 10 | 1.293 |
| Computerized Tomography Scanner | 49 | 9 | 58 | 7.500 |
| Positron Emission Tomography Scanner | 5 | 1 | 6 | 0.776 |
| Nuclear medicine | 69 | 11 | 80 | 10.345 |
| Mammograph [*] | 38 | 42 | 80 | 112.266 |
| Linear accelerator | 24 | 1 | 25 | 3.233 |
| Telecobalt unit (Cobalt-60) | 1 | 0 | 1 | 0.129 |
| Radiotherapy | 25 | 1 | 26 | 3.362 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ:

All the divisions and departments mentioned in this survey are part of the Medical Technology Administration of the Ministry of Health in Israel. The Administration is in charge of the regulation, licencing and policy making regarding all medical technologies in Israel (including medical devices).

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|--------|---|------|--------------------------------------|--------|
| Population (000s)* | 60'990 | Life expectancy at birth (years) ^a | 83 | World Bank income group ^β | High |
| Internet users (%) ^γ | 58.5% | Per capita total health expenditure (PPP Int \$) ^δ | 3040 | GNI per capita (US\$) ^ε | 35'860 |



National policy on health technology

Health technology (medical device) national policy: Yes, and it is part of the National Health Program/Plan or Policy

Web site: <http://www.salute.gov.it/dispositivi/paginaMenu.jsp?menu=tecnologie&lingua=italiano>

Language(s): Italian and English

MOH responsible for health technology policy implementation: Directorate General of Medicines and Medical Devices, Department of Innovation, Ministry of Health



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Directorate General for Medical Devices, Pharmaceutical Services and Safety in Healthcare, Department of Planning and Organization of the National Health Service, Ministry of Health

Web site: <http://www.salute.gov.it/dispositivi/dispomed.jsp>



National health technology assessment unit

Unit/department: AIFA, AGENAS

Web site: www.aifa.gov.it www.agenas.it



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: Directorate General for Medical Devices

Web site: <http://www.salute.gov.it/dispositivi/dispomed.jsp>

OTHER: Application/user training

Unit/department: Directorate General for Medical Devices

Web site: <http://www.salute.gov.it/dispositivi/dispomed.jsp>

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Nationally developed Use: For regulatory purposes and procurement

Nomenclature system name: CND Classificazione Nazionale dei Dispositivi Medici (correlated with GMDN)

Web site: <http://www.salute.gov.it/dispositivi/paginainterna.jsp?id=328&menu=strumentieservizi>



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: <http://www.salute.gov.it/dispositivi/dispomed.jsp>

National level procurement: No

Web site: —

DONATIONS

Policy or guideline: No

Web site: —

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: Yes

Web site: http://www.who.int/medical_devices/survey_resources/medical_device_technical_specifications_italy_1.pdf AND http://www.who.int/medical_devices/survey_resources/medical_device_technical_specifications_italy_2.pdf

http://www.who.int/medical_devices/survey_resources/medical_device_technical_specifications_italy_3.pdf

Medical device incorporation comments^Λ:

Go to the website and look for: [dispositivi/dispomed.jsp](http://www.salute.gov.it/dispositivi/dispomed.jsp) documents.



Inventory and maintenance

Type of inventories available: National inventory for medical equipment

Comments: –

Medical equipment management unit: Yes

National level = 0

Regional level = 0

Hospital level = 0

Management software: Yes

Software and comments^λ: more than one



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^δ:

Lists available: Yes

Unit: Directorate General of Health Programme

Web site: http://www.who.int/medical_devices/survey_resources/medical_devices_for_procurement_reimbursement_italy_1.pdf http://www.who.int/medical_devices/survey_resources/medical_devices_for_procurement_reimbursement_italy_2.pdf http://www.who.int/medical_devices/survey_resources/medical_devices_for_procurement_reimbursement_italy_3.pdf

Lists comments^λ:

Documents available at:
<http://www.salute.gov.it/programmazioneSanitariaELea/>

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: No list available

Web site - facilities: –

Web site - procedures: –

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: –

| | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|--------|-----------------------|---------------------------|----------|------------------------------------|



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | n/a | n/a | n/a | n/a |
| Health centre | n/a | n/a | n/a | n/a |
| District hospital | 17 | 50 | 67 | 0.110 |
| Provincial hospital | 554 | 561 | 1115 | 1.828 |
| Regional hospital | 84 | n/a | 84 | 0.138 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | n/a | n/a | n/a | n/a |
| Computerized Tomography Scanner | n/a | n/a | n/a | n/a |
| Positron Emission Tomography Scanner | n/a | n/a | n/a | n/a |
| Nuclear medicine | n/a | n/a | n/a | n/a |
| Mammograph* | n/a | n/a | n/a | n/a |
| Linear accelerator | n/a | n/a | n/a | n/a |
| Telecobalt unit (Cobalt-60) | n/a | n/a | n/a | n/a |
| Radiotherapy | n/a | n/a | n/a | n/a |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: –

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|--------|---|-----|--------------------------------------|--------------|
| Population (000s)* | 16'441 | Life expectancy at birth (years) ^a | 68 | World Bank income group ^β | Upper-middle |
| Internet users (%) ^γ | 54.0% | Per capita total health expenditure (PPP Int \$) ^δ | 608 | GNI per capita (US\$) ^ε | 11'550 |



National policy on health technology

Health technology (medical device) national policy: Yes, and it is part of the National Health Program/Plan or Policy

Web site: —

Language(s): Russian

MOH responsible for health technology policy implementation: Department of medical and pharmaceutical activity monitoring (MoH)



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: National Centre for Medicines, Medical Devices, and Medical Equipment Expertise

Web site: <http://dari.kz/category/mainpage>



National health technology assessment unit

Unit/department: Department of Medical Care

Web site: www.rcrz.kz



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: SK-Ltd Pharmacy

Web site: <http://www.sk-p.kz>

OTHER: Planning of medical equipment allocation/HTA/development of technical specifications/training/lease

Unit/department: AO Kazmedteh

Web site: <http://www.kmtlc.kz>

OTHER: Maintenance of the register/HTA

Unit/department: RSE: National Centre of Drugs

Web site: <http://www.dari.kz>



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Nationally developed Use: Not specified

Nomenclature system name: Medical State Register of Iekarstennyh Web site: <http://dari.kz>



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: —

National level procurement: Yes

Web site: <http://www.mz.gov.kz/en>

DONATIONS

Policy or guideline: No

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: Yes

Web site: <http://www.mz.gov.kz/en>

Medical device incorporation comments^λ:

Procurement at national level with the register of procurement of medical equipment. We have the National Register of medical devices



Inventory and maintenance

Type of inventories available: —

Comments: Medical State Register of lekarstennyh

Medical equipment management unit: Yes

National level = —

Regional level = —

Hospital level = —

Management software: Yes

Software and comments^λ: AIS-TEP program



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^α:

Lists available: Yes, but is only a recommendation

Unit: RSE

Web site: —

Lists comments^λ:

For list of approved medical devices for procurement we have the Medical State Register of lekarstennyh

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: —

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: —

Web site: —

| | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|--------|-----------------------|---------------------------|----------|------------------------------------|



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 3'668 | 16 | 3684 | 22.408 |
| Health centre | n/a | n/a | n/a | n/a |
| District hospital | 319 | 8 | 327 | 1.989 |
| Provincial hospital | 123 | 101 | 224 | 1.362 |
| Regional hospital | 27 | n/a | 27 | 0.164 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 18 | n/a | 18 | 1.095 |
| Computerized Tomography Scanner | 24 | n/a | 24 | 1.460 |
| Positron Emission Tomography Scanner | 1 | n/a | 1 | 0.061 |
| Nuclear medicine | 1 | n/a | 1 | 0.061 |
| Mammograph* | 34 | n/a | 34 | 22.101 |
| Linear accelerator | 7 | n/a | 7 | 0.426 |
| Telecobalt unit (Cobalt-60) | 15 | n/a | 15 | 0.912 |
| Radiotherapy | 22 | n/a | 22 | 1.338 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ:

Concerning the Infrastructure section: the division for 20 beds on health centers is not applicable for Kazakhstan centers network.

* UNPD as of 1 July 2012 (2013 update)

^α WHO 2012 data

^β WB 2014 classification

^γ WB 2013 data (2014 update)

^δ WHO 2012 data

^ε WB 2013 (2014 update)

n/a not applicable

^λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|-------|---|-----|--------------------------------------|--------------|
| Population (000s)* | 5'548 | Life expectancy at birth (years) ^a | 69 | World Bank income group ^β | Lower-middle |
| Internet users (%) ^γ | 23.4% | Per capita total health expenditure (PPP Int \$) ^δ | 175 | GNI per capita (US\$) ^ε | 1'210 |



National policy on health technology

Health technology (medical device) national policy: Yes, and it is part of the National Health Program/Plan or Policy

Web site: —

Language(s): Russian

MOH responsible for health technology policy implementation: Department of Drug Provision and Medical Equipment of Ministry of Health of the Kyrgyz Republic



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Department of Drug Provision and Medical Equipment, under the Ministry of Health of the Kyrgyz Republic

Web site: <http://www.pharm.med.kg>



National health technology assessment unit

Unit/department: Medical Equipment Committee Department of Drug Provision and Medical Equipment, Ministry of Health of the Kyrgyz Republic

Web site: <http://www.pharm.kg>



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: Department of Drug Provision and medical Equipment (DDPME), MOH

Web site: <http://www.pharm.kg>

OTHER: Planning of medical equipment allocation

Unit/department: Ministry of Health

Web site: <http://www.med.kg>

OTHER: Procurement of medical the equipment

Unit/department: Ministry of Health

Web site: <http://www.med.kg>



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on UMDNS (Universal Medical Device Nomenclature System) Use: Not specified

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: —

National level procurement: Yes

Web site: <http://www.med.kg>

DONATIONS

Policy or guideline: Yes

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ:

Kyrgyz Republic National Health Care Reform Program "Manas taalimi". Procurements carry out through the National (budget) or donor projects



Inventory and maintenance

Type of inventories available: National inventory for medical equipment, National functional inventory for medical equipment

Comments: The National Register for Medical Equipment and the National Functional Register for Medical Equipment The National Functional Register for the Medical Equipment is database for medical facilities of the public health institutions; The National Register of the Medical Equipment is National list of pharmaceuticals and medical equipment authorized/registered for utilization in the Kyrgyz Republic

Medical equipment management unit: No

National level = 0

Regional level = 0

Hospital level = 0

Management software: Yes

Software and comments^λ: Database for material and technical facilities/medical facilities of public health intuitions



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:

Lists available: Yes

Unit: Department of Drug Provision and Medical Equipment Ministry of Health of the Kyrgyz Republic

Web site: www.pharm.kg

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES OR SPECIFIC PROCEDURES: Lists available: For different healthcare facilities

Web site - facilities: http://www.who.int/medical_devices/survey_resources/medical_devices_by_facility_kyrgyzstan.pdf

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: One or more

Web site: —

Types:

| | | | | | | | |
|-----------------------|---|---------------------------|--|----------|--|------------------------------------|---|
| Communicable diseases | x | Non-communicable diseases | | Injuries | | Public health emergency situations | x |
|-----------------------|---|---------------------------|--|----------|--|------------------------------------|---|

Lists comments^λ:

Standards: The law on the Health Care institutions. We have lists for communicable diseases, and public health emergency situations, as well as clinical protocols. The register registered medical equipment on web-site Department of Drug Provision and Medical Equipment MoH of the Kyrgyz Republic



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 948 | n/a | 948 | 17.089 |
| Health centre | n/a | n/a | n/a | n/a |
| District hospital | 99 | n/a | 99 | 1.785 |
| Provincial hospital | 8 | n/a | 8 | 0.144 |
| Regional hospital | 39 | n/a | 39 | 0.703 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 2 | 3 | 5 | 0.901 |
| Computerized Tomography Scanner | 2 | 3 | 5 | 0.901 |
| Positron Emission Tomography Scanner | n/a | n/a | n/a | n/a |
| Nuclear medicine | 4 | n/a | 4 | 0.721 |
| Mammograph* | 6 | n/a | 6 | 16.449 |
| Linear accelerator | n/a | n/a | n/a | n/a |
| Telecobalt unit (Cobalt-60) | n/a | n/a | n/a | n/a |
| Radiotherapy | n/a | n/a | n/a | n/a |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ:

Concerning HT national policy we provide the following doc.: [257 Саламатты Казахстан.htm](#)

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|-------|---|------|--------------------------------------|--------|
| Population (000s)* | 2'050 | Life expectancy at birth (years) ^a | 74 | World Bank income group ^β | High |
| Internet users (%) ^γ | 75.2% | Per capita total health expenditure (PPP Int \$) ^δ | 1188 | GNI per capita (US\$) ^ε | 15'280 |



National policy on health technology

Health technology (medical device) national policy: Yes, but is not part of the National Health Program

Web site: <http://www.likumi.lv/>

Language(s): Latvian

MOH responsible for health technology policy implementation: Regulation of Cabinet of Ministers No 581 (adopted 02.08.2005)



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: State Agency of Medicines

Web site: <http://www.zva.gov.lv>



National health technology assessment unit

Unit/department: State Agency of Medicines

Web site: <http://www.zva.gov.lv>



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: Health Payment Center

Web site: <http://www.vnc.gov.lv>

OTHER: Planning of medical equipment allocation/HTA

Unit/department: Centre of Health Economics

Web site: <http://www.vec.gov.lv>

OTHER: Supervision of medical devices, market and exploit/Application/User training

Unit/department: Health Inspectorate

Web site: <http://www.vi.gov.lv>



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on GMDN (Global Medical Device Nomenclature)

Use: Not specified

Nomenclature system name: — Web site: <http://www.zva.gov.lv>



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: Yes

Web site: <http://www.vnc.gov.lv>

DONATIONS

Policy or guideline: No

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ:

Procurement of national devices at national level started from year 2010



Inventory and maintenance

Type of inventories available: None

Comments: –

Medical equipment management unit: Yes

National level = 0

Regional level = 0

Hospital level = 0

Management software: –

Software and comments^λ: –

Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^α

Lists available: No

Unit: –

Web site: –

Lists comments^λ:

Standards: Regulation of Cabinet of Ministers No 60 (adopted 20.01.2009). We have lists for public health emergency situations.

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: For different healthcare facilities and specific proceduresWeb site - facilities: <http://www.likumi.lv/doc.php?id=187621>Web site - procedures: <http://www.likumi.lv/doc.php?id=187621>

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: One or more

Web site: <http://www.mk.gov.lv/lv/mk/tap/?pid=302117018mode=mk&date>

Types:

Communicable diseases

Non-communicable diseases

Injuries

Public health emergency situations

x



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | n/a | n/a | n/a | n/a |
| Health centre | 31 | n/a | 31 | 1.512 |
| District hospital | 10 | n/a | 10 | 0.488 |
| Provincial hospital | 7 | n/a | 7 | 0.341 |
| Regional hospital | 15 | n/a | 15 | 0.732 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | n/a | n/a | n/a | n/a |
| Computerized Tomography Scanner | n/a | n/a | n/a | n/a |
| Positron Emission Tomography Scanner | 0 | 0 | 0 | 0.000 |
| Nuclear medicine | n/a | n/a | n/a | n/a |
| Mammograph [*] | n/a | n/a | n/a | n/a |
| Linear accelerator | n/a | n/a | n/a | n/a |
| Telecobalt unit (Cobalt-60) | n/a | n/a | n/a | n/a |
| Radiotherapy | n/a | n/a | n/a | n/a |

^{*} Density per 1,000,000 females aged from 50-69 old.Additional information and comments^λ: –^{*} UNPD as of 1 July 2012 (2013 update)^α WHO 2012 data^β WB 2014 classification^γ WB 2013 data (2014 update)^δ WHO 2012 data^ε WB 2013 (2014 update)

n/a not applicable

^λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|-------|---|------|--------------------------------------|--------|
| Population (000s)* | 3'017 | Life expectancy at birth (years) ^a | 74 | World Bank income group ^β | High |
| Internet users (%) ^γ | 68.5% | Per capita total health expenditure (PPP Int \$) ^δ | 1426 | GNI per capita (US\$) ^ε | 14'900 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: State Health Care Accreditation Agency under the Ministry of Health of the Republic of Lithuania

Web site: www.vaspvt.gov.lt



National health technology assessment unit

Unit/department: Medical Technology Division of State Health Care Accreditation Agency under the Ministry of Health

Web site: <http://www.vaspvt.gov.lt/en/node/270> <http://www.vaspvt.gov.lt/en/node/276>



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: Health Technology Assessment and Innovation Division of the Ministry of Health (Division starts from 1st, January, 2014).

Web site: <http://www.sam.lt>

OTHER: Market surveillance activities/registration of medical devices/in vitro diagnostic medical devices and medical devices of IIB and III class

Unit/department: Medical Devices Market Surveillance Division of State Health Care Accreditation Agency under the Ministry of Health

Web site: <http://www.vaspvt.gov.lt/en/node/275>

OTHER: Planning of medical equipment allocation/HTA/development of technical specifications

Unit/department: Health Technology Assessment and Innovation Division of the Ministry of Health (Division starts from 1st, January, 2014).

Web site: <http://www.sam.lt>



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=448409&p_query=&p_tr2=2 and http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=443967&p_query=&p_tr2=2

National level procurement: Yes

Web site: —

DONATIONS

Policy or guideline: Yes

Web site: http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=228695&p_query=&p_tr2=

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: Yes

Web site: http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=309940

Medical device incorporation comments^Λ:

Guidelines for procurement of expensive health technologies (i.e. MRI, CT etc.). Guidelines are in Lithuanian language only. Basic requirements for technical specification of medical devices, that are procured in a public centralized way.



Inventory and maintenance

Type of inventories available: National inventory only for high cost technologies (such as MRI, CT or PET scanners)

Comments: State Health Care Accreditation Agency under the Ministry of Health is responsible for the management of national data regarding expensive health technologies (i.e. MRI, CT, ec.).

Medical equipment management unit: Yes

National level = 1

Regional level = 0

Hospital level = 0

Management software: No

Software and comments^λ: –



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:

Lists available: Yes

Unit: Public Procurement Office operating under the Ministry of Economy.

Web site: –

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: For different healthcare facilities and specific procedures

Web site - facilities: http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=293780&p_query=&p_tr2=

Web site - procedures: http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=258027

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: One or more

Web site: http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=51602&p_query=&p_tr2= http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=419488&p_query=&p_tr2=2 http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=398965&p_query=&p_tr2=2

Types:

Communicable diseases

Non-communicable diseases

x

Injuries

Public health emergency situations

Lists comments^λ:

Licensing regulations for health care facilities. General and specific requirements for institutional health care services. There is a list of medical devices that are mandatory for specialized and surgical health care services. These are lists of indications and reimbursement regulations for expensive health technology (e.g. CT, MRI) examination techniques and diagnostic procedures



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 634 | n/a | 634 | 21.015 |
| Health centre | 358 | 642 | 1000 | 33.146 |
| District hospital | 50 | n/a | 50 | 1.657 |
| Provincial hospital | n/a | n/a | 0 | 0.000 |
| Regional hospital | 15 | n/a | 15 | 0.497 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 19 | 8 | 27 | 8.949 |
| Computerized Tomography Scanner | 57 | 4 | 61 | 20.219 |
| Positron Emission Tomography Scanner | 1 | 0 | 1 | 0.331 |
| Nuclear medicine | 9 | 0 | 9 | 2.983 |
| Mammograph* | 28 | 5 | 33 | 82.526 |
| Linear accelerator | 11 | 0 | 11 | 3.646 |
| Telecobalt unit (Cobalt-60) | 0 | 0 | 0 | 0.000 |
| Radiotherapy | 11 | 0 | 11 | 3.646 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: –

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|-------|---|------|--------------------------------------|--------|
| Population (000s)* | 530 | Life expectancy at birth (years) ^a | 82 | World Bank income group ^β | High |
| Internet users (%) ^γ | 93.8% | Per capita total health expenditure (PPP Int \$) ^δ | 6341 | GNI per capita (US\$) ^ε | 69'900 |



National policy on health technology

Health technology (medical device) national policy: Yes, but is not part of the National Health Program

Web site: <http://www.ms.public.lu/fr/activites/structures-soins-et-professionnels-sante/prevention-infection-nosocom/dispositifs-medicaux/index.html> ET <http://www.legilux.lu/leg/a/archives/2009/0054/a054.pdf>

Language(s): —

MOH responsible for health technology policy implementation: Division de la Médecine curative et Division de la Radioprotection



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Ministère de la santé

Web site: <http://www.ms.public.lu/fr/activites/structures-soins-et-professionnels-sante/prevention-infection-nosocom/dispositifs-medicaux/index.html>



National health technology assessment unit

Unit/department: Cellule d'expertise Médicale: CEM

Web site: <http://www.mss.public.lu/acteurs/igss/cem/index.html>



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: —

Web site: —

OTHER: Planning of medical equipment allocation/Application/user training

Unit/department: Division de la Radioprotection

Web site: —

OTHER: Planning of medical equipment allocation

Unit/department: Division de la Médecine curative

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: No

Web site: —

DONATIONS

Policy or guideline: No

Web site: —

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ: —



Inventory and maintenance

Type of inventories available: National inventory only for high cost technologies (such as MRI, CT or PET scanners)

Comments: –

Medical equipment management unit: Yes

National level = 0

Regional level = 0

Hospital level = 6

Management software: Yes

Software and comments^λ: software choisi par chaque hôpital individuellement



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^α

Lists available: No

Unit: –

Web site: –

Lists comments^λ:

Nous avons des listes dans les cas d'urgence de Santé Publique: Contenus notamment dans le plan pandémie grippale qui n'est pas sur l'internet public.

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: For specific procedures

Web site - facilities: –

Web site - procedures: <http://www.sante.public.lu/publications/rester-bonne-sante/cancer-prevention-depistage/guide-bonnes-pratiques-programme-mammographie/guide-bonnes-pratiques-programme-mammographie.pdf>

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: One or more

Web site: –

| | | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|---|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations | x |
|--------|-----------------------|---------------------------|----------|------------------------------------|---|



Healthcare facility

| | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | n/a | n/a | n/a | n/a |
| Health centre | n/a | n/a | n/a | n/a |
| District hospital | n/a | 1 | 1 | 0.189 |
| Provincial hospital | n/a | 1 | 1 | 0.189 |
| Regional hospital | 3 | 1 | 4 | 0.754 |



Medical equipment

| | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 5 | 2 | 7 | 13.198 |
| Computerized Tomography Scanner | 7 | 3 | 10 | 18.854 |
| Positron Emission Tomography Scanner | 1 | 0 | 1 | 1.885 |
| Nuclear medicine | 4 | 5 | 9 | 16.969 |
| Mammograph* | 7 | 3 | 10 | 168.302 |
| Linear accelerator | 2 | 0 | 2 | 3.771 |
| Telecobalt unit (Cobalt-60) | 0 | 0 | 0 | 0.000 |
| Radiotherapy | 2 | 0 | 2 | 3.771 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: –

* UNPD as of 1 July 2012 (2013 update)

^α WHO 2012 data

^β WB 2014 classification

^γ WB 2013 data (2014 update)

^δ WHO 2012 data

^ε WB 2013 (2014 update)

n/a not applicable

^λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|-------|---|-----|--------------------------------------|--------------|
| Population (000s)* | 2'107 | Life expectancy at birth (years) ^a | 76 | World Bank income group ^β | Upper-middle |
| Internet users (%) ^γ | 61.2% | Per capita total health expenditure (PPP Int \$) ^δ | 835 | GNI per capita (US\$) ^ε | 4'870 |



National policy on health technology

Health technology (medical device) national policy: —

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Bureau of drugs, Ministry of health is responsible for implementing the regulations for medical devices

Web site: www.zdravstvo.gov.mk



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): —

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: — Use: —

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: Yes.

Web site: —

DONATIONS

Policy or guideline: No

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ:



Inventory and maintenance

Type of inventories available: —

Comments: None

Medical equipment management unit: No

National level = —

Regional level = —

Hospital level = —

Management software: —

Software and comments^λ: —

Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^α

Lists comments^λ:

Lists available: No

Unit: —

Web site: —

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: —

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: —

| | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|--------|-----------------------|---------------------------|----------|------------------------------------|



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | n/a | n/a | n/a | n/a |
| Health centre | 36 | n/a | 36 | 1.708 |
| District hospital | 16 | n/a | 16 | 0.759 |
| Provincial hospital | 35 | n/a | 35 | 1.661 |
| Regional hospital | 35 | n/a | 35 | 1.661 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 7 | n/a | 7 | 3.322 |
| Computerized Tomography Scanner | 13 | n/a | 13 | 6.169 |
| Positron Emission Tomography Scanner | n/a | n/a | n/a | n/a |
| Nuclear medicine | 2 | n/a | 2 | 0.949 |
| Mammograph* | 20 | n/a | 20 | 79.810 |
| Linear accelerator | 2 | n/a | 2 | 0.949 |
| Telecobalt unit (Cobalt-60) | n/a | n/a | n/a | n/a |
| Radiotherapy | 2 | n/a | 2 | 0.949 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ:

Division of health facilities in public sector is different from this one that is listed: health centres 36; general hospitals 13; clinical hospitals 3; university hospitals 28; institute hospitals 35; special hospitals 7. There are not National Guidelines on donations however the donation are according the Law on donations and sponsorships (Official Gazette no.47/2006)

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|-------|---|------|--------------------------------------|--------|
| Population (000s)* | 429 | Life expectancy at birth (years) ^a | 81 | World Bank income group ^β | High |
| Internet users (%) ^γ | 68.9% | Per capita total health expenditure (PPP Int \$) ^δ | 2548 | GNI per capita (US\$) ^ε | 20'980 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Malta Standards Authority

Web site: <http://www.msa.org.mt>



National health technology assessment unit

Unit/department: Office of the Chief Medical Officer

Web site: https://ehealth.gov.mt/HealthPortal/chief_medical_officer/overview.aspx



National health technology management units

National health technology unit(s): No

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: Yes

Web site: <http://sahha.gov.mt> and <http://www.materdeihospital.org.mt>

DONATIONS

Policy or guideline: No

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ:

Procurement at national level: There is a strong collaboration between the two. For capital expenditure for new technologies it is usually the department, for others it is usually coordinated by the hospital itself.



Inventory and maintenance

Type of inventories available: None

Comments: —

Medical equipment management unit: Yes

National level = 0

Regional level = 0

Hospital level = 11

Management software: Yes

Software and comments^λ: the name of the Software is Clingo from the company Carestream Health Italia SRL

Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:Lists comments^λ: —

Lists available: No

Unit: —

Web site: —

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES**OR SPECIFIC PROCEDURES:** Lists available: No list available

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: —

Types:

| | | | |
|-----------------------|---------------------------|----------|------------------------------------|
| Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|-----------------------|---------------------------|----------|------------------------------------|



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 9 | n/a | 9 | 2.098 |
| Health centre | n/a | 8 | 8 | 1.865 |
| District hospital | 1 | 1 | 2 | 0.466 |
| Provincial hospital | n/a | 1 | 1 | 0.233 |
| Regional hospital | 1 | n/a | 1 | 0.233 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 1 | 3 | 4 | 9.324 |
| Computerized Tomography Scanner | 2 | 2 | 4 | 9.324 |
| Positron Emission Tomography Scanner | 0 | 1 | 1 | 2.331 |
| Nuclear medicine | 2 | 1 | 3 | 6.993 |
| Mammograph* | 3 | 3 | 6 | 99.689 |
| Linear accelerator | 1 | 0 | 1 | 2.331 |
| Telecobalt unit (Cobalt-60) | 1 | 0 | 1 | 2.331 |
| Radiotherapy | 2 | 0 | 2 | 4.662 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ:

The Ministry of Health has started to provide emphasis on new health technology and their assessment. Over the last 2 years We have developed a short form and guidelines for completion for all requestd for implementation of new health technologies and services. Together with our Director Generals for Startegy & Sustainability, and Healthcare Services we meet some 3 times a year to evaluate on the proposals received. It is envisaged that a health technology evaluation unit to be developed in the short term.

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|-------|---|------|--------------------------------------|------|
| Population (000s)* | 38 | Life expectancy at birth (years) ^a | 82 | World Bank income group ^β | High |
| Internet users (%) ^γ | 90.7% | Per capita total health expenditure (PPP Int \$) ^δ | 6026 | GNI per capita (US\$) ^ε | |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Direction de l'Action Sanitaire et Sociale

Web site: <http://www.gouv.mc/Gouvernement-et-Institutions/Le-Gouvernement/Departement-des-Affaires-Sociales-et-de-la-Sante>



National health technology assessment unit

Unit/department: Direction de l'Action Sanitaire et Sociale

Web site: —



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: —

Web site: —

OTHER: Planning of medical equipment allocation

Unit/department: Département des Affaires Sociales et de la Santé

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Nationally developed Use: For regulatory purposes

Nomenclature system name: Nomenclature under directive 93/42/CEE Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: —

National level procurement: No

Web site: —

DONATIONS

Policy or guideline: Yes

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: Yes

Web site: —

Medical device incorporation comments^λ:

Procurement guidelines: marquage CE requis



Inventory and maintenance

Type of inventories available: None

Comments: pas d'inventaire

Medical equipment management unit: Yes

National level = 0

Regional level = 0

Hospital level = 1

Management software: No

Software and comments^λ: —

Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^α:

Lists available: No

Unit: —

Web site: —

Lists comments^λ:

Standards can be found on the Directive 93/42/CEE. We have lists for Public health emergency situations known as "Plans d'urgence".

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: For different healthcare facilities

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: One or more

Web site: —

Types:

| | | | | |
|-----------------------|---------------------------|----------|------------------------------------|---|
| Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations | x |
|-----------------------|---------------------------|----------|------------------------------------|---|



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | n/a | n/a | n/a | n/a |
| Health centre | n/a | n/a | n/a | n/a |
| District hospital | n/a | n/a | n/a | n/a |
| Provincial hospital | 1 | 3 | 4 | 10.573 |
| Regional hospital | n/a | n/a | n/a | n/a |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 1 | 4 | 5 | 132.167 |
| Computerized Tomography Scanner | 2 | 3 | 5 | 132.167 |
| Positron Emission Tomography Scanner | 1 | 0 | 1 | 26.433 |
| Nuclear medicine | 1 | 0 | 1 | 26.433 |
| Mammograph* | 1 | 1 | 2 | 599.296 |
| Linear accelerator | 1 | 0 | 1 | 26.433 |
| Telecobalt unit (Cobalt-60) | 0 | 0 | 0 | 0.000 |
| Radiotherapy | 1 | 0 | 1 | 26.433 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: —

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

Montenegro



Country indicators

| | | | | | |
|---------------------------------|-------|---|------|--------------------------------------|--------------|
| Population (000s)* | 621 | Life expectancy at birth (years) ^a | 76 | World Bank income group ^β | Upper-middle |
| Internet users (%) ^γ | 56.8% | Per capita total health expenditure (PPP Int \$) ^δ | 1019 | GNI per capita (US\$) ^ε | 7'250 |



National policy on health technology

Health technology (medical device) national policy: Yes, and it is part of the National Health Program/ Plan or Policy

Web site: <http://www.mzdravlja.gov.me/rubrike/strategija-razvoja-zdravstva-crne-gore/97487/MASTER-PLAN-RAZVOJA-ZDRAVSTVA-CRNE-GORE-ZA-PERIOD-2010-2013.html>

Language(s): Montenegrin

MOH responsible for health technology policy implementation: Unit for management in health care



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Agency for Medicines and Medical Devices of Montenegro, Department for medical devices

Web site: <http://calims.me>

National health technology assessment unit

Unit/department: MoH Unit for management in health care

Web site: <http://www.gov.me/en/homepage>



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: Agency for medicines and medical devices

Web site: <http://calims.me>

OTHER: Medical Equipment insurance issues

Unit/department: Health insurance fund

Web site: <http://fzocg.me/index.php#sadrzaj%281%29>

OTHER: Planning of medical equipment allocation

Unit/department: MoH Unit for management in health care

Web site: <http://www.gov.me/eng/minzdr/>



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Nationally developed Use: For regulatory purposes

Nomenclature system name: Register (notification) of medical devices based on BMDN and adapted to country needs.

Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: <http://www.ujn.gov.me/novi-zakon-o-javnim-nabavkama-crne-gore/>

National level procurement: Yes

Web site: [http://fzocg.me/index.php#sadrzaj\(1\)](http://fzocg.me/index.php#sadrzaj(1))

DONATIONS

Policy or guideline: Yes

Web site: —

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: Yes, but not publically available

Web site: —

Medical device incorporation comments^λ:

Procurements of medical devices for public health institutions are in conformity with Law on public procurements. We recognize international standards in accordance with a law on medical devices.



Inventory and maintenance

Type of inventories available: National inventory only for high cost technologies (such as MRI, CT, or PET scanners)

Comments: There are no specific national inventories but Government of Montenegro every year provides specific amount of money that can be used in special cases (public health emergency situation etc.).

Medical equipment management unit: No

National level = 0

Regional level = 0

Hospital level = 0

Management software: No

Software and comments^λ: —



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:

Lists available: Yes

Unit: Health insurance fond

Web site: <http://fzocg.me/#sadrzaj%2844%29>

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES OR SPECIFIC PROCEDURES: Lists available: For different healthcare facilities

Web site - facilities: <https://www.google.me/search?client=firefox-a&hs=Cfx&rls=org.mozilla%3Aen-US%3Aofficial&q=PRAVILNIK+O+BLI%C5%BDIM+USLOVIMA+ZA+OBAVLJANJE+ZDRAVSTVENE+DJELATNOSTI+U+BOLNICAMA+I+PRIRODN>

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: One or more

Web site: <http://www.mzdravlja.gov.me/biblioteka/zakoni>

Types: Communicable diseases Non-communicable diseases Injuries Public health emergency situations

Lists comments^λ:

There is a list of medical devices that are provided or reimbursed to the patient by Health insurance fond, based on opinion of team of doctors. The list is created as result of different indications mostly for treatment, alleviation or compensation for an injury or handicap. There is the Law on Protection of Population against Communicable Diseases. Also , we have National strategy for



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 3 | 96 | 99 | 15.932 |
| Health centre | 18 | n/a | 18 | 2.897 |
| District hospital | 7 | 2 | 9 | 1.448 |
| Provincial hospital | 3 | n/a | 3 | 0.483 |
| Regional hospital | 1 | n/a | 1 | 0.161 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 2 | 0 | 2 | 3.219 |
| Computerized Tomography Scanner | 9 | 1 | 10 | 16.093 |
| Positron Emission Tomography Scanner | 0 | 0 | 0 | 0.000 |
| Nuclear medicine | 1 | 0 | 1 | 1.609 |
| Mammograph* | 13 | 2 | 15 | 196.479 |
| Linear accelerator | 2 | 0 | 2 | 3.219 |
| Telecobalt unit (Cobalt-60) | 0 | 0 | 0 | 0.000 |
| Radiotherapy | 2 | 0 | 2 | 3.219 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ:

Concerning Infrastructure section: We would like to inform you that we have specialized hospitals for only one specialty as psychiatric, orthopedic and lungs diseases. We have 3 institutions like this.

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

Netherlands



Country indicators

| | | | | | |
|---------------------------------|--------|---|------|--------------------------------------|--------|
| Population (000s)* | 16'759 | Life expectancy at birth (years) ^a | 81 | World Bank income group ^β | High |
| Internet users (%) ^γ | 94.0% | Per capita total health expenditure (PPP Int \$) ^δ | 5385 | GNI per capita (US\$) ^ε | 51'060 |



National policy on health technology

Health technology (medical device) national policy: Yes, and it is part of the National Health Program/Plan or Policy

Web site: —

Language(s): Dutch

MOH responsible for health technology policy implementation: Department Pharmaceutical Affairs and Medical Technology



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Dutch Healthcare Inspectorate

Web site: http://www.igz.nl/english/medical_devices



National health technology assessment unit

Unit/department: Health Care Insurance Board (CVZ)

Web site: <http://www.rijksoverheid.nl/ministeries/vws#ref-minvws>



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: —

Web site: —

OTHER: Reimbursement of medical devices/HTA

Unit/department: Health Care Insurance Board (CVZ)

Web site: <http://www.gipdatabank.nl/> , <http://www.cvz.nl/>

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on GMDN (Global Medical Device Nomenclature)

Use: Not specified

Nomenclature system name: — Web site: <http://www.gmdnagency.com/>



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: No

Web site: —

DONATIONS

Policy or guideline: No

Web site: —

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: Yes

Web site: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:131:0017:0030:nl:PDF>

Medical device incorporation comments^λ:

Commission decision of 7 May 2002 on common technical specifications for in vitro-diagnostic medical devices



Inventory and maintenance

Type of inventories available: None

Comments: The Netherlands has no national inventory for medical devices

Medical equipment management unit: Yes

National level = 0

Regional level = 0

Hospital level = 0

Management software: —

Software and comments^λ: —



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^α

Lists available: Yes

Unit: Department of Pharmaceutical Affairs and Medical Technology

Web site: —

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES OR SPECIFIC PROCEDURES: Lists available: No list available

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: —

| | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|--------|-----------------------|---------------------------|----------|------------------------------------|

Lists comments^λ:

In the Netherlands, the professional has to decide/recommend/indicate a medical device. The koepel of the professionals can publish a guideline for specific procedures. The regeling zorgverzekering takes care of the reimbursement of extramural medical devices in the Netherlands.



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | n/a | n/a | n/a | n/a |
| Health centre | n/a | n/a | n/a | n/a |
| District hospital | n/a | n/a | n/a | n/a |
| Provincial hospital | n/a | n/a | n/a | n/a |
| Regional hospital | 128 | n/a | 128 | 0.764 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 191 | 12 | 203 | 12.113 |
| Computerized Tomography Scanner | 187 | 18 | 205 | 12.232 |
| Positron Emission Tomography Scanner | 38 | 2 | 40 | 2.387 |
| Nuclear medicine | 176 | 3 | 179 | 10.681 |
| Mammograph* | n/a | n/a | n/a | n/a |
| Linear accelerator | 86 | 35 | 121 | 7.220 |
| Telecobalt unit (Cobalt-60) | 0 | 0 | 0 | 0.000 |
| Radiotherapy | 86 | 35 | 121 | 7.220 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: —

* UNPD as of 1 July 2012 (2013 update)

^α WHO 2012 data

^β WB 2014 classification

^γ WB 2013 data (2014 update)

^δ WHO 2012 data

^ε WB 2013 (2014 update)

n/a not applicable

^λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

Norway



Country indicators

| | | | | | |
|---------------------------------|-------|---|------|--------------------------------------|---------|
| Population (000s)* | 5'043 | Life expectancy at birth (years) ^a | 82 | World Bank income group ^β | High |
| Internet users (%) ^γ | 95.1% | Per capita total health expenditure (PPP Int \$) ^δ | 5970 | GNI per capita (US\$) ^ε | 102'610 |



National policy on health technology

Health technology (medical device) national policy: Yes, and it is part of the National Health Program/Plan or Policy

Web site: <http://www.regjeringen.no/nb/dep/hod/dok/regpubl/stmeld/2012-2013/meld-st-10-20122013/8.html?id=709112>

Language(s): —

MOH responsible for health technology policy implementation: The department of specialized health care services



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Directorate of Health, department of medical devices and medicinal products

Web site: <http://www.helsedir.no>



National health technology assessment unit

Unit/department: Norwegian knowledge center for the health care services, department for evidence-based health care

Web site: <http://www.kunnskapscenteret.no>



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: Norwegian knowledge center for the health care services, department for evidence-based health care

Web site: <http://www.kunnskapscenteret.no>

OTHER: Planning of medical equipment allocation/Application/user training

Unit/department: Norwegian knowledge center for the health care services, department for evidence-based health care

Web site: <http://www.kunnskapscenteret.no>

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on GMDN (Global Medical Device Nomenclature)

Use: For regulatory purposes

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: —

National level procurement: Yes

Web site: <http://www.helfo.no>

DONATIONS

Policy or guideline: No

Web site: —

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: Yes, but not publically available

Web site: —

Medical device incorporation comments^λ:

Only procurement of devices being reimbursed via the blue prescription system is carried out at national level, by The Norwegian Labour and Welfare Administration



Inventory and maintenance

Type of inventories available: —

Comments: —

Medical equipment management unit: —

National level = —

Regional level = —

Hospital level = —

Management software: Yes

Software and comments^λ: —

Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^δ:

Lists available: Yes

Unit: —

Web site: —

Lists comments^λ:

A few devices - those being reimbursed via the blue prescription system i- are listed. Lists are made by The Norwegian Labour and Welfare Administration, cf. question 3.2.1

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: For different healthcare facilities and specific procedures

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: —

Web site: —

| | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|--------|-----------------------|---------------------------|----------|------------------------------------|



Healthcare facility

| | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | n/a | n/a | n/a | n/a |
| Health centre | n/a | n/a | n/a | n/a |
| District hospital | n/a | n/a | n/a | n/a |
| Provincial hospital | n/a | n/a | n/a | n/a |
| Regional hospital | n/a | n/a | n/a | n/a |



Medical equipment

| | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | n/a | n/a | n/a | n/a |
| Computerized Tomography Scanner | n/a | n/a | n/a | n/a |
| Positron Emission Tomography Scanner | 0 | 0 | 0 | 0.000 |
| Nuclear medicine | n/a | n/a | n/a | n/a |
| Mammograph* | n/a | n/a | n/a | n/a |
| Linear accelerator | n/a | n/a | n/a | n/a |
| Telecobalt unit (Cobalt-60) | n/a | n/a | n/a | n/a |
| Radiotherapy | n/a | n/a | n/a | n/a |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ:

Concerning HT national policy we provide the following doc.: plan van aanpak patientveiligheid medische technologie. pdf. Concerning Regulation section: No national strategy but the Norwegian Knowledge Centre for the Health Services (<http://www.kunnskapssenteret.no>) do HTAs on selected procedures and devices upon request.

Concerning infrastructure section: As of 01.01.2009: 11 885 beds in specialised healthcare. 117 of these in private sector.

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

Poland



Country indicators

| | | | | | |
|---------------------------------|--------|---|------|--------------------------------------|--------|
| Population (000s)* | 38'217 | Life expectancy at birth (years) ^a | 77 | World Bank income group ^β | High |
| Internet users (%) ^γ | 62.8% | Per capita total health expenditure (PPP Int \$) ^δ | 1489 | GNI per capita (US\$) ^ε | 13'240 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: The Office for Registration of Medicinal Products, Medical Devices, and Biocidal Products

Web site: <http://en.urpl.gov.pl/general-information>



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on GMDN (Global Medical Device Nomenclature)

Use: Not specified

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: No

Web site: —

DONATIONS

Policy or guideline: No

Web site: —

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ: —



Inventory and maintenance

Type of inventories available: National inventory only for high cost technologies (such as MRI, CT or PET scanners)

Comments: –

Medical equipment management unit: –

National level = 0

Regional level = 0

Hospital level = 0

Management software: No

Software and comments^λ: –



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^α:

Lists available: No

Unit: –

Web site: –

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: –

Web site - facilities: –

Web site - procedures: –

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: –

| | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|--------|-----------------------|---------------------------|----------|------------------------------------|

Lists comments^λ:

Polish competent Authority for medical devices - The Office for registration of Medicinal Products, Medical Devices and Biocidal Products keeps the Register of medical devices but this database is used only for market surveillance and vigilance purpose. On Polish market can be placed all CE - marked medical devices according to European New approach directives (90/385/



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | n/a | n/a | n/a | n/a |
| Health centre | n/a | n/a | n/a | n/a |
| District hospital | 70 | n/a | 70 | 0.183 |
| Provincial hospital | 234 | n/a | 234 | 0.612 |
| Regional hospital | 57 | n/a | 57 | 0.149 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 125 | n/a | 125 | 3.271 |
| Computerized Tomography Scanner | 405 | n/a | 405 | 10.597 |
| Positron Emission Tomography Scanner | 9 | 4 | 13 | 0.340 |
| Nuclear medicine | 107 | n/a | 107 | 2.800 |
| Mammograph* | 529 | n/a | 529 | 100.695 |
| Linear accelerator | 99 | n/a | 99 | 2.590 |
| Telecobalt unit (Cobalt-60) | 5 | n/a | 5 | 0.131 |
| Radiotherapy | 104 | n/a | 104 | 2.721 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: –

* UNPD as of 1 July 2012 (2013 update)

^α WHO 2012 data

^β WB 2014 classification

^γ WB 2013 data (2014 update)

^δ WHO 2012 data

^ε WB 2013 (2014 update)

n/a not applicable

^λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

Portugal



Country indicators

| | | | | | |
|---------------------------------|--------|---|------|--------------------------------------|--------|
| Population (000s)* | 10'608 | Life expectancy at birth (years) ^a | 81 | World Bank income group ^β | High |
| Internet users (%) ^γ | 62.1% | Per capita total health expenditure (PPP Int \$) ^δ | 2400 | GNI per capita (US\$) ^ε | 21'260 |



National policy on health technology

Health technology (medical device) national policy: Yes, and it is part of the National Health Program/Plan or Policy

Web site: <http://www.dgs.pt>

Language(s): Anglais et Portugais

MOH responsible for health technology policy implementation: Administração Central do Sistema de Saúde (ACSS, IP)



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: INFARMED-IP

Web site: <http://www.infarmed.pt>



National health technology assessment unit

Unit/department: ACSS, IP

Web site: <http://www.acss.min-saude.pt>



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: —

Web site: —

OTHER: HTA

Unit/department: DGS

Web site: <http://www.dgs.pt>

OTHER: Planning of medical equipment allocation

Unit/department: ACSS, IP

Web site: <http://www.acss.min-saude.pt>



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on GMDN (Global Medical Device Nomenclature)

Use: Not specified

Nomenclature system name: En élaboration Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: Yes

Web site: <http://www.acss.min-saude.pt>

DONATIONS

Policy or guideline: No

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: —

Web site: —

Medical device incorporation comments^λ:

Go to the website and search for the “contratosequisicoes” documents



Inventory and maintenance

Type of inventories available: National inventory only for high cost technologies (such as MRI, CT or PET scanners)

Comments: –

Medical equipment management unit: No

National level = –

Regional level = –

Hospital level = –

Management software: –

Software and comments^λ: –



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^α:

Lists available: No

Unit: –

Web site: –

Lists comments^λ:

We have lists for communicable diseases, and public health emergency situations.

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: For specific procedures

Web site - facilities: –

Web site - procedures: –

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: One or more

Web site: <http://www.acss.min-saude.pt>; Gripe A

| | | | | | | | | |
|--------|-----------------------|---|---------------------------|--|----------|--|------------------------------------|---|
| Types: | Communicable diseases | x | Non-communicable diseases | | Injuries | | Public health emergency situations | x |
|--------|-----------------------|---|---------------------------|--|----------|--|------------------------------------|---|



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 327 | n/a | 327 | 3.083 |
| Health centre | 19 | n/a | 19 | 0.179 |
| District hospital | n/a | n/a | n/a | n/a |
| Provincial hospital | n/a | n/a | n/a | n/a |
| Regional hospital | n/a | n/a | n/a | n/a |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 29 | 76 | 105 | 9.898 |
| Computerized Tomography Scanner | 82 | 209 | 291 | 27.432 |
| Positron Emission Tomography Scanner | 4 | 3 | 7 | 0.660 |
| Nuclear medicine | 30 | 24 | 54 | 5.090 |
| Mammograph* | 53 | 322 | 375 | 272.049 |
| Linear accelerator | 25 | 12 | 37 | 3.488 |
| Telecobalt unit (Cobalt-60) | 3 | 3 | 6 | 0.566 |
| Radiotherapy | 28 | 15 | 43 | 4.053 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: –

* UNPD as of 1 July 2012 (2013 update)

^α WHO 2012 data

^β WB 2014 classification

^γ WB 2013 data (2014 update)

^δ WHO 2012 data

^ε WB 2013 (2014 update)

n/a not applicable

^λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

Moldova, Republic of



Country indicators

| | | | | | |
|---------------------------------|-------|---|-----|--------------------------------------|--------------|
| Population (000s)* | 3'487 | Life expectancy at birth (years) ^a | 71 | World Bank income group ^β | Lower-middle |
| Internet users (%) ^γ | 48.8% | Per capita total health expenditure (PPP Int \$) ^δ | 490 | GNI per capita (US\$) ^ε | 2'470 |



National policy on health technology

Health technology (medical device) national policy: Yes, and it is part of the National Health Program/Plan or Policy

Web site: http://www.ms.gov.md/-files/1002-politicanationala_zom_zus_finall.pdf

Language(s): Rumanian and Russian

MOH responsible for health technology policy implementation: Department of Medicines and Medical Devices



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Agency of Medicines and Medical Devices

Web site: www.amed.md



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: Agency of Medicines and Medical Devices

Web site: www.amed.md

OTHER: Regulations

Unit/department: Department of medical devices of Agency of Medicines and Medical Devices

Web site: www.amed.md

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: —

Web site: www.ms.gov.md/ministry/auction/

National level procurement: Yes

Web site: www.amed.md

DONATIONS

Policy or guideline: Yes

Web site: <http://lex.justice.md>

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: Yes

Web site: www.ms.gov.md

Medical device incorporation comments^λ:

Procurement guidelines: Government Decree No. 568 (10.09.09). Guidelines on technical specifications: Decree 190 from 25.06.2009 establishes standard specifications for biochemical and immunology test.



Inventory and maintenance

Type of inventories available: None

Comments: Not developed.

Medical equipment management unit: Yes

National level = 1

Regional level = 0

Hospital level = 10

Management software: No

Software and comments^λ: A project to support management of medical equipment is being developed: openMedis



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^δ:

Lists available: No

Unit: —

Web site: —

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES OR SPECIFIC PROCEDURES^δ: Lists available: For different healthcare facilities and specific procedures

Web site - facilities: www.ms.gov.md/sites/default/files/legislative

Web site - procedures: www.ms.gov.md/public/info/ghid

NATIONAL LIST FOR DISEASES AND SITUATIONS^δ:

Lists available: One or more

Web site: www.ms.gov.md/public/infoghid/stand/diagnostic/

Types:

| | | | | | | |
|-----------------------|---|---------------------------|---|----------|---|------------------------------------|
| Communicable diseases | x | Non-communicable diseases | x | Injuries | x | Public health emergency situations |
|-----------------------|---|---------------------------|---|----------|---|------------------------------------|

Lists comments^λ:

Standards are in the Order of Ministry of Health No 695 (13.10.2010) - lists of medical devices for health centers - . Medical standards on diagnostic and treatment for pathological conditions in surgery, therapeutic profile for adults and children, have been developed. Also development of guidelines based on international recommendations for family physicians and



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 1'025 | n/a | 1025 | 29.393 |
| Health centre | 345 | 7 | 352 | 10.094 |
| District hospital | 34 | n/a | 34 | 0.975 |
| Provincial hospital | 10 | 13 | 23 | 0.660 |
| Regional hospital | 17 | n/a | 17 | 0.487 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 1 | 4 | 5 | 1.434 |
| Computerized Tomography Scanner | 12 | 7 | 19 | 5.448 |
| Positron Emission Tomography Scanner | 0 | 0 | 0 | 0.000 |
| Nuclear medicine | 4 | 0 | 4 | 1.147 |
| Mammograph* | 13 | 6 | 19 | 40.951 |
| Linear accelerator | 1 | 0 | 1 | 0.287 |
| Telecobalt unit (Cobalt-60) | 1 | 0 | 1 | 0.287 |
| Radiotherapy | 2 | 0 | 2 | 0.574 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ:

The strategy to develop Health System during the period 2005-2017 as well as the Plan of Action contains specific goals on strengthening the bases of technical material for healthcare.

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|--------|---|-----|--------------------------------------|--------------|
| Population (000s)* | 21'699 | Life expectancy at birth (years) ^a | 74 | World Bank income group ^β | Upper-middle |
| Internet users (%) ^γ | 49.8% | Per capita total health expenditure (PPP Int \$) ^δ | 873 | GNI per capita (US\$) ^ε | 9'060 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: National Agency for Medicines and Medical Devices

Web site: <http://www.anm.ro/anmdm/en/>



National health technology assessment unit

Unit/department: Technical office for medical devices

Web site: <http://www.otdm.ro>



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: —

Web site: —

OTHER: Planning of medical equipment allocation

Unit/department: MoH

Web site: <http://www.ms.ro>

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: Yes

Web site: <http://www.ms.ro>

DONATIONS

Policy or guideline: No

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ:

Procurement is carried out at the national level for high technologies devices. Go to the website and search for the corresponding documents



Inventory and maintenance

Type of inventories available: National inventory only for high cost technologies (such as MRI, CT or PET scanners)

Comments: –

Medical equipment management unit: –

National level = 0

Regional level = 0

Hospital level = 0

Management software: No

Software and comments^λ: –



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^δ

Lists comments^λ:

Lists available: No

Unit: –

Web site: –

Standards are orders of MoH: NO.
153/2003, 1301/2007, 1764/2006,
1500/2009

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: For different healthcare facilities and specific procedures

Web site - facilities: –

Web site - procedures: –

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: One or more

Web site: –

Types:

| | | | | | |
|-----------------------|---------------------------|----------|---|------------------------------------|---|
| Communicable diseases | Non-communicable diseases | Injuries | x | Public health emergency situations | x |
|-----------------------|---------------------------|----------|---|------------------------------------|---|



Healthcare facility

| | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 4 | n/a | 4 | 0.018 |
| Health centre | 13 | n/a | 13 | 0.060 |
| District hospital | 92 | n/a | 92 | 0.424 |
| Provincial hospital | 109 | n/a | 109 | 0.502 |
| Regional hospital | 163 | n/a | 163 | 0.751 |



Medical equipment

| | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 18 | 25 | 43 | 1.982 |
| Computerized Tomography Scanner | 68 | 50 | 118 | 5.438 |
| Positron Emission Tomography Scanner | 0 | 1 | 1 | 0.046 |
| Nuclear medicine | 25 | 0 | 25 | 1.152 |
| Mammograph [*] | 73 | 39 | 112 | 41.844 |
| Linear accelerator | 11 | 0 | 11 | 0.507 |
| Telecobalt unit (Cobalt-60) | 14 | 0 | 14 | 0.645 |
| Radiotherapy | 25 | 0 | 25 | 1.152 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: –

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

Russian Federation



Country indicators

| | | | | | |
|---------------------------------|---------|---|------|--------------------------------------|--------|
| Population (000s)* | 142'834 | Life expectancy at birth (years) ^a | 69 | World Bank income group ^β | High |
| Internet users (%) ^γ | 61.4% | Per capita total health expenditure (PPP Int \$) ^δ | 1474 | GNI per capita (US\$) ^ε | 13'850 |



National policy on health technology

Health technology (medical device) national policy: Yes, and it is part of the National Health Program/Plan or Policy

Web site: www.minzdravsoc.ru/docs/laws/104

Language(s): Russian

MOH responsible for health technology policy implementation: translation



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Federal Service on Surveillance (Roszdravnadzor), Federal Agency for Technical Regulation and Metrology (Gosstandart), Federal Service for Supervision in the Area of Consumer Rights and Welfare Protection (Rospotrebnadzor)

Web site: <http://roszdravnadzor.ru/>



National health technology assessment unit

Unit/department: Department of the pharmaceutical and medical devices market development

Web site: <http://www.rosminzdrav.ru/>



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: —

Web site: —

OTHER: —

Unit/department: Department of Health Care and Health Development

Web site: www.minzdravsoc.ru

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Nationally developed Use: Not specified

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: <http://minzdravsoc.samregion.ru/>

National level procurement: No

Web site: —

DONATIONS

Policy or guideline: Yes

Web site: —

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: Yes, but not publically available

Web site: www.minzdravsoc.ru

Medical device incorporation comments^λ: —



Inventory and maintenance

Type of inventories available: None

Comments: –

Medical equipment management unit: Yes

National level = 1300

Regional level = 0

Hospital level = 0

Management software: –

Software and comments^λ: –

Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^δ:

Lists available: Yes, but it is only a recommendation

Unit: Department of Health Care and Health Development

Web site: –

Lists comments^λ:

We have lists available for communicable and non communicable diseases, injuries, and public health emergency situations.

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: For different healthcare facilities and specific procedures

Web site - facilities: –

Web site - procedures: –

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: One or more

Web site: <http://www.rosminzdrav.ru/>Types:

| | | | | | | | |
|-----------------------|---|---------------------------|---|----------|---|------------------------------------|---|
| Communicable diseases | x | Non-communicable diseases | x | Injuries | x | Public health emergency situations | x |
|-----------------------|---|---------------------------|---|----------|---|------------------------------------|---|



Healthcare facility

| | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | n/a | n/a | n/a | n/a |
| Health centre | n/a | n/a | n/a | n/a |
| District hospital | n/a | n/a | n/a | n/a |
| Provincial hospital | n/a | n/a | n/a | n/a |
| Regional hospital | n/a | n/a | n/a | n/a |



Medical equipment

| | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | n/a | n/a | n/a | n/a |
| Computerized Tomography Scanner | n/a | n/a | n/a | n/a |
| Positron Emission Tomography Scanner | n/a | n/a | n/a | n/a |
| Nuclear medicine | n/a | n/a | n/a | n/a |
| Mammograph* | n/a | n/a | n/a | n/a |
| Linear accelerator | n/a | n/a | n/a | n/a |
| Telecobalt unit (Cobalt-60) | n/a | n/a | n/a | n/a |
| Radiotherapy | n/a | n/a | n/a | n/a |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: –

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

San Marino



Country indicators

| | | | | | |
|---------------------------------|-------|---|------|--------------------------------------|------|
| Population (000s)* | 31 | Life expectancy at birth (years) ^a | 83 | World Bank income group ^β | High |
| Internet users (%) ^γ | 50.8% | Per capita total health expenditure (PPP Int \$) ^δ | 3736 | GNI per capita (US\$) ^ε | |



National policy on health technology

Health technology (medical device) national policy: Yes, and it is part of the National Health Program/Plan or Policy
Web site: <http://www.sanita.sm/on-line/Home/Authority/PianoSanitarioeSocio-Sanitario/Pianosanitarioesocio-sanitario.html>

Language(s): italiano

MOH responsible for health technology policy implementation: Health Authority for Authorization, Accreditation and Quality of Health Services



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Health Authority for Authorization, Accreditation and Quality of Health Services

Web site: <http://www.sanita.sm/on-line/Home/Authority.html>



National health technology assessment unit

Unit/department: Health Authority for Authorization, Accreditation and Quality of Health Services

Web site: <http://www.sanita.sm/on-line/Home/Authority.html>



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: —

Web site: —

OTHER: Planning of medical equipment allocation

Unit/department: Health Authority for Authorization, Accreditation and Quality of Health Services

Web site: <http://www.sanita.sm/on-line/Home/Authority.html>

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: No

Web site: —

DONATIONS

Policy or guideline: Yes

Web site: —

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ: —



Inventory and maintenance

Type of inventories available: None

Comments: —

Medical equipment management unit: Yes

National level = 1

Regional level = 0

Hospital level = 0

Management software: —

Software and comments^λ: —

Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^δ:

Lists available: No

Unit: —

Web site: —

Lists comments^λ:

We have lists of public health emergency situations.

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: No list available

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: One or more

Web site: <http://www.sanita.sm/on-line/Home/Sanita/Promozioneeprevenzione/Aviaria/articolo2000923.html>Types:

| | | | | |
|-----------------------|---------------------------|----------|------------------------------------|---|
| Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations | x |
|-----------------------|---------------------------|----------|------------------------------------|---|



Healthcare facility

| | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 3 | n/a | 3 | 9.540 |
| Health centre | n/a | n/a | 0 | 0.000 |
| District hospital | n/a | n/a | 0 | 0.000 |
| Provincial hospital | 1 | n/a | 1 | 3.180 |
| Regional hospital | n/a | n/a | 0 | 0.000 |



Medical equipment

| | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 1 | 1 | 2 | 63.597 |
| Computerized Tomography Scanner | 1 | 0 | 1 | 31.799 |
| Positron Emission Tomography Scanner | 0 | 0 | 0 | 0.000 |
| Nuclear medicine | 0 | 0 | 0 | 0.000 |
| Mammograph* | 1 | 0 | 1 | 229.114 |
| Linear accelerator | 0 | 0 | 0 | 0.000 |
| Telecobalt unit (Cobalt-60) | 0 | 0 | 0 | 0.000 |
| Radiotherapy | 0 | 0 | 0 | 0.000 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ:

For specialized care and diagnostics, patients can be treated in Italian hospitals that have agreements with San Marino.

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|-------|---|------|--------------------------------------|--------------|
| Population (000s)* | 9'511 | Life expectancy at birth (years) ^a | 75 | World Bank income group ^β | Upper-middle |
| Internet users (%) ^γ | 51.5% | Per capita total health expenditure (PPP Int \$) ^δ | 1250 | GNI per capita (US\$) ^ε | 6'050 |



National policy on health technology

Health technology (medical device) national policy: Yes, and it is part of the National Health Program/Plan or Policy

Web site: <http://www.zdravlje.gov.rs/index.php?>

Language(s): Serbian and English

MOH responsible for health technology policy implementation: Committee for health technology assessment



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Agency for Drugs and Medical Devices

Web site: www.alims.gov.rs



National health technology assessment unit

Unit/department: Ministry of Health - Committee for health technology assessment

Web site: <http://www.zdravlje.gov.rs>



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Nationally developed Use: Not specified

Nomenclature system name: Book of regulations on detailed conditions for the performance of health services. Web site: <http://www.zdravlje.gov.rs>



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: Yes

Web site: <http://www.zdravlje.gov.rs/showpage.php?id=243>

DONATIONS

Policy or guideline: No

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ:

Go to the website and search for the corresponding documents.



Inventory and maintenance

Type of inventories available: National inventory for medical equipment

Comments: According to methodology in 2000, inventory made. In 2003, European Agency for Reconstruction commissioned a project performed by IPH Serbia, but the methodology was not included in the national Law on Health Records and Statistics and has not been adopted, so the inventory continued to be performed on annual basis based on the existing Law on Health Records and classification of medical equipment (dating in 1980ies). The inventory is actually not available.

Medical equipment management unit: No

National level = 0

Regional level = 0

Hospital level = 0

Management software: Yes

Software and comments^λ: —



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:

Lists available: Yes

Unit: Committee for health technology assessment

Web site: —

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: For different healthcare facilities

Web site - facilities: <http://www.zdravlje.gov.rs/mz-admin/downloads/zakoni/Pravilnik%20Obavljanje%20Zdravstvene%20delatnosti.pdf>

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: —

Types: Communicable diseases Non-communicable diseases Injuries Public health emergency situations

Lists comments^λ:

There are no specific national standards nor recommended medical devices for specific procedures. No, there are no lists recommending health technology for above mentioned diseases



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 158 | n/a | 158 | 1.661 |
| Health centre | 158 | n/a | 158 | 1.661 |
| District hospital | 40 | n/a | 40 | 0.421 |
| Provincial hospital | 41 | n/a | 41 | 0.431 |
| Regional hospital | 23 | n/a | 23 | 0.242 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 38 | 21 | 59 | 6.204 |
| Computerized Tomography Scanner | 90 | 40 | 130 | 13.669 |
| Positron Emission Tomography Scanner | 2 | 0 | 2 | 0.210 |
| Nuclear medicine | 1 | 2 | 3 | 0.315 |
| Mammograph* | 75 | 30 | 105 | 84.557 |
| Linear accelerator | 13 | 0 | 13 | 1.367 |
| Telecobalt unit (Cobalt-60) | 1 | 0 | 1 | 0.105 |
| Radiotherapy | 14 | 0 | 14 | 1.472 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ:

Institute of Public Health of Serbia has a department for health technology assessment mainly responsible for updating nomenclature and type of technology

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

Slovakia



Country indicators

| | | | | | |
|---------------------------------|-------|---|------|--------------------------------------|--------|
| Population (000s)* | 5'450 | Life expectancy at birth (years) ^a | 76 | World Bank income group ^β | High |
| Internet users (%) ^γ | 77.9% | Per capita total health expenditure (PPP Int \$) ^δ | 1977 | GNI per capita (US\$) ^ε | 17'810 |



National policy on health technology

Health technology (medical device) national policy: Yes, but is not part of the National Health Program

Web site: <http://www.skmed.sk>

Language(s): Slovak

MOH responsible for health technology policy implementation: Department of Categorization Pricing and Drug Policy



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: State Institute for Drug Control

Web site: <http://www.sukl.sk/sk>



National health technology assessment unit

Unit/department: The Working Group for Pharmacoeconomics, Clinical Outcomes and Health Technology Assessment of the Slovak Ministry of Health

Web site: <http://www.health.gov.sk>



National health technology management units

National health technology unit(s): No

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Nationally developed Use: Not specified

Nomenclature system name: — Web site: <http://www.health.gov.sk>



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: No

Web site: —

DONATIONS

Policy or guideline: No

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ: —



Inventory and maintenance

Type of inventories available: National functional inventory for medical equipment

Comments: —

Medical equipment management unit: Yes

National level = 1

Regional level = 0

Hospital level = 0

Management software: Yes

Software and comments^λ: —



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^α:

Lists available: Yes

Unit: Ministry of Health

Web site: —

Lists comments^λ:

We do not have any available lists for communicable and non-communicable diseases, injuries, and public health emergency situations.

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: No list available

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: —

| | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|--------|-----------------------|---------------------------|----------|------------------------------------|



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 16 | n/a | 16 | 0.294 |
| Health centre | n/a | n/a | n/a | n/a |
| District hospital | 6 | n/a | 6 | 0.110 |
| Provincial hospital | 26 | n/a | 26 | 0.477 |
| Regional hospital | 52 | n/a | 52 | 0.954 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | n/a | n/a | n/a | n/a |
| Computerized Tomography Scanner | n/a | n/a | n/a | n/a |
| Positron Emission Tomography Scanner | n/a | n/a | n/a | n/a |
| Nuclear medicine | n/a | n/a | n/a | n/a |
| Mammograph* | n/a | n/a | n/a | n/a |
| Linear accelerator | n/a | n/a | n/a | n/a |
| Telecobalt unit (Cobalt-60) | n/a | n/a | n/a | n/a |
| Radiotherapy | n/a | n/a | n/a | n/a |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ:

Concerning HT national policy we provide the following doc.: Zakon o zdravstvenoj zastiti-1235-05-engleski.doc

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

Slovenia



Country indicators

| | | | | | |
|---------------------------------|-------|---|------|--------------------------------------|--------|
| Population (000s)* | 2'072 | Life expectancy at birth (years) ^a | 80 | World Bank income group ^β | High |
| Internet users (%) ^γ | 72.7% | Per capita total health expenditure (PPP Int \$) ^δ | 2420 | GNI per capita (US\$) ^ε | 23'210 |



National policy on health technology

Health technology (medical device) national policy: Yes, and it is part of the National Health Program/Plan or Policy

Web site: http://www.uradni-list.si/files/RS_-2008-074-03286-OB-PO01-0000.PDF

Language(s): Slovenian

MOH responsible for health technology policy implementation: Healthcare Economics Directorate



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Javna Agencija za zdravila in medicinske pripomočke / Agency for Medicinal Products and Medical Devices of the Republic of Slovenia

Web site: <http://www.jazmp.si>



National health technology assessment unit

Unit/department: Agency for Medicinal Products and Medical Devices of the Republic of Slovenia

Web site: <http://www.jazmp.si>



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: —

Web site: —

OTHER: —

Unit/department: Division of investments and public procurement

Web site: http://www.mz.gov.si/si/delovna_podrocja/zdravstvena_ekonomika/sektor_za_investicije_in_javna_narocila/

OTHER: HTA

Unit/department: Health Council

Web site: http://www.mz.gov.si/si/o_ministrstvu/zdravstveni_svet_in_rsk_ji/zdravstveni_svet/



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Nationally developed Use: For regulatory purposes

Nomenclature system name: CPV code system Web site: <http://www.jazmp.si>



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: Yes

Web site: http://www.mz.gov.si/si/delovna_podrocja/zdravstvena_ekonomika

DONATIONS

Policy or guideline: No

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ: —



Inventory and maintenance

Type of inventories available: National functional inventory for medical equipment

Comments: –

Medical equipment management unit: No

National level = 0

Regional level = 0

Hospital level = 0

Management software: No

Software and comments^λ: –



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^α:

Lists available: No

Unit: –

Web site: –

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES OR SPECIFIC PROCEDURES: Lists available: For different healthcare facilities

Web site - facilities: –

Web site - procedures: –

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: –

| | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|--------|-----------------------|---------------------------|----------|------------------------------------|

Lists comments^λ:

There are many boards, each responsible for one area of medicine. Those bodies produce recommendations on specific procedures where deemed necessary. Recommendations are currently under development at the Ministry of Health



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 83 | n/a | 83 | 4.006 |
| Health centre | 57 | n/a | 57 | 2.751 |
| District hospital | 14 | n/a | 14 | 0.676 |
| Provincial hospital | 10 | n/a | 10 | 0.483 |
| Regional hospital | 2 | n/a | 2 | 0.097 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 13 | 5 | 18 | 8.687 |
| Computerized Tomography Scanner | 28 | n/a | 28 | 13.514 |
| Positron Emission Tomography Scanner | 2 | n/a | 2 | 0.965 |
| Nuclear medicine | 17 | n/a | 17 | 8.205 |
| Mammograph* | 37 | n/a | 37 | 136.168 |
| Linear accelerator | 11 | n/a | 11 | 5.309 |
| Telecobalt unit (Cobalt-60) | 1 | n/a | 1 | 0.483 |
| Radiotherapy | 12 | n/a | 12 | 5.792 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: –

* UNPD as of 1 July 2012 (2013 update)

^α WHO 2012 data

^β WB 2014 classification

^γ WB 2013 data (2014 update)

^δ WHO 2012 data

^ε WB 2013 (2014 update)

n/a not applicable

^λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

Spain



Country indicators

| | | | | | |
|---------------------------------|--------|---|------|--------------------------------------|--------|
| Population (000s)* | 46'927 | Life expectancy at birth (years) ^a | 82 | World Bank income group ^β | High |
| Internet users (%) ^γ | 71.6% | Per capita total health expenditure (PPP Int \$) ^δ | 3145 | GNI per capita (US\$) ^ε | 29'920 |



National policy on health technology

Health technology (medical device) national policy: Yes, and it is part of the National Health Program/Plan or Policy

Web site: <http://www.msps.es/organizacion/sns/planCalidadSNS/home.htm>

Language(s): Español

MOH responsible for health technology policy implementation: Agencia de Calidad del Sistema Nacional de Salud



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Agencia Española de Medicamentos y Productos Sanitarios

Web site: <http://www.aemps.es>



National health technology assessment unit

Unit/department: AETS-ISCI, Spanish Network of Agencies for Health Technology Assessment and Services of the National Health System

Web site: <http://www.isciii.es>



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on more than one system Use: Not specified

Nomenclature system name: UMDNS and GMDN (in the future only GMDN) Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: No

Web site: —

DONATIONS

Policy or guideline: No

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ: —



Inventory and maintenance

Type of inventories available: National inventory for medical equipment

Comments: –

Medical equipment management unit: No

National level = 0

Regional level = 0

Hospital level = 0

Management software: –

Software and comments^λ: –



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:

Lists comments^λ: –

Lists available: Yes

Unit: DIRECCION GENERAL DE ORDENACION PROFESIONAL, COHESION DEL SNS
Y ALTA INSPECCION

Web site: –

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: No list available

Web site - facilities: –

Web site - procedures: –

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: –

| | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|--------|-----------------------|---------------------------|----------|------------------------------------|



Healthcare facility

| | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | n/a | n/a | n/a | n/a |
| Health centre | n/a | n/a | n/a | n/a |
| District hospital | 168 | 382 | 550 | 1.172 |
| Provincial hospital | 105 | 36 | 141 | 0.300 |
| Regional hospital | 72 | 4 | 76 | 0.162 |



Medical equipment

| | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 170 | 212 | 382 | 8.140 |
| Computerized Tomography Scanner | 438 | 212 | 650 | 13.851 |
| Positron Emission Tomography Scanner | n/a | n/a | n/a | n/a |
| Nuclear medicine | 171 | 52 | 223 | 4.752 |
| Mammograph* | n/a | n/a | n/a | n/a |
| Linear accelerator | 124 | 40 | 164 | 3.495 |
| Telecobalt unit (Cobalt-60) | 28 | 3 | 31 | 0.661 |
| Radiotherapy | 152 | 43 | 195 | 4.155 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: –

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

Sweden



Country indicators

| | | | | | |
|---------------------------------|-------|---|------|--------------------------------------|--------|
| Population (000s)* | 9'571 | Life expectancy at birth (years) ^a | 82 | World Bank income group ^β | High |
| Internet users (%) ^γ | 94.8% | Per capita total health expenditure (PPP Int \$) ^δ | 4158 | GNI per capita (US\$) ^ε | 61'760 |



National policy on health technology

Health technology (medical device) national policy: —

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Medical Products Agency

Web site: <http://www.lakemedelsverket.se/english/>



National health technology assessment unit

Unit/department: The Swedish Council on Health Technology Assessment, SBU

Web site: www.sbu.se/en/



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: The Dental and Pharmaceutical Benefits Agency

Web site: <http://www.tlv.se/in-english-old/in-english/>

OTHER: —

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on GMDN (Global Medical Device Nomenclature)

Use: —

Nomenclature system name: GMDN Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: No

Web site: —

DONATIONS

Policy or guideline: No

Web site: —

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ:

The national law for procurement is based on the EU directive. Concerning procurement it can be done on the level of county or within a single hospital.



Inventory and maintenance

Type of inventories available: —

Comments: None

Medical equipment management unit: Yes

National level = —

Regional level = —

Hospital level = —

Management software: Yes

Software and comments^λ: —

Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:Lists comments^λ:

Lists available: No

Unit: —

Web site: —

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES**OR SPECIFIC PROCEDURES:** Lists available: —

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: —

Types:

| | | | |
|-----------------------|---------------------------|----------|------------------------------------|
| Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|-----------------------|---------------------------|----------|------------------------------------|



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | n/a | n/a | n/a | n/a |
| Health centre | n/a | n/a | n/a | n/a |
| District hospital | n/a | n/a | n/a | n/a |
| Provincial hospital | n/a | n/a | n/a | n/a |
| Regional hospital | n/a | n/a | n/a | n/a |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | n/a | n/a | n/a | n/a |
| Computerized Tomography Scanner | n/a | n/a | n/a | n/a |
| Positron Emission Tomography Scanner | n/a | n/a | n/a | n/a |
| Nuclear medicine | n/a | n/a | n/a | n/a |
| Mammograph* | n/a | n/a | n/a | n/a |
| Linear accelerator | n/a | n/a | n/a | n/a |
| Telecobalt unit (Cobalt-60) | n/a | n/a | n/a | n/a |
| Radiotherapy | n/a | n/a | n/a | n/a |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: —

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|-------|---|------|--------------------------------------|--------|
| Population (000s)* | 8'078 | Life expectancy at birth (years) ^a | 83 | World Bank income group ^β | High |
| Internet users (%) ^γ | 86.7% | Per capita total health expenditure (PPP Int \$) ^δ | 6062 | GNI per capita (US\$) ^ε | 90'760 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Swissmedic

Web site: <http://www.swissmedic.ch/md.asp>



National health technology assessment unit

Unit/department: Health and Accident Insurance Directorate

Web site: <http://www.bag.admin.ch/themen/krankenversicherung/00263/00264/index.html?lang=de>



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on more than one system Use: Not specified

Nomenclature system name: UMDNS and GMDN (preference given to GMDN, however if manufacturers do not know GMDN, then UMDNS is used) Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: No

Web site: —

DONATIONS

Policy or guideline: No

Web site: —

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: Yes

Web site: —

Medical device incorporation comments^λ:

Medical devices must fulfill the requirements described in the European medical device directives. Legal basis (Swiss Medical devices ordinance): http://www.admin.ch/ch/d/sr/c812_213.html. The hospital / high cost technology planning is at cantonal level. Coordinated planning of certain highly specialized areas of health care is under way (see <http://www.gdk-cds.ch/291.0.html>)



Inventory and maintenance

Type of inventories available: National inventory only for high cost technologies (such as MRI, CT or PET scanners)

Comments: Go to the website and search for the 291.O.html documentation.

Medical equipment management unit: Yes

National level = 0

Regional level = 0

Hospital level = 0

Management software: –

Software and comments^λ: –



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^δ:

Lists available: Yes

Unit: Swiss Federal Office of Public Health

Web site: –

Lists comments^λ:

Reimbursement list for medical devices used by the patients themselves: <http://www.bag.admin.ch/themen/>

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: No list available

Web site - facilities: –

Web site - procedures: –

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: One or more

Web site: <http://www.lba.admin.ch/internet/lba/de/home/themen/sanit/koordinierterO.html>

| | | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|---|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations | x |
|--------|-----------------------|---------------------------|----------|------------------------------------|---|



Healthcare facility

| | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | n/a | n/a | n/a | n/a |
| Health centre | n/a | n/a | n/a | n/a |
| District hospital | n/a | n/a | n/a | n/a |
| Provincial hospital | n/a | n/a | n/a | n/a |
| Regional hospital | n/a | n/a | n/a | n/a |



Medical equipment

| | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | n/a | n/a | n/a | n/a |
| Computerized Tomography Scanner | n/a | n/a | n/a | n/a |
| Positron Emission Tomography Scanner | n/a | n/a | n/a | n/a |
| Nuclear medicine | n/a | n/a | n/a | n/a |
| Mammograph [*] | n/a | n/a | n/a | n/a |
| Linear accelerator | n/a | n/a | n/a | n/a |
| Telecobalt unit (Cobalt-60) | n/a | n/a | n/a | n/a |
| Radiotherapy | n/a | n/a | n/a | n/a |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: –

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

Tajikistan



Country indicators

| | | | | | |
|---------------------------------|-------|---|-----|--------------------------------------|-----|
| Population (000s)* | 8'208 | Life expectancy at birth (years) ^a | 68 | World Bank income group ^β | Low |
| Internet users (%) ^γ | 16.0% | Per capita total health expenditure (PPP Int \$) ^δ | 129 | GNI per capita (US\$) ^ε | 990 |



National policy on health technology

Health technology (medical device) national policy: Yes, and it is part of the National Health Program/Plan or Policy

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: —

Web site: <http://www.health.tj/en>



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: Management Unit

Web site: —

OTHER: Planning of medical equipment allocation/development technical specification/application/user training

Unit/department: Medical Devices Unit

Web site: —

OTHER: Planning of medical equipment allocation/HTA/development technical specification/application/user training

Unit/department: Management Unit

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on GMDN (Global Medical Device Nomenclature)

Use: For procurement

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: —

National level procurement: Yes

Web site: —

DONATIONS

Policy or guideline: Yes

Web site: —

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: Yes

Web site: —

Medical device incorporation comments^λ: —



Inventory and maintenance

Type of inventories available: National Register of medical devices

Comments: –

Medical equipment management unit: –

National level = –

Regional level = –

Hospital level = –

Management software: –

Software and comments^λ: –

Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:Lists comments^λ: –

Lists available: Yes

Unit: –

Web site: –

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES**OR SPECIFIC PROCEDURES:** Lists available: –

Web site - facilities: –

Web site - procedures: –

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: –

Web site: –

| | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|--------|-----------------------|---------------------------|----------|------------------------------------|



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 1'701 | n/a | 1701 | 20.724 |
| Health centre | 840 | n/a | 840 | 10.234 |
| District hospital | 249 | n/a | 249 | 3.034 |
| Provincial hospital | 132 | n/a | 132 | 1.608 |
| Regional hospital | 3 | n/a | 3 | 0.037 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 3 | n/a | 3 | 0.366 |
| Computerized Tomography Scanner | 9 | n/a | 9 | 1.097 |
| Positron Emission Tomography Scanner | n/a | n/a | n/a | n/a |
| Nuclear medicine | n/a | n/a | n/a | n/a |
| Mammograph* | 5 | n/a | 5 | 12.587 |
| Linear accelerator | 0 | n/a | 0 | 0.000 |
| Telecobalt unit (Cobalt-60) | 1 | n/a | 1 | 0.122 |
| Radiotherapy | 1 | n/a | 1 | 0.122 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: –

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|--------|---|------|--------------------------------------|--------------|
| Population (000s)* | 74'933 | Life expectancy at birth (years) ^a | 75 | World Bank income group ^β | Upper-middle |
| Internet users (%) ^γ | 46.3% | Per capita total health expenditure (PPP Int \$) ^δ | 1144 | GNI per capita (US\$) ^ε | 10'970 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Turkey Medicines and Medical Devices Agency, Ministry of Health

Web site: <http://www.saglik.gov.tr/TR/belge/1-1949/turkiye-ilac-ve-tibbi-cihaz-kurumu.html&usg=ALkJrhg9H6Pb2roUGPwfxqZ8K7su3kPpVQ>



National health technology assessment unit

Unit/department: General Directorate of Health Research Department of HTA

Web site: www.hta.gov.tr



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: Department of Strategy Development

Web site: <http://www.sgb.saglik.gov.tr>

OTHER: Market Surveillance/application/user training

Unit/department: Directorate of Pharmacy and Pharmaceuticals

Web site: <http://www.iegm.gov.tr>

OTHER: Health technology management

Unit/department: General Directorate of Health for Borders and Coasts

Web site: <http://www.hssgm.gov.tr/>



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Nationally developed Use: Not specified

Nomenclature system name: UNSPSC: based on GMDN adapted to national needs. Web site: <http://www.huap.org.tr/branskodlari/>



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: <http://www.saglik.gov.tr/TR/Genel/DosyaGoster.aspx?BELGEANAH=44239&DIL=1&DOSYASIM=genelge-2010-10.docx>

National level procurement: No

Web site: —

DONATIONS

Policy or guideline: Yes

Web site: <http://www.saglik.gov.tr/>

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ: —



Inventory and maintenance

Type of inventories available: National inventory for medical equipment

Comments: Go to the previous website and search for sbhbt. However, the full online inventory databank on site <http://sbu.saglik.gov.tr/sbhbf/> but its use is restricted to authorities.

Medical equipment management unit: Yes

National level = —

Regional level = —

Hospital level = —

Management software: —

Software and comments^λ: —



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:

Lists available: Yes

Unit: Social Security Institution

Web site: —

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: For different healthcare facilities and specific procedures

Web site - facilities: <http://www.saglik.gov.tr>

Web site - procedures: <http://www.saglik.gov.tr>

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: One or more

Web site: <http://www.saglik.gov.tr> and <http://www.grip.gov.tr>

Types:

| | | | | | | | |
|-----------------------|---|---------------------------|---|----------|--|------------------------------------|---|
| Communicable diseases | x | Non-communicable diseases | x | Injuries | | Public health emergency situations | x |
|-----------------------|---|---------------------------|---|----------|--|------------------------------------|---|

Lists comments^λ:

These standards are not centrally organized and published. Each department has its own relevant departments and headlines (see www.saglik.gov.tr>Saglik Mevzuati>Genelgeler, Tebligler, Yönergeler, Yönetmelikler>). Each directorate and department has its relevant health technology reference documents (guidelines, circulars, regulatory statute etc) in its own links in the website.



Healthcare facility

| | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 6'305 | 1'213 | 7518 | 10.033 |
| Health centre | 169 | 34 | 203 | 0.271 |
| District hospital | n/a | n/a | n/a | n/a |
| Provincial hospital | 519 | 405 | 924 | 1.233 |
| Regional hospital | 198 | 39 | 237 | 0.316 |



Medical equipment

| | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 292 | 168 | 460 | 6.139 |
| Computerized Tomography Scanner | 792 | 296 | 1088 | 14.520 |
| Positron Emission Tomography Scanner | 31 | 36 | 67 | 0.894 |
| Nuclear medicine | 159 | 127 | 286 | 3.817 |
| Mammograph* | 1146 | 308 | 1454 | 230.356 |
| Linear accelerator | 65 | 42 | 107 | 1.428 |
| Telecobalt unit (Cobalt-60) | 34 | 11 | 45 | 0.601 |
| Radiotherapy | 99 | 53 | 152 | 2.028 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ:

Concerning medical equipment and structure section: there is a draft document (Health Statistics Yearbook) at the link http://www.tusak.saglik.gov.tr/saglik_istatistikleri2008.pdf. But it is not appropriate to use it as a reference since the original document will be available in the future. Some numbers can be variable because of the dynamic situation in Turkey. Especially for the last 5-7 years, the health technology situation is changing and developing rapidly.

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|--------|---|-----|--------------------------------------|--------------|
| Population (000s)* | 45'239 | Life expectancy at birth (years) ^a | 71 | World Bank income group ^β | Lower-middle |
| Internet users (%) ^γ | 41.8% | Per capita total health expenditure (PPP Int \$) ^δ | 562 | GNI per capita (US\$) ^ε | 3'960 |



National policy on health technology

Health technology (medical device) national policy: Yes, but is not part of the National Health Program

Web site: Bases legislation ohoron zdorov.doc

Language(s): Ukranian

MOH responsible for health technology policy implementation: Department of Regulatory Policy in the treatment of drugs and products in the health care system of the Ministry of Health



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: The State Service of Ukraine drugs

Web site: <http://www.diklz.gov.ua>



National health technology assessment unit

Unit/department: Department of Regulatory Policy in the treatment of drugs and products in the health care system

Web site: <http://www.moz.gov.ua>



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: Department management and quality control of medical services

Web site: <http://www.moz.gov.ua>

OTHER: Planning of medical equipment allocation/development of technical specifications

Unit/department: Control of monitoring and maintenance of state programs

Web site: <http://www.moz.gov.ua>

OTHER: Development of technical specifications

Unit/department: Department of procurement

Web site: <http://www.moz.gov.ua>



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: Yes

Web site: —

DONATIONS

Policy or guideline: Yes

Web site: <http://www.moz.gov.ua/portal/> AND <http://www.kmu.gov.ua/control/>

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ: —



Inventory and maintenance

Type of inventories available: National Register of medical devices

Comments: Not enough memory to load the registry

Medical equipment management unit: No

National level = —

Regional level = —

Hospital level = —

Management software: No

Software and comments^λ: —



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^δ

Lists available: Yes

Unit: Department of medical care, the Department of motherhood, childhood and spa provide MSS

Web site: List of free oborud.doc

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: For different healthcare facilities and specific procedures

Web site - facilities: www.moz.gov.ua

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: One or more

Web site: <http://www.moz.gov.ua>

Types: Communicable diseases x Non-communicable diseases x Injuries Public health emergency situations x

Lists comments^λ:

We follow orders of the Ministry of Health approval of protocols of care for various diseases. We have lists available for communicable and non communicable diseases, and public health emergency situations.



Healthcare facility

| | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | n/a | n/a | n/a | n/a |
| Health centre | n/a | n/a | n/a | n/a |
| District hospital | n/a | n/a | n/a | n/a |
| Provincial hospital | n/a | n/a | n/a | n/a |
| Regional hospital | n/a | n/a | n/a | n/a |



Medical equipment

| | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | n/a | n/a | n/a | n/a |
| Computerized Tomography Scanner | n/a | n/a | n/a | n/a |
| Positron Emission Tomography Scanner | n/a | n/a | n/a | n/a |
| Nuclear medicine | n/a | n/a | n/a | n/a |
| Mammograph* | n/a | n/a | n/a | n/a |
| Linear accelerator | n/a | n/a | n/a | n/a |
| Telecobalt unit (Cobalt-60) | n/a | n/a | n/a | n/a |
| Radiotherapy | n/a | n/a | n/a | n/a |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: —

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

United Kingdom of Great Britain and Northern Ireland

Country indicators



| | | | | | |
|---------------------------------|--------|---|------|--------------------------------------|--------|
| Population (000s)* | 63'136 | Life expectancy at birth (years) ^a | 81 | World Bank income group ^β | High |
| Internet users (%) ^γ | 89.8% | Per capita total health expenditure (PPP Int \$) ^δ | 3495 | GNI per capita (US\$) ^ε | 41'680 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: The Medicines and Healthcare products Regulatory Agency (MHRA)

Web site: www.mhra.gov.uk



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): No

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Nationally developed Use: Not specified

Nomenclature system name: MHRA will be moving forward to using solely GMDN with their own system being phased out. The nomenclature used by the NHS for the procurement of medical devices is that used by the

“Official Journal of the European Union” (ojeu) CPV codes. Web site: <http://www.mhra.gov.uk/Howweregulate/Devices/Registrationofmedicaldevices/index.htm> AND www.nhseclass.nhs.uk



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: <http://nhscep.useconnect.co.uk> AND http://www.nhsns.org/pages/divisions/national_procurement.php

National level procurement: Yes

Web site: <http://www.supplychain.nhs.uk> AND <http://www.nhsns.org>

DONATIONS

Policy or guideline: Yes

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: Yes

Web site: <http://nhscep.useconnect.co.uk>

Medical device incorporation comments^λ:

Medical devices may be procured at a number of levels, either locally (NHS Trust level), regionally (collaborative procurement hub level) or nationally (NHS Supply chain). Also in Scotland, there is system for National Procurement for the NHS



Inventory and maintenance

Type of inventories available: None

Comments^λ: A recent amendment of the Medical Devices Directive has lifted the confidentiality requirement on information supplied by manufacturers to Competent Authorities under their obligation to register certain types of medical devices. The devices include low risk class I devices CE marked on the basis of a self declaration of conformity...

Medical equipment management unit: Yes

National level = 165

Regional level = 0

Hospital level = 0

Management software: —

Software and comments^λ: —



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:

Lists available: No

Unit: —

Web site: —

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES OR SPECIFIC PROCEDURES: Lists available: —

Web site - facilities: —

Web site - procedures: <http://nhscep.useconnect.co.uk>

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: One or more

Web site: <http://www.nice.org.uk/guidance/index.jsp?action=ByType&type=6&status=3&p=off> also see www.dh.gsi.gov.uk/cep

Lists comments^λ:

There is no approved list of medical devices for procurement. However we have lists for communicable and non communicable diseases, and public health emergency situations. Guidance is produced by NICE and CEP which was disbanded 31 March 2010. NHS Supply Chain provides a catalogue of products that can be purchased by the NHS which are approved...

| | | | | | | | |
|--------|-----------------------|---|---------------------------|---|----------|---|------------------------------------|
| Types: | Communicable diseases | x | Non-communicable diseases | x | Injuries | x | Public health emergency situations |
|--------|-----------------------|---|---------------------------|---|----------|---|------------------------------------|



Healthcare facility

| | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | n/a | n/a | n/a | n/a |
| Health centre | n/a | n/a | n/a | n/a |
| District hospital | n/a | n/a | n/a | n/a |
| Provincial hospital | n/a | n/a | n/a | n/a |
| Regional hospital | n/a | n/a | n/a | n/a |



Medical equipment

| | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | n/a | n/a | n/a | n/a |
| Computerized Tomography Scanner | n/a | n/a | n/a | n/a |
| Positron Emission Tomography Scanner | n/a | n/a | n/a | n/a |
| Nuclear medicine | n/a | n/a | n/a | n/a |
| Mammograph* | n/a | n/a | n/a | n/a |
| Linear accelerator | n/a | n/a | n/a | n/a |
| Telecobalt unit (Cobalt-60) | n/a | n/a | n/a | n/a |
| Radiotherapy | n/a | n/a | n/a | n/a |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ:

Concerning HT national policy we provide the following doc.: http://www.president.gov.ua/docs/Programa_reform_FINAL_1.pdf; www.rada.gov.ua. The UK comprises of 4 Devolved Administrations: England, Wales, Northern Ireland and Scotland. Each Administration is responsible for delivery of its own healthcare system as well as collating and maintaining its own data. There is therefore no centrally held data that covers whole of UK. A range of initiatives around more...

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

4.6 South-East Asia Region facts and country profiles

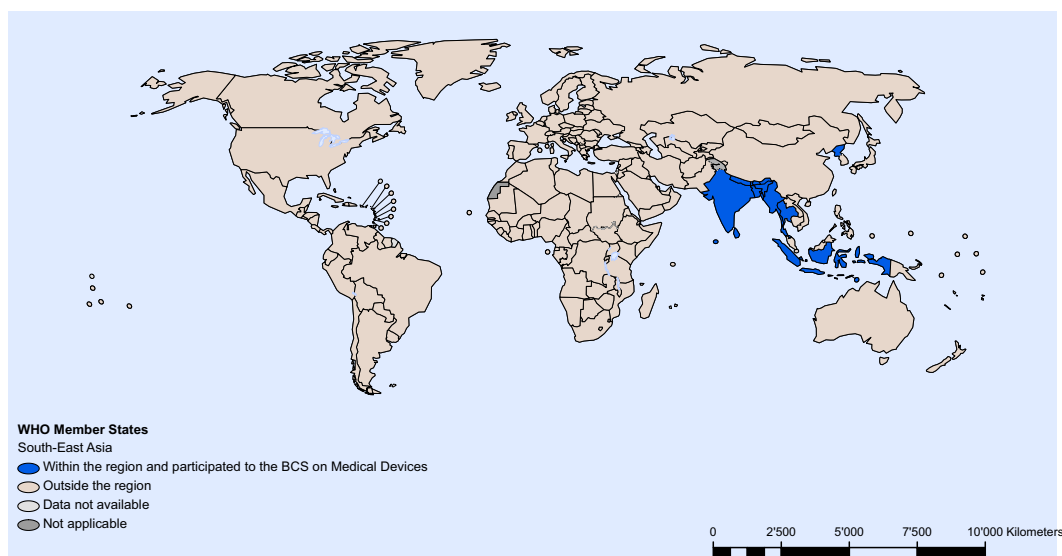


Fig. 4.6-1. Baseline Country Survey on Medical Devices South-East Asia Region participation

Participation: South-East Asia Region's survey participation was 100% (11/11). Participating countries are shown in Fig. 4.6-1.

National policy on health technology: 60% of the respondent SEAR states (6/10) have a Health Technology policy, additionally in 83% of them the HT policy is part of the national health programme.

Regulatory agency:²³ 64% of the SEAR Member States (7/11) have a regulatory authority responsible for medical devices.

National health technology assessment unit:²⁴ 62.5% of the respondent countries (5/8) have a national agency/unit/committee that produces Health Technology Assessment (HTA) reports for the Ministry of Health..

National health technology management units: 70% of the respondent SEAR states (7/10) have a national unit which technically manages medical devices. Of these countries, 57% (4/7) have a national unit in charge of technical specifications development for procurement process; 57% (4/7) have a unit in charge of planning of medical devices allocation, and 43% (3/7) have a unit to support user/training application of medical devices (Fig. 4.6-2).

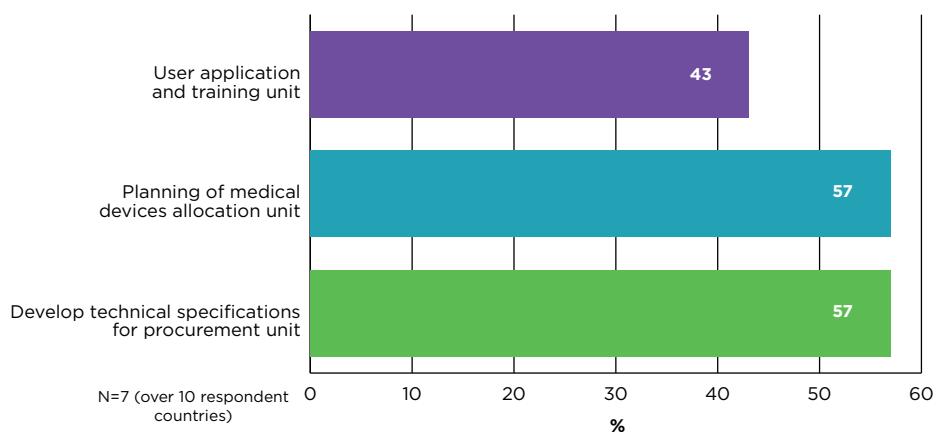


Fig. 4.6-2. Proportion of SEAR countries having different types of health technology units (percentages taken from countries that have at least one health technology national unit)



Medical device nomenclature system: Only 36% of the respondent SEAR states (4/11) have an official nomenclature system for medical devices (Fig. 4.6-3).

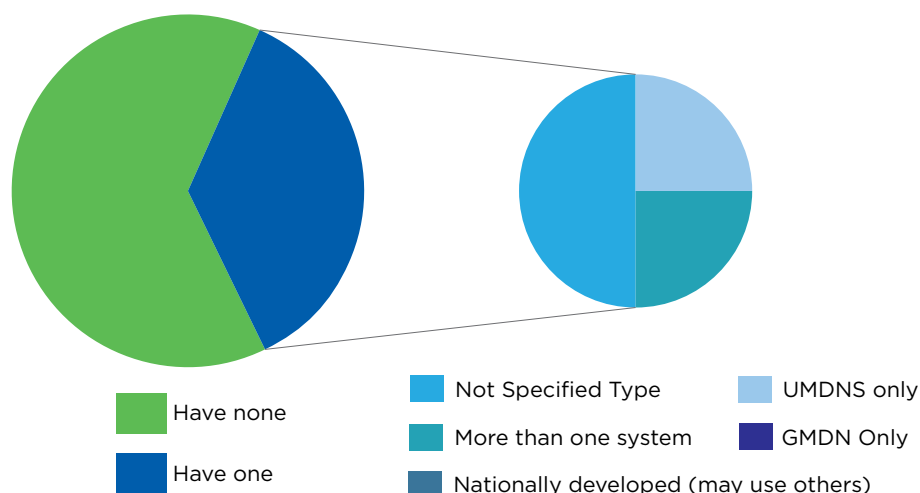


Fig. 4.6-3. Proportion of SEAR countries with official nomenclature system for medical devices and their corresponding type (percentages taken from all respondent countries)

Medical device incorporation: 70% of the respondent SEAR states (7/10) have national guidelines, policies or recommendations on the procurement of medical devices. In total, 80% of the respondent states (8/10) carried out the procurement of medical devices at national level, and 67% of the respondent states (6/9) have recommended technical specifications of medical devices to support procurement or donations.

Inventory and maintenance: 66% of the respondent SEAR states (5/9) have an available inventory for medical devices. Of those countries, 80% (4/5) have a national inventory for medical equipment.

Lists of medical devices: 56% of the respondent SEAR states (5/9) have national standards or recommended list(s) of medical devices for different types of healthcare facilities. In total, 62% of the respondent states (5/8) have national list(s) of recommended medical devices for specific procedures, and 22% of the respondent states (2/9) have national list(s) of recommended medical devices for high burden diseases or injuries or health emergency situations.

Healthcare facilities: The regional density of health posts is one of the highest among all regions, but the regional density of regional/specialized/teaching and research hospitals per 100 000 population is one of the lowest of the six regions (Fig. 4.6-4).

| Healthcare facility | Have at least one per 100,000 pop. (%) | Number of responding countries | Regional Density per 100,000 pop. |
|--|--|--------------------------------|-----------------------------------|
| Health posts | 100% | 8 | 12.13 |
| Health centre | 57% | 7 | 2.02 |
| Distric/Rural hospitals | 44% | 9 | 0.64 |
| Regional/ Specialized/ Teaching and Research hospitals | 0% | 5 | 0.06 |

Fig. 4.6-3. Proportion of SEAR countries and regional densities regarding healthcare infrastructure (percentages taken from all respondent countries)

Medical equipment: 50% or more of the respondent countries have a CT and mammograph per million population. The regional density of medical high technology equipment (per million population) in this region is very low for all seven medical devices surveyed compared to the other regions (see Fig. 4.6-4).

| Medical Equipment | Have at least one unit per 1,000,000 pop. (%) | Number of responding countries | Regional density per 1,000,000 pop. |
|--|---|--------------------------------|-------------------------------------|
| Magnetic Resonance Imaging (MRI) | 50% | 4 | 0.20 |
| Computed Tomography (CT Scanner) | 80% | 5 | 3.1 |
| Positron Emission Tomography (PET Scanner) | 0% | 4 | 0.06 |
| Gamma Camera or Nuclear Medicine | 0% | 5 | 0.26 |
| *Mammographs | 60% | 5 | 1.58 |
| Radiotherapy Unit: Linear Accelerator (LA) | 25% | 4 | 0.5 |
| Radiotherapy Unit:Telecobalt Unit (TU) | 20% | 5 | 0.25 |
| Radiotherapy Unit (LA+TU) | 20% | 5 | 0.56 |

* Mammographs density is per 100,000 females aged between 50 and 69 years old, and the regional density per million females of the same age

Fig. 4.6-4. Proportion of SEAR countries and regional densities regarding high technology equipment (percentages taken from all respondent countries)



List of country profiles for WHO South East Asia Region

| | | | |
|--|-----|-------------|-----|
| Bangladesh | 398 | Maldives | 408 |
| Bhutan | 400 | Myanmar | 410 |
| Democratic People's Republic of Korea | 402 | Nepal | 412 |
| India | 404 | Sri Lanka | 414 |
| Indonesia | 406 | Thailand | 416 |
| | | Timor-Leste | 418 |

Bangladesh



Country indicators

| | | | | | |
|---------------------------------|---------|---|----|--------------------------------------|-------|
| Population (000s)* | 156'595 | Life expectancy at birth (years) ^a | 70 | World Bank income group ^β | Low |
| Internet users (%) ^γ | 6.5% | Per capita total health expenditure (PPP Int \$) ^δ | 68 | GNI per capita (US\$) ^ε | 1'010 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: —

Name of principal institution: Directorate General of Drug Administration

Web site: <http://dgda.gov.bd/>



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): No

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: <http://www.cptu.gov.bd/default.aspx>

National level procurement: Yes

Web site: <http://www.cptu.gov.bd/default.aspx>

DONATIONS

Policy or guideline: Yes

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: Yes

Web site: <http://www.cptu.gov.bd/default.aspx>

Medical device incorporation comments^λ: —



Inventory and maintenance

Type of inventories available: —

Comments: Central Medical Stores Depot, Tejgaon, Dhaka-1208, Dhaka has all the data in this regards

Medical equipment management unit: Yes

National level = 1

Regional level = —

Hospital level = —

Management software: —

Software and comments^λ: —



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:

Lists comments^λ: —

Lists available: —

Unit: —

Web site: —

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: For different healthcare facilities

Web site - facilities: http://www.mohfw.gov.bd/index.php?option=com_content&view=article&id=104&Itemid=139&lang=en

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: —

| | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|--------|-----------------------|---------------------------|----------|------------------------------------|



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 9'722 | n/a | 9722 | 6.208 |
| Health centre | 27 | n/a | 27 | 0.017 |
| District hospital | 59 | n/a | 59 | 0.038 |
| Provincial hospital | 28 | 105 | 133 | 0.085 |
| Regional hospital | 25 | 44 | 69 | 0.044 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | n/a | n/a | n/a | n/a |
| Computerized Tomography Scanner | n/a | n/a | n/a | n/a |
| Positron Emission Tomography Scanner | n/a | n/a | n/a | n/a |
| Nuclear medicine | n/a | n/a | n/a | n/a |
| Mammograph* | n/a | n/a | n/a | n/a |
| Linear accelerator | n/a | n/a | n/a | n/a |
| Telecobalt unit (Cobalt-60) | n/a | n/a | n/a | n/a |
| Radiotherapy | n/a | n/a | n/a | n/a |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: —

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

Bhutan



Country indicators

| | | | | | |
|---------------------------------|-------|---|-----|--------------------------------------|--------------|
| Population (000s)* | 754 | Life expectancy at birth (years) ^a | 68 | World Bank income group ^β | Lower-middle |
| Internet users (%) ^γ | 29.9% | Per capita total health expenditure (PPP Int \$) ^δ | 253 | GNI per capita (US\$) ^ε | 2'330 |



National policy on health technology

Health technology (medical device) national policy: Yes, and it is part of the National Health Program/Plan or Policy

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: No

Name of principal institution: —

Web site: —



National health technology assessment unit

Unit/department: Essential Medicine & Technology Division

Web site: www.health.gov.bt



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: Biomedical Engineering Division

Web site: —

OTHER: Planning of medical equipment allocation/Acquisition

Unit/department: Drug Vaccine and Equipment Division

Web site: —

OTHER: Planning of medical equipment allocation/Quality of equipments/Procurement

Unit/department: Quality Assurance and Standardization Division

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Nationally developed Use: Not specified

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: <http://www.mof.gov.bt/>

National level procurement: Yes

Web site: <http://www.health.gov.bt/dms/dved/procurementProc.pdf>

DONATIONS

Policy or guideline: Yes

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ:

All medical devices are procured by the MoH following the Procurement Rules and Regulations of the Min of Finance Bhutan (see: [procurementmanual1.pdf](#)). Drug Vaccine and Equipment Division (DVED) is the agency in the MoH that does the procurement of drugs and medical devices for the whole country.



Inventory and maintenance

Type of inventories available: National inventory for medical equipment

Comments: Biomedical Engineering Division under the Department of Medical Services has maintained an Inventory of equipments above Rupees 25,000 only.

Medical equipment management unit: Yes

National level = 1

Regional level = 0

Hospital level = —

Management software: No

Software and comments^λ: —



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:

Lists available: Yes

Unit: Health Care Diagnostic Division, Department of Medical Services

Web site: —

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: For different healthcare facilities

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: —

Lists comments^λ:

We don't have national lists of recommended medical devices but we are now developing a standard list of Equipments and non drug items for each level of health facilities in Bhutan (all levels). The standard list of equipments will be based on the standard services that will be provided at each level of health center. The standard list will be available soon. We have a list for

| | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|--------|-----------------------|---------------------------|----------|------------------------------------|



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 192 | n/a | 192 | 25.466 |
| Health centre | 12 | n/a | 12 | 1.592 |
| District hospital | 10 | n/a | 10 | 1.326 |
| Provincial hospital | 2 | n/a | 2 | 0.265 |
| Regional hospital | 1 | n/a | 1 | 0.133 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 1 | 0 | 1 | 1.326 |
| Computerized Tomography Scanner | 1 | 0 | 1 | 1.326 |
| Positron Emission Tomography Scanner | 0 | 0 | 0 | 0.000 |
| Nuclear medicine | 0 | 0 | 0 | 0.000 |
| Mammograph* | 0 | 0 | 0 | 0.000 |
| Linear accelerator | 0 | 0 | 0 | 0.000 |
| Telecobalt unit (Cobalt-60) | 0 | 0 | 0 | 0.000 |
| Radiotherapy | 0 | 0 | 0 | 0.000 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ:

Concerning Section Infrastructure: We have 1 National Referral Hospital with 350 beds, 2 Regional referral hospitals with 150 beds each, we have 10 district hospitals with 60 to 40 beds. We have 12 district hospitals with 20 beds. Out of our 192 health posts 18 are Basic Health Unit grade I with 10 beds, and the remaining 174 health centres with 2 to 5 beds are Basic Health Unit grade II.

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|--------|---|----|--------------------------------------|-----|
| Population (000s)* | 24'895 | Life expectancy at birth (years) ^a | 70 | World Bank income group ^β | Low |
| Internet users (%) ^γ | | Per capita total health expenditure (PPP Int \$) ^δ | | GNI per capita (US\$) ^ε | |



National policy on health technology

Health technology (medical device) national policy: Yes, and it is part of the National Health Program/Plan or Policy

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Department of Medical Device Management and Production

Web site: —



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: Dep. Medical Equipment

Web site: —

OTHER: Planning of medical equipment allocation/application/user training

Unit/department: Dep. Medical Equipment

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Nationally developed Use: Not specified

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: —

National level procurement: Yes

Web site: —

DONATIONS

Policy or guideline: Yes

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: Yes

Web site: —

Medical device incorporation comments^λ: —



Inventory and maintenance

Type of inventories available: National inventory for medical equipment

Comments: –

Medical equipment management unit: Yes

National level = –

Regional level = –

Hospital level = –

Management software: –

Software and comments^λ: –



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:

Lists comments^λ: –

Lists available: Yes

Unit: –

Web site: –

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: For different healthcare facilities and specific procedures

Web site - facilities: –

Web site - procedures: –

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: –

Web site: –

| | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|--------|-----------------------|---------------------------|----------|------------------------------------|



Healthcare facility

| | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 6'263 | n/a | 6263 | 25.157 |
| Health centre | 974 | n/a | 974 | 3.912 |
| District hospital | 1'575 | n/a | 1575 | 6.326 |
| Provincial hospital | 133 | n/a | 133 | 0.534 |
| Regional hospital | n/a | n/a | n/a | n/a |



Medical equipment

| | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | n/a | n/a | n/a | n/a |
| Computerized Tomography Scanner | n/a | n/a | n/a | n/a |
| Positron Emission Tomography Scanner | n/a | n/a | n/a | n/a |
| Nuclear medicine | n/a | n/a | n/a | n/a |
| Mammograph* | n/a | n/a | n/a | n/a |
| Linear accelerator | n/a | n/a | n/a | n/a |
| Telecobalt unit (Cobalt-60) | n/a | n/a | n/a | n/a |
| Radiotherapy | n/a | n/a | n/a | n/a |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: –

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|-----------|---|-----|--------------------------------------|--------------|
| Population (000s)* | 1'252'140 | Life expectancy at birth (years) ^a | 66 | World Bank income group ^β | Lower-middle |
| Internet users (%) ^γ | 15.1% | Per capita total health expenditure (PPP Int \$) ^δ | 157 | GNI per capita (US\$) ^ε | 1'570 |



National policy on health technology

Health technology (medical device) national policy: National Medical Device Policy (Draft); Drugs & Cosmetics Act & Rules thereof

Web site: —

Language(s): English

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Central Drugs Standard Control Organisation

Web site: <http://cdsco.nic.in>



National health technology assessment unit

Unit/department: Ministry of Health & Family Welfare

Web site: <http://www.mohfw.nic.in> www.dhr.gov.in www.nhsrindia.org



National health technology management units

National health technology unit(s): —

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: Division of Healthcare Technology (A WHO Collaborating Centre), National Health Systems Resource Centre, Ministry of Health & Family Welfare, Govt. of India

Web site: www.nhsrindia.org

OTHER: —

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: http://finmin.nic.in/the_ministry/dept_expenditure/ppcell/index.asp

National level procurement: —

Web site: —

DONATIONS

Policy or guideline: —

Web site: —

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: Yes

Web site: www.nhsrindia.org

Medical device incorporation comments^λ: —



Inventory and maintenance

Type of inventories available: Complete inventory of equipment with functional/non-functional status

Comments: –

Medical equipment management unit:

At the level of states

National level = –

Regional level = –

Hospital level = –

Management software: Available

Software and comments^λ: www.bmems.co.in



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:

Lists comments^λ: –

Lists available: Yes, for procurement

Unit: n/a

Web site: n/a

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: n/a

Web site - facilities: n/a

Web site - procedures: n/a

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: n/a

Web site: n/a

Types:

Communicable
diseases

Non-communicable
diseases

Injuries

Public health
emergency situations



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | n/a | n/a | n/a | n/a |
| Health centre | n/a | n/a | n/a | n/a |
| District hospital | n/a | n/a | n/a | n/a |
| Provincial hospital | n/a | n/a | n/a | n/a |
| Regional hospital | n/a | n/a | n/a | n/a |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | n/a | n/a | n/a | n/a |
| Computerized Tomography Scanner | n/a | n/a | n/a | n/a |
| Positron Emission Tomography Scanner | n/a | n/a | n/a | n/a |
| Nuclear medicine | n/a | n/a | n/a | n/a |
| Mammograph* | n/a | n/a | n/a | n/a |
| Linear accelerator | n/a | n/a | n/a | n/a |
| Telecobalt unit (Cobalt-60) | n/a | n/a | n/a | n/a |
| Radiotherapy | n/a | n/a | n/a | n/a |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: –

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

Indonesia



Country indicators

| | | | | | |
|---------------------------------|---------|---|-----|--------------------------------------|--------------|
| Population (000s)* | 249'866 | Life expectancy at birth (years) ^a | 71 | World Bank income group ^β | Lower-middle |
| Internet users (%) ^γ | 15.8% | Per capita total health expenditure (PPP Int \$) ^δ | 150 | GNI per capita (US\$) ^ε | 3'580 |



National policy on health technology

Health technology (medical device) national policy: Yes, and it is part of the National Health Program/Plan or Policy

Web site: —

Language(s): Indonesian

MOH responsible for health technology policy implementation: 1. Directorate of Production and Distribution of Medical Devices, DG of Pharmaceutical and Med. Dev, MoH 2. Directorate of Basic Medical Services, DG of Medical Services, MoH



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: —

Web site: <http://www.binfar.depkes.go.id>



National health technology assessment unit

Unit/department: Komite Penilaian Teknologi Kesehatan (Komite PTK)

Web site: —



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on more than one system Use: Not specified

Nomenclature system name: We use HS code at the moment (after harmonization we'll use GMDN) Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: —

National level procurement: Yes

Web site: <http://www.depkes.go.id/>

DONATIONS

Policy or guideline: Yes

Web site: —

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: —

Web site: —

Medical device incorporation comments^λ:

We follow Presidential Decree no 80 for general procurement. Both, yes and no. Yes, for vertical public hospitals, procurement conducted at national level. No, since recentralization, procurement of medical devices at province/district's hospital conducted at local level (province and district level), see yanmed on the website.



Inventory and maintenance

Type of inventories available: None

Comments: Inventories are still on going.

Medical equipment management unit: No

Management software: —

Software and comments^λ: —

National level = 0

Regional level = 0

Hospital level = 0



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^α:

Lists available: No

Unit: —

Web site: —

Lists comments^λ:

Guidelines are still in progress.
No lists availables, we use WHO recommendations

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: —

Web site - facilities: It's still in progress

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: —

| | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|--------|-----------------------|---------------------------|----------|------------------------------------|



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 23'163 | n/a | 23163 | 9.270 |
| Health centre | 8'548 | n/a | 8548 | 3.421 |
| District hospital | 612 | 467 | 1079 | 0.432 |
| Provincial hospital | n/a | n/a | n/a | n/a |
| Regional hospital | n/a | n/a | n/a | n/a |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | n/a | n/a | n/a | n/a |
| Computerized Tomography Scanner | n/a | n/a | n/a | n/a |
| Positron Emission Tomography Scanner | n/a | n/a | n/a | n/a |
| Nuclear medicine | n/a | n/a | n/a | n/a |
| Mammograph* | n/a | n/a | n/a | n/a |
| Linear accelerator | n/a | n/a | n/a | n/a |
| Telecobalt unit (Cobalt-60) | n/a | n/a | n/a | n/a |
| Radiotherapy | n/a | n/a | n/a | n/a |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: —

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|-------|---|-----|--------------------------------------|--------------|
| Population (000s)* | 345 | Life expectancy at birth (years) ^a | 77 | World Bank income group ^β | Upper-middle |
| Internet users (%) ^γ | 44.1% | Per capita total health expenditure (PPP Int \$) ^δ | 771 | GNI per capita (US\$) ^ε | 5'600 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Medicine and Therapeutic Goods / Maldives Food and Drug Authority

Web site: <http://www.health.gov.mv/>



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): No

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: Yes

Web site: <http://www.health.gov.mv>

DONATIONS

Policy or guideline: No

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: Yes, but not publically available

Web site: —

Medical device incorporation comments^λ:
Procurement at national level as well as for government health facilities



Inventory and maintenance

Type of inventories available: None

Comments: —

Medical equipment management unit: Yes

National level = 1

Regional level = 0

Hospital level = 0

Management software: No

Software and comments^λ: —

Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:Lists comments^λ: —

Lists available: No

Unit: —

Web site: —

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES**OR SPECIFIC PROCEDURES:** Lists available: No list available

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: —

| | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|--------|-----------------------|---------------------------|----------|------------------------------------|



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 38 | n/a | 38 | 11.014 |
| Health centre | 124 | n/a | 124 | 35.940 |
| District hospital | 21 | n/a | 21 | 6.087 |
| Provincial hospital | 1 | 1 | 2 | 0.580 |
| Regional hospital | n/a | n/a | n/a | n/a |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 0 | 1 | 1 | 2.898 |
| Computerized Tomography Scanner | 1 | 1 | 2 | 5.797 |
| Positron Emission Tomography Scanner | 0 | 0 | 0 | 0.000 |
| Nuclear medicine | 0 | 0 | 0 | 0.000 |
| Mammograph* | 1 | 0 | 1 | 57.087 |
| Linear accelerator | 0 | 0 | 0 | 0.000 |
| Telecobalt unit (Cobalt-60) | 0 | 0 | 0 | 0.000 |
| Radiotherapy | 0 | 0 | 0 | 0.000 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: —

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

Myanmar



Country indicators

| | | | | | |
|---------------------------------|--------|---|----|--------------------------------------|-----|
| Population (000s)* | 53'259 | Life expectancy at birth (years) ^a | 66 | World Bank income group ^β | Low |
| Internet users (%) ^γ | 1.2% | Per capita total health expenditure (PPP Int \$) ^δ | 25 | GNI per capita (US\$) ^ε | |



National policy on health technology

Health technology (medical device) national policy: Yes, and it is part of the National Health Program/Plan or Policy

Web site: —

Language(s): Myanmar and English

MOH responsible for health technology policy implementation: Medical Care Division, Department of Health



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Food and Drug Administration

Web site: <http://www.moh.gov.mm/>



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: —

National level procurement: Yes

Web site: —

DONATIONS

Policy or guideline: Yes

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: Yes, but not publically available

Web site: —

Medical device incorporation comments^λ: —



Inventory and maintenance

Type of inventories available: National inventory for medical equipment, National functional inventory for medical equipment

Comments: —

Medical equipment management unit: Yes

National level = —

Regional level = —

Hospital level = —

Management software: No

Software and comments^λ: —



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:

Lists available: Yes

Unit: —

Web site: —

Lists comments^λ:

Lists available for communicable and non communicable diseases, injuries, and public health emergency situations.

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: For different healthcare facilities and specific procedures

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: One or more

Web site: —

Types: Communicable diseases x Non-communicable diseases x Injuries x Public health emergency situations x



Healthcare facility

| | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 2'018 | n/a | 2018 | 3.789 |
| Health centre | 508 | n/a | 508 | 0.954 |
| District hospital | 273 | n/a | 273 | 0.513 |
| Provincial hospital | 38 | n/a | 38 | 0.071 |
| Regional hospital | 27 | n/a | 27 | 0.051 |



Medical equipment

| | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 4 | n/a | 4 | 0.075 |
| Computerized Tomography Scanner | 4 | n/a | 4 | 0.075 |
| Positron Emission Tomography Scanner | n/a | n/a | n/a | n/a |
| Nuclear medicine | 3 | n/a | 3 | 0.056 |
| Mammograph* | 3 | n/a | 3 | 0.708 |
| Linear accelerator | n/a | n/a | n/a | n/a |
| Telecobalt unit (Cobalt-60) | 3 | n/a | 3 | 0.056 |
| Radiotherapy | 3 | n/a | 3 | 0.056 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: —

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|--------|---|----|--------------------------------------|-----|
| Population (000s)* | 27'797 | Life expectancy at birth (years) ^a | 68 | World Bank income group ^β | Low |
| Internet users (%) ^γ | 13.3% | Per capita total health expenditure (PPP Int \$) ^δ | 80 | GNI per capita (US\$) ^ε | 730 |



National policy on health technology

Health technology (medical device) national policy: Yes, and it is part of the National Health Program/Plan or Policy

Web site: —

Language(s): English

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Department of Health Services and Logistics management Division

Web site: <http://www.dohslmd.gov.np>



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: Planning, Procurement unit, LMD

Web site: —

OTHER: Planning of medical equipment allocation/development of technical specifications

Unit/department: Logistics Management Division

Web site: <http://www.dohslmd.gov.np>

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: Yes

Web site: <http://www.dohslmd.gov.np/>

DONATIONS

Policy or guideline: No

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ:

We follow the Public Procurement Act and regulation of Nepal for procurement of medical devices also. Partially carried out at national level procurement of medical devices



Inventory and maintenance

Type of inventories available: None

Comments: Working on to develop national inventories

Medical equipment management unit: No

National level = 0

Regional level = 0

Hospital level = 0

Management software: Yes

Software and comments^λ: Web-based LMIS web based equipment/instrument Inventory Management System (non expendable item)



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:

Lists comments^λ: –

Lists available: No

Unit: –

Web site: –

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: No list available

Web site - facilities: –

Web site - procedures: –

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: –

| | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|--------|-----------------------|---------------------------|----------|------------------------------------|



Healthcare facility

| | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 699 | n/a | 699 | 2.515 |
| Health centre | 201 | n/a | 201 | 0.723 |
| District hospital | 65 | n/a | 65 | 0.234 |
| Provincial hospital | 29 | n/a | 29 | 0.104 |
| Regional hospital | 12 | n/a | 12 | 0.043 |



Medical equipment

| | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | n/a | n/a | n/a | n/a |
| Computerized Tomography Scanner | n/a | n/a | n/a | n/a |
| Positron Emission Tomography Scanner | n/a | n/a | n/a | n/a |
| Nuclear medicine | n/a | n/a | n/a | n/a |
| Mammograph* | n/a | n/a | n/a | n/a |
| Linear accelerator | n/a | n/a | n/a | n/a |
| Telecobalt unit (Cobalt-60) | n/a | n/a | n/a | n/a |
| Radiotherapy | n/a | n/a | n/a | n/a |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: –

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|--------|---|-----|--------------------------------------|--------------|
| Population (000s)* | 21'273 | Life expectancy at birth (years) ^a | 75 | World Bank income group ^β | Lower-middle |
| Internet users (%) ^γ | 21.9% | Per capita total health expenditure (PPP Int \$) ^δ | 189 | GNI per capita (US\$) ^ε | 3'170 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Cosmetics, Devices and Drugs Authority

Web site: <http://www.health.gov.lk>



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: Division of Biomedical Services

Web site: —

OTHER: Planning of medical equipment allocation/development of technical specifications/Application/ user training

Unit/department: Division of Biomedical Services

Web site: —

OTHER: Technical Evaluation Committee and Biomedical Engineering Services

Unit/department: Division of Biomedical Services

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on UMDNS (Universal Medical Device Nomenclature System) Use: Not specified

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: —

National level procurement: Yes

Web site: —

DONATIONS

Policy or guideline: Yes

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: Yes

Web site: —

Medical device incorporation comments^λ: —



Inventory and maintenance

Type of inventories available: National inventory only for high cost technologies (such as MRI, CT or PET scanners)

Comments: –

Medical equipment management unit: Yes

National level = 1

Regional level = 3

Hospital level = 22

Management software: Yes

Software and comments^λ: VH Temp



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:

Lists comments^λ: –

Lists available: Yes

Unit: –

Web site: –

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: For different healthcare facilities and specific procedures

Web site - facilities: –

Web site - procedures: –

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: –

| | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|--------|-----------------------|---------------------------|----------|------------------------------------|



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | n/a | n/a | n/a | n/a |
| Health centre | n/a | n/a | n/a | n/a |
| District hospital | 18 | n/a | 18 | 0.085 |
| Provincial hospital | 3 | n/a | 3 | 0.014 |
| Regional hospital | n/a | n/a | n/a | n/a |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 5 | 4 | 9 | 0.423 |
| Computerized Tomography Scanner | 24 | 12 | 36 | 1.692 |
| Positron Emission Tomography Scanner | 0 | 0 | 0 | 0.000 |
| Nuclear medicine | n/a | 4 | 4 | 0.188 |
| Mammograph* | 6 | n/a | 6 | 2.814 |
| Linear accelerator | 2 | 1 | 3 | 1.407 |
| Telecobalt unit (Cobalt-60) | 9 | n/a | 9 | 4.221 |
| Radiotherapy | 11 | 1 | 12 | 5.627 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: –

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

Thailand



Country indicators

| | | | | | |
|---------------------------------|--------|---|-----|--------------------------------------|--------------|
| Population (000s)* | 67'011 | Life expectancy at birth (years) ^a | 75 | World Bank income group ^β | Upper-middle |
| Internet users (%) ^γ | 28.9% | Per capita total health expenditure (PPP Int \$) ^δ | 386 | GNI per capita (US\$) ^ε | 5'340 |



National policy on health technology

Health technology (medical device) national policy: Yes, but is not part of the National Health Program

Web site: <http://www.fda.moph.go.th/New50/MDCD/25.pdf>

Language(s): Thai

MOH responsible for health technology policy implementation: Food and Drugs Administration



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Food and Drug Administration

Web site: <http://www.fda.moph.go.th/>



National health technology assessment unit

Unit/department: Health Intervention and Technology Assessment Program

Web site: www.hitap.net



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: —

Web site: —

OTHER: Pre and post marketing control of medical device.

Unit/department: Food and Drug Administration

Web site: <http://www.fda.moph.go.th/>

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: <http://www.fda.moph.go.th/>

National level procurement: No

Web site: —

DONATIONS

Policy or guideline: Yes

Web site: <http://www.moph.go.th/moph2/index4.php>

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: Yes

Web site: <http://www.moph.go.th/moph2/index4.php>

Medical device incorporation comments^λ:

The procurement was performed by individual agencies. For technical specifications go to the web site and find the law section, search for the corresponding documents



Inventory and maintenance

Type of inventories available: None

Comments: –

Medical equipment management unit: Yes

National level = 1

Regional level = 9

Hospital level = –

Management software: Yes

Software and comments^λ: RMC2005

Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^α:

Lists available: Yes

Unit: 1.National Health Security Office 2.The Comptroller General's Department
3.Social security office

Web site: –

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES OR SPECIFIC PROCEDURES: Lists available: No list available

Web site - facilities: –

Web site - procedures: –

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: –

Types:

| | | | |
|-----------------------|---------------------------|----------|------------------------------------|
| Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|-----------------------|---------------------------|----------|------------------------------------|

Lists comments^λ:

There are lists of recommended procedures in organization level such as the procedure of the Physical Therapy Council. The approved medical devices list is only available for the reimbursements of the three health insurances, namely the National Health Security Office, the Comptroller General's Department, and the Social security office.



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 9'836 | 18'503 | 28339 | 42.290 |
| Health centre | n/a | n/a | n/a | n/a |
| District hospital | 737 | n/a | 737 | 1.100 |
| Provincial hospital | 97 | 316 | 413 | 0.616 |
| Regional hospital | 85 | 1 | 86 | 0.128 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | n/a | n/a | n/a | n/a |
| Computerized Tomography Scanner | 145 | 254 | 399 | 5.954 |
| Positron Emission Tomography Scanner | 2 | 3 | 5 | 0.075 |
| Nuclear medicine | 29 | 1 | 30 | 0.448 |
| Mammograph* | 85 | 130 | 215 | 27.871 |
| Linear accelerator | 34 | 8 | 42 | 0.627 |
| Telecobalt unit (Cobalt-60) | 20 | 3 | 23 | 0.343 |
| Radiotherapy | 54 | 11 | 65 | 0.970 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: –

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|-------|---|----|--------------------------------------|--------------|
| Population (000s)* | 1'133 | Life expectancy at birth (years) ^a | 66 | World Bank income group ^β | Lower-middle |
| Internet users (%) ^γ | 1.1% | Per capita total health expenditure (PPP Int \$) ^δ | 80 | GNI per capita (US\$) ^ε | |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: No

Name of principal institution: —

Web site: —



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): No

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: No

Web site: —

DONATIONS

Policy or guideline: No

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ: —



Inventory and maintenance

Type of inventories available: National inventory for medical equipment

Comments: The Inventory from 2002- 2009

Medical equipment management unit: Yes

National level = 0

Regional level = 0

Hospital level = 0

Management software: No

Software and comments^λ: —



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^δ

Lists available: No

Unit: —

Web site: —

Lists comments^λ:

We have lists available for non communicable diseases.

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: For specific procedures

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: One or more

Web site: —

| | | | | | |
|--------|-----------------------|---------------------------|---|----------|------------------------------------|
| Types: | Communicable diseases | Non-communicable diseases | x | Injuries | Public health emergency situations |
|--------|-----------------------|---------------------------|---|----------|------------------------------------|



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | n/a | n/a | n/a | n/a |
| Health centre | n/a | n/a | n/a | n/a |
| District hospital | n/a | n/a | n/a | n/a |
| Provincial hospital | n/a | n/a | n/a | n/a |
| Regional hospital | n/a | n/a | n/a | n/a |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | n/a | n/a | n/a | n/a |
| Computerized Tomography Scanner | n/a | n/a | n/a | n/a |
| Positron Emission Tomography Scanner | n/a | n/a | n/a | n/a |
| Nuclear medicine | n/a | n/a | n/a | n/a |
| Mammograph* | n/a | n/a | n/a | n/a |
| Linear accelerator | n/a | n/a | n/a | n/a |
| Telecobalt unit (Cobalt-60) | n/a | n/a | n/a | n/a |
| Radiotherapy | n/a | n/a | n/a | n/a |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ:

Not have considered standards for medical equipment.

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

4.7 Western Pacific Region facts and country profiles

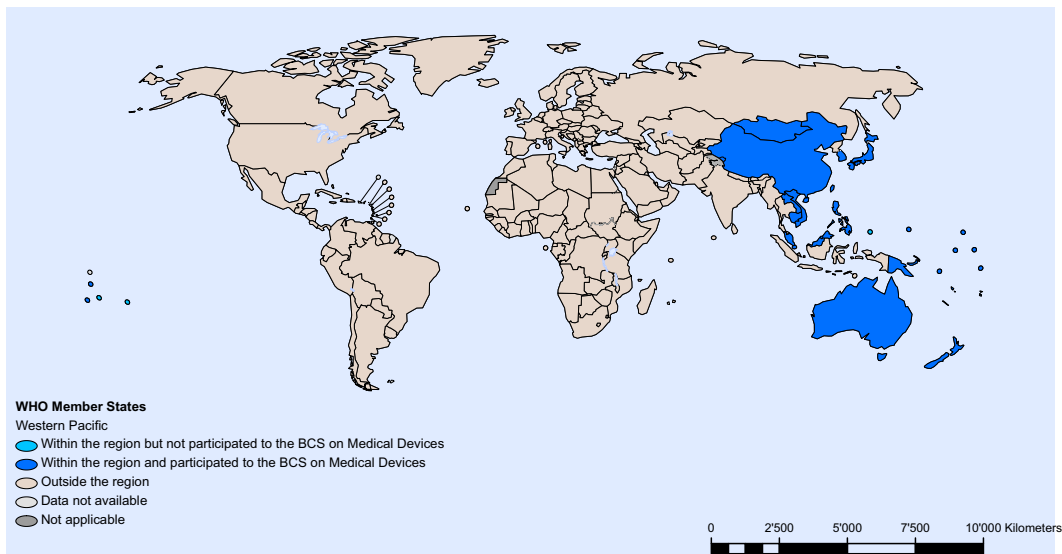


Fig. 4.7-1. Baseline Country Survey on Medical Devices Western Pacific Region participation

Participation: Western Pacific Region's survey participation was 89% (24/27). Participating countries are shown in Fig. 4.7-1.

National policy on health technology: Almost two third of the respondent WPR countries (58%: 14/24) do not have a Health Technology policy. However for 70% of the countries which have a HT policy it is also part of the national health programme.

Regulatory agency:²³ 48% of the respondent WPR states (13/27) have an authority responsible for implementing and enforcing medical device specific product regulations.

National health technology assessment unit:²⁴ 61.5% of the respondent countries (8/13) have a national agency/unit/committee that produces Health Technology Assessment (HTA) reports for the Ministry of Health.

National health technology management units: 65% of the respondent WPR states (15/23) have a national unit which technically manages medical devices. Of these countries, 80% (12/15) have a national unit which is in charge of technical specifications development for procurement process; 53% (8/15) have a unit in charge of planning of medical devices, and 67% (10/15) have a unit in charge of user/training application of medical devices (Fig. 4.7-2).

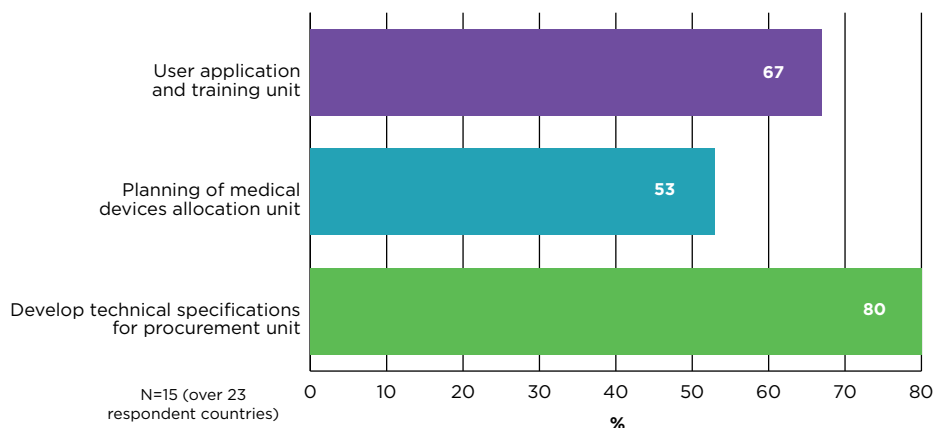
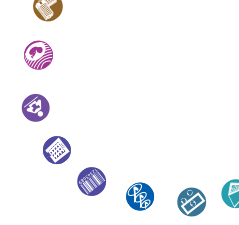


Fig. 4.7-2. Proportion of countries having different types of health technology units (percentages taken from countries that have at least one health technology national unit)



Medical device nomenclature system: 46% of the respondent states (10/22) have an official nomenclature system for medical devices. The type of nomenclature is distributed similarly between UMDNS 30%, Not specified (30%), GMDN (20%), and nationally developed (20%) (Fig. 4.7-3).

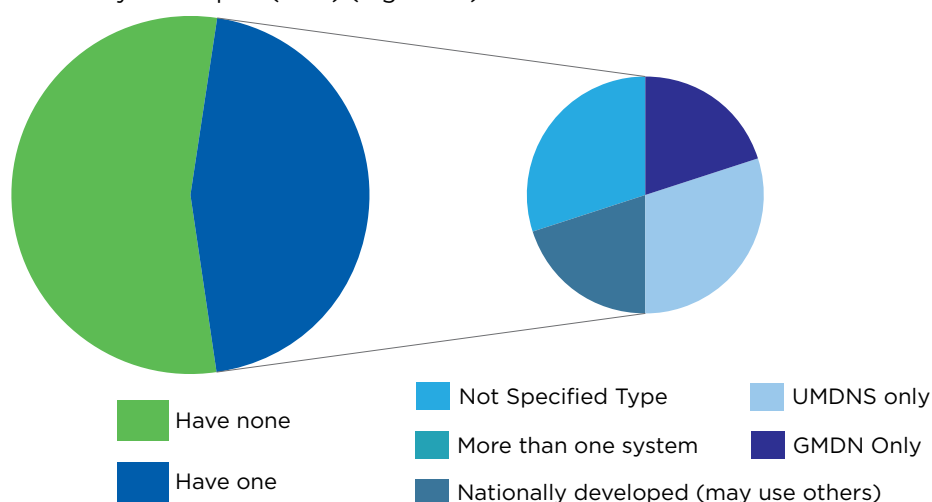


Fig. 4.7-3. Proportion of countries with official nomenclature system for medical devices and their corresponding type (percentages taken from all respondent countries)

Medical device incorporation: 45% of the respondent WPR states (10/22) have national guidelines, policies or recommendations on the procurement of medical devices. In total, 55% of the respondent states (12/22) carried out the procurement of medical devices at national level, however 57% of the respondent states (12/21) do not have recommended technical specifications of medical devices to support procurement or donations.

Inventory and maintenance: 80% of the respondent WPR states (16/20) have an available inventory for medical devices. Of those countries, 88% (14/16) have a national inventory for medical equipment.

Lists of medical devices: 57% of the respondent WPR states (12/21) have national standards or recommended list(s) of medical devices for different types of healthcare facilities. A total of 70% of the respondent states (14/20) have national list(s) of recommended medical devices for specific procedures, and 18% of the respondent states (4/22) have national list(s) of recommended medical devices for high burden diseases or injuries or health emergency situations.

Healthcare facilities: 82% of the respondent WPR countries have at least one health post per 100 000 population, 77% of the respondent countries have a least one health centre per 100 000 population, and 60% have at least one district hospital per 100 000 population. Therefore, the regional density of health posts, health centres, and district hospitals per 100 000 population, are one of the highest of all WHO regions (see Fig. 4.7-4).

| Healthcare facility | Have at least one per 100,000 pop. (%) | Number of responding countries | Regional Density per 100,000 pop. |
|--|--|--------------------------------|-----------------------------------|
| Health posts | 82% | 11 | 23.86 |
| Health centre | 85% | 13 | 37.66 |
| District/Rural hospitals | 60% | 15 | 1.54 |
| Regional/ Specialized/ Teaching and Research hospitals | 7% | 14 | 0.1 |

Fig. 4.7-4. Proportion of WPR countries and regional densities regarding healthcare infrastructure (percentages taken from all respondent countries)

Medical equipment: The regional density of the surveyed high technology medical equipment is one of the highest in the world per million population (Fig. 4.7-5).

| Medical Equipment | Have at least one unit per 1,000,000 pop. (%) | Number of responding countries | Regional density per 1,000,000 pop. |
|--|---|--------------------------------|-------------------------------------|
| Magnetic Resonance Imaging (MRI) | 41% | 17 | 20.32 |
| Computed Tomography (CT Scanner) | 65% | 17 | 43.62 |
| Positron Emission Tomography (PET Scanner) | 15% | 13 | 3.03 |
| Gamma Camera or Nuclear Medicine | 8% | 13 | 3.73 |
| *Mammographs | 69% | 16 | 20.43 |
| Radiotherapy Unit: Linear Accelerator (LA) | 25% | 16 | 1.30 |
| Radiotherapy Unit:Telecobalt Unit (TU) | 0% | 13 | 0.16 |
| Radiotherapy Unit (LA+TU) | 25% | 16 | 1.35 |

* Mammographs density is per 100,000 females aged between 50 and 69 years old, and the regional density per million females of the same age

Fig. 4.7-5. Proportion of WPR countries and regional densities regarding high technology equipment (percentages taken from all respondent countries)



List of country profiles for the WHO Western Pacific Region

| | | | |
|----------------------------------|-----|--------------------|-----|
| Australia | 424 | Nauru | 448 |
| Brunei Darussalam | 426 | New Zealand | 450 |
| Cambodia | 428 | Papua New Guinea | 452 |
| China | 430 | Philippines | 454 |
| Fiji | 432 | Korea, Republic of | 456 |
| Japan | 434 | Samoa | 458 |
| Kiribati | 436 | Singapore | 460 |
| Lao People's Democratic Republic | 438 | Solomon Islands | 462 |
| Malaysia | 440 | Tonga | 464 |
| Marshall Islands | 442 | Tuvalu | 466 |
| Micronesia, Federated States of | 444 | Vanuatu | 468 |
| Mongolia | 446 | Viet Nam | 470 |

Australia



Country indicators

| | | | | | |
|---------------------------------|--------|---|------|--------------------------------------|--------|
| Population (000s)* | 23'343 | Life expectancy at birth (years) ^a | 83 | World Bank income group ^β | High |
| Internet users (%) ^γ | 83.0% | Per capita total health expenditure (PPP Int \$) ^δ | 4068 | GNI per capita (US\$) ^ε | 65'390 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Therapeutic Goods Administration

Web site: www.tga.gov.au



National health technology assessment unit

Unit/department: Pharmaceutical Benefits Advisory Committee; Medical Services Advisory Committee; Prosthesis List Advisory Committee

Web site: www.pbs.gov.au; www.msac.gov.au; <https://www.health.gov.au/internet/main/publishing.nsf/Content/health-privatehealth-plac>



National health technology management units

National health technology unit(s): —

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: — Type: — Use: —

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: —

Web site: —

National level procurement: —

Web site: —

DONATIONS

Policy or guideline: —

Web site: —

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: —

Web site: —

Medical device incorporation comments^λ: —



Inventory and maintenance

Type of inventories available: —

Comments: —

Medical equipment management unit: —

National level = —

Regional level = —

Hospital level = —

Management software: —

Software and comments^λ: —

Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:Lists comments^λ: —

Lists available: —

Unit: —

Web site: —

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES**OR SPECIFIC PROCEDURES:** Lists available: —

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: —

Web site: —

Types:

| | | | |
|-----------------------|---------------------------|----------|------------------------------------|
| Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|-----------------------|---------------------------|----------|------------------------------------|



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | n/a | n/a | n/a | n/a |
| Health centre | n/a | n/a | n/a | n/a |
| District hospital | n/a | n/a | n/a | n/a |
| Provincial hospital | n/a | n/a | n/a | n/a |
| Regional hospital | n/a | n/a | n/a | n/a |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | n/a | n/a | n/a | n/a |
| Computerized Tomography Scanner | n/a | n/a | n/a | n/a |
| Positron Emission Tomography Scanner | n/a | n/a | n/a | n/a |
| Nuclear medicine | n/a | n/a | n/a | n/a |
| Mammograph* | n/a | n/a | n/a | n/a |
| Linear accelerator | 94 | n/a | 94 | 4.027 |
| Telecobalt unit (Cobalt-60) | n/a | n/a | n/a | n/a |
| Radiotherapy | 94 | n/a | 94 | 4.027 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: —

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|-------|---|------|--------------------------------------|------|
| Population (000s)* | 418 | Life expectancy at birth (years) ^a | 77 | World Bank income group ^β | High |
| Internet users (%) ^γ | 64.5% | Per capita total health expenditure (PPP Int \$) ^δ | 1219 | GNI per capita (US\$) ^ε | |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: No

Name of principal institution: —

Web site: —



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: BME

Web site: —

OTHER: Planning of medical equipment allocation/Application/user training

Unit/department: BME

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: No

Web site: —

DONATIONS

Policy or guideline: Yes

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: Yes, but not publically available

Web site: —

Medical device incorporation comments^λ: —



Inventory and maintenance

Type of inventories available: None

Comments: —

Medical equipment management unit: Yes

National level = 0

Regional level = 0

Hospital level = 4

Management software: No

Software and comments^λ: —

Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:Lists comments^λ: —

Lists available: No

Unit: —

Web site: —

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES OR SPECIFIC PROCEDURES: Lists available: No list available

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: —

Types:

| | | | |
|-----------------------|---------------------------|----------|------------------------------------|
| Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|-----------------------|---------------------------|----------|------------------------------------|



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 14 | n/a | 14 | 3.351 |
| Health centre | n/a | 2 | 2 | 0.479 |
| District hospital | 3 | n/a | 3 | 0.718 |
| Provincial hospital | 1 | 1 | 2 | 0.479 |
| Regional hospital | n/a | 1 | 1 | 0.239 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | n/a | 1 | 1 | 2.394 |
| Computerized Tomography Scanner | 2 | 1 | 3 | 7.181 |
| Positron Emission Tomography Scanner | n/a | n/a | n/a | n/a |
| Nuclear medicine | n/a | n/a | n/a | n/a |
| Mammograph* | 2 | 1 | 3 | 91.926 |
| Linear accelerator | n/a | n/a | n/a | n/a |
| Telecobalt unit (Cobalt-60) | n/a | n/a | n/a | n/a |
| Radiotherapy | n/a | n/a | n/a | n/a |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: —

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

Cambodia



Country indicators

| | | | | | |
|---------------------------------|--------|---|-----|--------------------------------------|-----|
| Population (000s)* | 15'135 | Life expectancy at birth (years) ^a | 72 | World Bank income group ^β | Low |
| Internet users (%) ^γ | 6.0% | Per capita total health expenditure (PPP Int \$) ^δ | 135 | GNI per capita (US\$) ^ε | 950 |



National policy on health technology

Health technology (medical device) national policy: Yes, and it is part of the National Health Program/Plan or Policy

Web site: —

Language(s): Khmer and English

MOH responsible for health technology policy implementation: Hospital Services and Biomedical Engineering bureau, Department of Hospital Services, MoH



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: No

Name of principal institution: —

Web site: —



National health technology assessment unit

Unit/department: Department of Hospital Service

Web site: —



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: Procurement unit

Web site: —

OTHER: Planning of medical equipment allocation

Unit/department: Department of Planning and Health Information

Web site: —

OTHER: Planning of medical equipment allocation

Unit/department: Health Sector support program

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Nationally developed Use: For procurement

Nomenclature system name: Medical Equipment Standard Name List in Manual of Medical Equipment Management for National and CPA3 Referral Hospitals Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: Yes

Web site: —

DONATIONS

Policy or guideline: No

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: Yes

Web site: —

Medical device incorporation comments^λ:

Procurement: Health Sector Support Program (HSSP2) is the implementation project team in MoH under the direction of Health Sector Strategic Plan (HSP2) of MoH. Medical Equipment standard list for CPA1,2,3 referral hospitals.



Inventory and maintenance

Type of inventories available: National functional inventory for medical equipment

Comments: Department of Hospital service is managing inventories for medical equipment of 4 National hospitals and 18 CPA3 level hospitals. Controlled medical equipment is the device that requires management (monitoring), maintenance and repair.

Medical equipment management unit: Yes

National level = –

Regional level = –

Hospital level = 4

Management software: Yes

Software and comments^λ: MEDEMIS (originally developed by MoH)



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:

Lists available: No

Unit: –

Web site: –

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: For different healthcare facilities

Web site - facilities: –

Web site - procedures: –

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: –

| | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|--------|-----------------------|---------------------------|----------|------------------------------------|

Lists comments^λ:

We have lists for: a) Medical Equipment Standard list for CPA referral Hospitals. b) Medical Equipment Standard list for MPA (Health Centre). However any list for: communicable and non communicable diseases, injuries, and public health emergency situations.



Healthcare facility

| | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 113 | n/a | 113 | 0.747 |
| Health centre | 992 | n/a | 992 | 6.554 |
| District hospital | 61 | n/a | 61 | 0.403 |
| Provincial hospital | 17 | n/a | 17 | 0.112 |
| Regional hospital | 9 | n/a | 9 | 0.059 |



Medical equipment

| | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 1 | 0 | 1 | 0.066 |
| Computerized Tomography Scanner | 6 | 12 | 18 | 1.189 |
| Positron Emission Tomography Scanner | 0 | 0 | 0 | 0.000 |
| Nuclear medicine | 0 | 0 | 0 | 0.000 |
| Mammograph* | n/a | n/a | n/a | n/a |
| Linear accelerator | 0 | 0 | 0 | 0.000 |
| Telecobalt unit (Cobalt-60) | 1 | 0 | 1 | 0.066 |
| Radiotherapy | 1 | 0 | 1 | 0.066 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: –

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

China



Country indicators

| | | | | | |
|---------------------------------|-----------|---|-----|--------------------------------------|--------------|
| Population (000s)* | 1'385'567 | Life expectancy at birth (years) ^a | 75 | World Bank income group ^β | Upper-middle |
| Internet users (%) ^γ | 45.8% | Per capita total health expenditure (PPP Int \$) ^δ | 480 | GNI per capita (US\$) ^ε | 6'560 |



National policy on health technology

Health technology (medical device) national policy: Yes, and it is part of the National Health Program/Plan or Policy

Web site: <http://www.moh.gov.cn>, <http://www.sfda.gov.cn>

Language(s): —

MOH responsible for health technology policy implementation: Department of planning and finance, State Food and drug Administration



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: China Food and Drug Administration

Web site: <http://www.sfda.gov.cn/WS01/CL0001/>



National health technology assessment unit

Unit/department: China National Health Development Research Center

Web site: http://www.nhei.cn/nhei/center/web/yjs_index.jsp?page_type=wsjspg



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: Department of planning and finance

Web site: —

OTHER: Application/user training/HTA

Unit/department: Department of technology and education

Web site: —

OTHER: Application/user training/HTA

Unit/department: Department of medical service management

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on UMDNS (Universal Medical Device Nomenclature System) Use: Not specified

Nomenclature system name: — Web site: <http://http://www.sfda.gov.cn/>



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: —

National level procurement: Yes

Web site: <http://www.moh.gov.cn>

DONATIONS

Policy or guideline: Yes

Web site: <http://www.moh.gov.cn/publicfiles/business/htmlfiles/mohghcws/s3581/200804/16467.htm>

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ: —



Inventory and maintenance

Type of inventories available: National inventory only for high cost technologies (such as MRI, CT or PET scanners)

Comments: —

Medical equipment management unit: Yes

National level = —

Regional level = —

Hospital level = —

Management software: —

Software and comments^λ: —



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:

Lists comments^λ: —

Lists available: Yes

Unit: —

Web site: —

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: For different healthcare facilities and specific procedures

Web site - facilities: <http://www.moh.gov.cn/publicfiles/business/htmlfiles/mohghcws/s3585/200906/41440.htm>

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: —

| | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|--------|-----------------------|---------------------------|----------|------------------------------------|



Healthcare facility

| | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | n/a | n/a | n/a | n/a |
| Health centre | n/a | n/a | n/a | n/a |
| District hospital | n/a | n/a | n/a | n/a |
| Provincial hospital | n/a | n/a | n/a | n/a |
| Regional hospital | n/a | n/a | n/a | n/a |



Medical equipment

| | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | n/a | n/a | n/a | n/a |
| Computerized Tomography Scanner | n/a | n/a | n/a | n/a |
| Positron Emission Tomography Scanner | n/a | n/a | n/a | n/a |
| Nuclear medicine | n/a | n/a | n/a | n/a |
| Mammograph* | n/a | n/a | n/a | n/a |
| Linear accelerator | n/a | n/a | n/a | n/a |
| Telecobalt unit (Cobalt-60) | n/a | n/a | n/a | n/a |
| Radiotherapy | n/a | n/a | n/a | n/a |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: —

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|-------|---|-----|--------------------------------------|--------------|
| Population (000s)* | 881 | Life expectancy at birth (years) ^a | 69 | World Bank income group ^β | Upper-middle |
| Internet users (%) ^γ | 37.1% | Per capita total health expenditure (PPP Int \$) ^δ | 197 | GNI per capita (US\$) ^ε | 4'370 |



National policy on health technology

Health technology (medical device) national policy: Yes, and it is part of the National Health Program/Plan or Policy

Web site: <http://www.health.gov.fj>

Language(s): English

MOH responsible for health technology policy implementation: Clinical Services MOH HQ



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Biomedical Engineering, CWMH

Web site: <http://www.health.gov.fj/>



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: Biomedical Engineering

Web site: —

OTHER: Planning of medical equipment allocation/development of technical specifications/application/user training

Unit/department: Biomedical Engineering

Web site: —

OTHER: Planning of medical equipment allocation/HTA

Unit/department: HQ PSH

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: <http://www.health.gov.fj>

National level procurement: Yes

Web site: —

DONATIONS

Policy or guideline: Yes

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: Yes

Web site: <http://www.health.gov.fj>

Medical device incorporation comments^λ:

Mainly standardization of all medical equipment as per the national biomedical catalogue. Also, supported by MoH central procurement centre at Fiji Pharmaceutical Services



Inventory and maintenance

Type of inventories available: National functional inventory for medical equipment

Comments: BME Equipment Inventory. The inventory has more than 8,600 items.

Medical equipment management unit: Yes

National level = –

Regional level = –

Hospital level = 4

Management software: Yes

Software and comments^λ: EMS, EPICOR



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^α:

Lists available: Yes

Unit: Biomedical Engineering Units

Web site: –

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: For different healthcare facilities and specific procedures

Web site - facilities: <http://www.health.gov.fj>

Web site - procedures: <http://www.health.gov.fj>

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: –

| | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|--------|-----------------------|---------------------------|----------|------------------------------------|

Lists comments^λ:

Lists for procedures and healthcare facilities can be obtained from MoH, HQ. The biomedical catalogue for procurement can be obtained by FHSIP



Healthcare facility

| | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | n/a | n/a | n/a | n/a |
| Health centre | n/a | n/a | n/a | n/a |
| District hospital | n/a | n/a | n/a | n/a |
| Provincial hospital | n/a | n/a | 0 | 0.000 |
| Regional hospital | n/a | n/a | 0 | 0.000 |



Medical equipment

| | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 1 | 0 | 1 | 1.135 |
| Computerized Tomography Scanner | 3 | 0 | 3 | 3.405 |
| Positron Emission Tomography Scanner | 0 | 0 | 0 | 0.000 |
| Nuclear medicine | 0 | 0 | 0 | 0.000 |
| Mammograph [*] | 2 | 0 | 2 | 28.828 |
| Linear accelerator | 0 | 0 | 0 | 0.000 |
| Telecobalt unit (Cobalt-60) | 0 | 0 | 0 | 0.000 |
| Radiotherapy | 0 | 0 | 0 | 0.000 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: –

* UNPD as of 1 July 2012 (2013 update)

^α WHO 2012 data

^β WB 2014 classification

^γ WB 2013 data (2014 update)

^δ WHO 2012 data

^ε WB 2013 (2014 update)

n/a not applicable

^λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

Japan



Country indicators

| | | | | | |
|---------------------------------|---------|---|------|--------------------------------------|--------|
| Population (000s)* | 127'144 | Life expectancy at birth (years) ^a | 84 | World Bank income group ^β | High |
| Internet users (%) ^γ | 86.3% | Per capita total health expenditure (PPP Int \$) ^δ | 3578 | GNI per capita (US\$) ^ε | 46'330 |



National policy on health technology

Health technology (medical device) national policy: Yes, and it is part of the National Health Program/Plan or Policy

Web site: —

Language(s): Japanese

MOH responsible for health technology policy implementation: Economic affairs division, Health Policy Bureau



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Pharmaceutical and Medical Devices Agency (PMDA), Ministry of Health, Labour and Welfare

Web site: <http://www.mhlw.go.jp/index.html> and www.pmda.go.jp



National health technology assessment unit

Unit/department: Health Technology Assessment Office Health Insurance Bureau, Ministry of Health, Labour and Welfare

Web site: —



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Nationally developed Use: For regulatory purposes

Nomenclature system name: Japanese Medical Device Nomenclature was developed from GMDN2003 version. Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: No

Web site: —

DONATIONS

Policy or guideline: No

Web site: —

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ: —



Inventory and maintenance

Type of inventories available: None

Comments: –

Medical equipment management unit: No

National level = 0

Regional level = 0

Hospital level = 0

Management software: No

Software and comments^λ: –

Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^α

Lists available: Yes

Unit: Medical Economics Division, Health Insurance Bureau

Web site: –

Lists comments^λ:

New Medical Devices which begin to be reimbursed have been published by the Central Social Insurance Medical Council.

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: No list available

Web site - facilities: –

Web site - procedures: –

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: –

| | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|--------|-----------------------|---------------------------|----------|------------------------------------|



Healthcare facility

| | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | n/a | n/a | n/a | n/a |
| Health centre | n/a | n/a | n/a | n/a |
| District hospital | n/a | n/a | n/a | n/a |
| Provincial hospital | n/a | n/a | n/a | n/a |
| Regional hospital | n/a | n/a | n/a | n/a |



Medical equipment

| | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 1434 | 4407 | 5841 | 45.940 |
| Computerized Tomography Scanner | 2276 | 10589 | 12865 | 101.185 |
| Positron Emission Tomography Scanner | 167 | 386 | 553 | 4.349 |
| Nuclear medicine | n/a | n/a | n/a | n/a |
| Mammograph* | 1098 | 2834 | 3932 | 227.304 |
| Linear accelerator | n/a | n/a | n/a | n/a |
| Telecobalt unit (Cobalt-60) | n/a | n/a | n/a | n/a |
| Radiotherapy | n/a | n/a | n/a | n/a |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: –

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|-------|---|-----|--------------------------------------|--------------|
| Population (000s)* | 102 | Life expectancy at birth (years) ^a | 66 | World Bank income group ^β | Lower-middle |
| Internet users (%) ^γ | 11.5% | Per capita total health expenditure (PPP Int \$) ^δ | 264 | GNI per capita (US\$) ^ε | 2'620 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: —

Name of principal institution: Medical Equipment Management Committee (MEMC)

Web site: —



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): No

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: —

National level procurement: Yes

Web site: —

DONATIONS

Policy or guideline: Yes

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: Yes

Web site: —

Medical device incorporation comments^λ:

Donations from churches (LDS & CCatholics) second-hand medical devices such as defibrillator, computer, patient monitor-propaq, dressing trolleys.



Inventory and maintenance

Type of inventories available: National inventory for medical equipment, National functional inventory for medical equipment

Comments: We have the inventory record and monitoring system with medical stores/clinical wards/community health centres

Medical equipment management unit: Yes

National level = 0

Regional level = 0

Hospital level = 3

Management software: No

Software and comments^λ: if no, refer to overseas medical supplier for assistance and good advices



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:

Lists available: Yes

Unit: tungaru central hospital, medical and pharmacy stores

Web site: —

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: For specific procedures

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: One or more

Web site: —

Types:

| | | | | |
|-----------------------|---------------------------|----------|------------------------------------|---|
| Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations | x |
|-----------------------|---------------------------|----------|------------------------------------|---|

Lists comments^λ:

We do not have a standard list in place but we did overseas/local procurement for specific medical devices needed for MoHe.g. 2009: overseas procurement for medical devices was made through medical healthcare (doctors and head nurses) prioritization of medical devices need from medical suppliers from (south austral and braun) orders we made were selected as quality,



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 85 | n/a | 85 | 83.048 |
| Health centre | 144 | n/a | 144 | 140.692 |
| District hospital | n/a | n/a | 0 | 0.000 |
| Provincial hospital | n/a | n/a | 0 | 0.000 |
| Regional hospital | n/a | n/a | 0 | 0.000 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 0 | 0 | 0 | 0.000 |
| Computerized Tomography Scanner | 0 | 0 | 0 | 0.000 |
| Positron Emission Tomography Scanner | 0 | 0 | 0 | 0.000 |
| Nuclear medicine | 0 | 0 | 0 | 0.000 |
| Mammograph* | 0 | 0 | 0 | 0.000 |
| Linear accelerator | 0 | 0 | 0 | 0.000 |
| Telecobalt unit (Cobalt-60) | 0 | 0 | 0 | 0.000 |
| Radiotherapy | 0 | 0 | 0 | 0.000 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ:

Medical devices components such as tools, knowledge, skills, repair and maintenance are very crucial and essential therefore kiribati is very fortunate to be part of this surveillance thus only way to maintain our QA/QI (quality assurance and quality improvement) to achieve MoH objectives (utilization of quality medical/nursing care to all kiribati individual patient/client to provide patient's safety, quality health care services and patient' satisfaction). We would appreciate to be advised in on-going training especially for nurses.

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|-------|---|----|--------------------------------------|--------------|
| Population (000s)* | 6'770 | Life expectancy at birth (years) ^a | 66 | World Bank income group ^β | Lower-middle |
| Internet users (%) ^γ | 12.5% | Per capita total health expenditure (PPP Int \$) ^δ | 84 | GNI per capita (US\$) ^ε | 1'450 |



National policy on health technology

Health technology (medical device) national policy: Yes, and it is part of the National Health Program/Plan or Policy

Web site: —

Language(s): Lao and English

MOH responsible for health technology policy implementation: Medical Products Supply Center



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Food and Drug Department

Web site: —



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: Medical Product Supply Center

Web site: —

OTHER: Planning of medical equipment allocation

Unit/department: Health Care Department

Web site: —

OTHER: Planning of medical equipment allocation/Application/user training

Unit/department: Medical Product Supply Center

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: Yes **Type:** Based on UMDNS (Universal Medical Device Nomenclature System) **Use:** Not specified

Nomenclature system name: — **Web site:** —



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: —

National level procurement: Yes

Web site: —

DONATIONS

Policy or guideline: Yes

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ:

The procurement at national level are only for sophisticate equipment and high value.



Inventory and maintenance

Type of inventories available: National inventory for medical equipment

Comments: the inventories are ongoing in the whole country

Medical equipment management unit: Yes

National level = 1

Regional level = 0

Hospital level = 6

Management software: Yes

Software and comments^λ: PLAMAHS



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^α:

Lists available: No

Unit: —

Web site: —

Lists comments^λ:

The MOH is developing the standards for the health facilities and medical devices at district and health center level.

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: For different healthcare facilities

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: —

| | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|--------|-----------------------|---------------------------|----------|------------------------------------|



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | n/a | n/a | n/a | n/a |
| Health centre | 877 | n/a | 877 | 12.955 |
| District hospital | 129 | n/a | 129 | 1.906 |
| Provincial hospital | 16 | n/a | 16 | 0.236 |
| Regional hospital | 7 | n/a | 7 | 0.103 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 0 | 0 | 0 | 0.000 |
| Computerized Tomography Scanner | 4 | 1 | 5 | 0.739 |
| Positron Emission Tomography Scanner | 0 | 0 | 0 | 0.000 |
| Nuclear medicine | 0 | 0 | 0 | 0.000 |
| Mammograph* | 0 | 0 | 0 | 0.000 |
| Linear accelerator | 0 | 0 | 0 | 0.000 |
| Telecobalt unit (Cobalt-60) | 0 | 0 | 0 | 0.000 |
| Radiotherapy | 0 | 0 | 0 | 0.000 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: —

* UNPD as of 1 July 2012 (2013 update)

^α WHO 2012 data

^β WB 2014 classification

^γ WB 2013 data (2014 update)

^δ WHO 2012 data

^ε WB 2013 (2014 update)

n/a not applicable

^λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|--------|---|-----|--------------------------------------|--------------|
| Population (000s)* | 29'717 | Life expectancy at birth (years) ^a | 74 | World Bank income group ^β | Upper-middle |
| Internet users (%) ^γ | 67.0% | Per capita total health expenditure (PPP Int \$) ^δ | 692 | GNI per capita (US\$) ^ε | 10'430 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: No

Name of principal institution: Medical Device Authority, MoH Malaysia

Web site: <http://www.mdb.gov.my>



National health technology assessment unit

Unit/department: Health Technology Assessment Unit, Medical Development Division, Malaysian Health Technology Assessment Section (MaHTAS)

Web site: <http://medicaldev.gov.my> www.moh.gov.my



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: Engineering Services Division

Web site: <http://engineering.moh.gov.my>

OTHER: Application/user training

Unit/department: Training Management Division

Web site: <http://latihan.moh.gov.my>

OTHER: Medical devices management

Unit/department: Medical Device Authority

Web site: <http://www.mdb.gov.my>



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on GMDN (Global Medical Device Nomenclature)

Use: Not specified

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: No

Web site: —

DONATIONS

Policy or guideline: No

Web site: —

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ:

Depending on the types of Medical Devices. Some are procured at national level, some at state level & some at hospital level



Inventory and maintenance

Type of inventories available: National inventory for medical equipment

Comments: –

Medical equipment management unit: Yes

National level = 0

Regional level = 0

Hospital level = 0

Management software: Yes

Software and comments^λ: Central Management Information System



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^α:

Lists comments^λ:

Lists available: No

The corresponding lists are only prepared based on the needs

Unit: –

Web site: –

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: No list available

Web site - facilities: –

Web site - procedures: –

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: –

| | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|--------|-----------------------|---------------------------|----------|------------------------------------|



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | n/a | n/a | n/a | n/a |
| Health centre | n/a | n/a | n/a | n/a |
| District hospital | 95 | n/a | 95 | 0.320 |
| Provincial hospital | 21 | n/a | 21 | 0.071 |
| Regional hospital | 23 | n/a | 23 | 0.077 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 27 | 59 | 86 | 2.894 |
| Computerized Tomography Scanner | 60 | 131 | 191 | 6.427 |
| Positron Emission Tomography Scanner | 2 | 9 | 11 | 0.370 |
| Nuclear medicine | 15 | 6 | 21 | 0.707 |
| Mammograph* | 73 | 121 | 194 | 86.698 |
| Linear accelerator | 11 | 31 | 42 | 1.413 |
| Telecobalt unit (Cobalt-60) | n/a | n/a | n/a | n/a |
| Radiotherapy | 11 | 31 | 42 | 1.413 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: –

* UNPD as of 1 July 2012 (2013 update)

^α WHO 2012 data

^β WB 2014 classification

^γ WB 2013 data (2014 update)

^δ WHO 2012 data

^ε WB 2013 (2014 update)

n/a not applicable

^λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

Marshall Islands



Country indicators

| | | | | | |
|---------------------------------|-------|---|-----|--------------------------------------|--------------|
| Population (000s)* | 53 | Life expectancy at birth (years) ^a | 70 | World Bank income group ^β | Upper-middle |
| Internet users (%) ^γ | 11.7% | Per capita total health expenditure (PPP Int \$) ^δ | 418 | GNI per capita (US\$) ^ε | 4'310 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: No

Name of principal institution: MOH BOARD

Web site: —



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): No

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: No

Web site: —

DONATIONS

Policy or guideline: No

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ: —



Inventory and maintenance

Type of inventories available: National inventory for medical equipment

Comments: Inventory not available

Medical equipment management unit: —

National level = —

Regional level = —

Hospital level = —

Management software: —

Software and comments^λ: —



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^δ:

Lists available: No

Unit: —

Web site: —

Lists comments^λ:

We have lists for public health emergency situations only.

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: No list available

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: One or more

Web site: —

| | | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|---|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations | x |
|--------|-----------------------|---------------------------|----------|------------------------------------|---|



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | n/a | 1 | 1 | 1.900 |
| Health centre | 52 | n/a | 52 | 98.795 |
| District hospital | n/a | n/a | 0 | 0.000 |
| Provincial hospital | 2 | n/a | 2 | 3.800 |
| Regional hospital | n/a | n/a | 0 | 0.000 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 0 | 0 | 0 | 0.000 |
| Computerized Tomography Scanner | 1 | 0 | 1 | 18.999 |
| Positron Emission Tomography Scanner | 0 | 0 | 0 | 0.000 |
| Nuclear medicine | 0 | 0 | 0 | 0.000 |
| Mammograph* | 1 | 0 | 1 | 142.727 |
| Linear accelerator | 0 | 0 | 0 | 0.000 |
| Telecobalt unit (Cobalt-60) | 0 | 0 | 0 | 0.000 |
| Radiotherapy | 0 | 0 | 0 | 0.000 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: —

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|-------|---|-----|--------------------------------------|--------------|
| Population (000s)* | 104 | Life expectancy at birth (years) ^a | 69 | World Bank income group ^β | Lower-middle |
| Internet users (%) ^γ | 27.8% | Per capita total health expenditure (PPP Int \$) ^δ | 489 | GNI per capita (US\$) ^ε | 3'280 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: No

Name of principal institution: —

Web site: —



National health technology assessment unit

Unit/department: Budget & Planning

Web site: <http://www.fsmhealth.fm>



National health technology management units

National health technology unit(s): No

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: No

Web site: —

DONATIONS

Policy or guideline: No

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ:

Medical devices may be purchased by the National Dept of Health & Social Affairs, or the State Health Services. At the national level purchases are made by the coordinator of the program receiving the grant or funds for the purchase, in consultation with the department to receive the device (e.g. manager of state hospital radiography department, or chief of ancillary services). Guidelines are only for competitive quotes or bidding processes



Inventory and maintenance

Type of inventories available: National inventory for medical equipment

Comments: FSM National Dept of Health and Social Affairs, as well as state health services, keep assets registries for fixed assets over \$1,000. Medical Devices will be included on these registers. Individual units (e.g. state laboratory) should have functional inventory of devices/equipment

Medical equipment management unit: Yes

National level = 0

Regional level = 0

Hospital level = 3

Management software: No

Software and comments^λ: —



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:

Lists comments^λ:

Lists available: No

No lists available

Unit: —

Web site: —

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: No list available

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: —

| | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|--------|-----------------------|---------------------------|----------|------------------------------------|



Healthcare facility

| | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 118 | 4 | 122 | 117.819 |
| Health centre | n/a | n/a | 0 | 0.000 |
| District hospital | 4 | 1 | 5 | 4.829 |
| Provincial hospital | n/a | n/a | 0 | 0.000 |
| Regional hospital | n/a | n/a | 0 | 0.000 |



Medical equipment

| | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 0 | 0 | 0 | 0.000 |
| Computerized Tomography Scanner | 0 | 0 | 0 | 0.000 |
| Positron Emission Tomography Scanner | 0 | 0 | 0 | 0.000 |
| Nuclear medicine | 0 | 0 | 0 | 0.000 |
| Mammograph* | 0 | 0 | 0 | 0.000 |
| Linear accelerator | 0 | 0 | 0 | 0.000 |
| Telecobalt unit (Cobalt-60) | 0 | 0 | 0 | 0.000 |
| Radiotherapy | 0 | 0 | 0 | 0.000 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ:

Limited expertise in-country. No qualified radiographers, no pathologists. Only 3 over 30 laboratory technicians have bachelors degree in medical laboratory science.

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

Mongolia



Country indicators

| | | | | | |
|---------------------------------|-------|---|-----|--------------------------------------|--------------|
| Population (000s)* | 2'839 | Life expectancy at birth (years) ^a | 67 | World Bank income group ^β | Lower-middle |
| Internet users (%) ^γ | 17.7% | Per capita total health expenditure (PPP Int \$) ^δ | 345 | GNI per capita (US\$) ^ε | 3'770 |



National policy on health technology

Health technology (medical device) national policy: Yes, but is not part of the National Health Program

Web site: —

Language(s): Mongolian

MOH responsible for health technology policy implementation: Department of Strategic Policy and Planning



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: No

Name of principal institution: Drug Regulation Division, Centre for Health Development of Mongolia

Web site: www.chd.moh.mn



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): No

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: —

Web site: —

DONATIONS

Policy or guideline: No

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ: —



Inventory and maintenance

Type of inventories available: National inventory for medical equipment

Comments: –

Medical equipment management unit: Yes

National level = –

Regional level = –

Hospital level = 4

Management software: No

Software and comments^λ: –



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:

Lists comments^λ: –

Lists available: No

Unit: –

Web site: –

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES OR SPECIFIC PROCEDURES: Lists available: For different healthcare facilities

Web site - facilities: –

Web site - procedures: –

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: –

| | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|--------|-----------------------|---------------------------|----------|------------------------------------|



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 218 | 947 | 1165 | 41.035 |
| Health centre | 311 | 153 | 464 | 16.343 |
| District hospital | 35 | n/a | 35 | 1.233 |
| Provincial hospital | 23 | 13 | 36 | 1.268 |
| Regional hospital | n/a | n/a | n/a | n/a |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 1 | 3 | 4 | 1.409 |
| Computerized Tomography Scanner | 11 | 12 | 23 | 8.101 |
| Positron Emission Tomography Scanner | n/a | n/a | n/a | n/a |
| Nuclear medicine | 2 | n/a | 2 | 0.704 |
| Mammograph* | 4 | 2 | 6 | 33.259 |
| Linear accelerator | 1 | n/a | 1 | 0.352 |
| Telecobalt unit (Cobalt-60) | 1 | n/a | 1 | 0.352 |
| Radiotherapy | 2 | n/a | 2 | 0.704 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: –

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|----|---|-----|--------------------------------------|--------------|
| Population (000s)* | 10 | Life expectancy at birth (years) ^a | 79 | World Bank income group ^β | Upper-middle |
| Internet users (%) ^γ | | Per capita total health expenditure (PPP Int \$) ^δ | 277 | GNI per capita (US\$) ^ε | |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: No

Name of principal institution: —

Web site: —



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): No

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: No

Web site: —

DONATIONS

Policy or guideline: No

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ:

The procurement for the medical devices is based on the Hospital's Senior Management Team decision and the availability of fund



Inventory and maintenance

Type of inventories available: National inventory for medical equipment

Comments: We keep an asset register at our Administration Office and the Pharmaceutical Store which include all the medical equipment in the hospital

Medical equipment management unit: No

National level = 0

Regional level = 0

Hospital level = 0

Management software: No

Software and comments^λ: –



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:

Lists available: No

Unit: –

Web site: –

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: –

Web site - facilities: –

Web site - procedures: –

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: One or more

Web site: –

Types:

| |
|-----------------------|
| Communicable diseases |
|-----------------------|

| |
|---------------------------|
| Non-communicable diseases |
|---------------------------|

| |
|----------|
| Injuries |
|----------|

| |
|------------------------------------|
| Public health emergency situations |
|------------------------------------|

 x

Lists comments^λ:

Lists available for public health emergency situations. SPC assist us with our supplies for the Pandemic preparedness but we do not have a list as most of these are consumables



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | n/a | n/a | n/a | n/a |
| Health centre | n/a | n/a | n/a | n/a |
| District hospital | n/a | n/a | n/a | n/a |
| Provincial hospital | 1 | n/a | 1 | 9.949 |
| Regional hospital | n/a | n/a | n/a | n/a |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | n/a | n/a | n/a | n/a |
| Computerized Tomography Scanner | n/a | n/a | n/a | n/a |
| Positron Emission Tomography Scanner | n/a | n/a | n/a | n/a |
| Nuclear medicine | n/a | n/a | n/a | n/a |
| Mammograph* | n/a | n/a | n/a | n/a |
| Linear accelerator | n/a | n/a | n/a | n/a |
| Telecobalt unit (Cobalt-60) | n/a | n/a | n/a | n/a |
| Radiotherapy | n/a | n/a | n/a | n/a |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: –

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

New Zealand



Country indicators

| | | | | | |
|---------------------------------|-------|---|------|--------------------------------------|--------|
| Population (000s)* | 4'506 | Life expectancy at birth (years) ^a | 82 | World Bank income group ^β | High |
| Internet users (%) ^γ | 82.8% | Per capita total health expenditure (PPP Int \$) ^δ | 3292 | GNI per capita (US\$) ^ε | 35'760 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: The Medicines and Medical Devices Safety Authority (Medsafe), a business unit of the Ministry of Health

Web site: <http://www.medsafe.govt.nz>



National health technology assessment unit

Unit/department: National Health Committee

Web site: <https://nhc.health.govt.nz/>



National health technology management units

National health technology unit(s): No

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on GMDN (Global Medical Device Nomenclature)

Use: Not specified

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: —

National level procurement: No

Web site: —

DONATIONS

Policy or guideline: No

Web site: —

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ:

National requirements apply only to procurement of electro-medical devices through a set of AS/NZ standards such as AS/NZ3551:2004 which are mandated under a national law. Government publishes standards that are applicable to some devices.



Inventory and maintenance

Type of inventories available: None

Comments: —

Medical equipment management unit: Yes

National level = 0

Regional level = 0

Hospital level = 0

Management software: Yes

Software and comments^λ: Hardcat, Tektrak and Beims are all used in NZ

Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^α:

Lists available: No

Unit: —

Web site: —

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES OR SPECIFIC PROCEDURES: Lists available: No list available

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: —

Types:

| | | | |
|-----------------------|---------------------------|----------|------------------------------------|
| Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|-----------------------|---------------------------|----------|------------------------------------|

Lists comments^λ:

Under New Zealand law there is no approval system for medical devices and hence no pre-market scrutiny of their safety and performance. There is a legal requirement for the sponsor (importer/exporter/supplier) of a medical device (with some exceptions) to notify the device to a database maintained by Medsafe within 30 working days of becoming the sponsor for the...



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | n/a | n/a | n/a | n/a |
| Health centre | n/a | n/a | n/a | n/a |
| District hospital | n/a | n/a | n/a | n/a |
| Provincial hospital | n/a | n/a | n/a | n/a |
| Regional hospital | n/a | n/a | n/a | n/a |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | n/a | n/a | n/a | n/a |
| Computerized Tomography Scanner | n/a | n/a | n/a | n/a |
| Positron Emission Tomography Scanner | n/a | n/a | n/a | n/a |
| Nuclear medicine | n/a | n/a | n/a | n/a |
| Mammograph* | n/a | n/a | n/a | n/a |
| Linear accelerator | n/a | n/a | n/a | n/a |
| Telecobalt unit (Cobalt-60) | 0 | 0 | 0 | 0.000 |
| Radiotherapy | 0 | 0 | 0 | 0.000 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ:

The definition of medical device used in NZ law (the Medicines Act 1981) is not currently aligned with the GHTF approach. Consequently, some products that are regarded as devices in other countries are currently regulated as medicines in NZ. Examples include pregnancy tests, condoms with spermicide, IUCDs with copper, nasal irrigation solutions.

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

Papua New Guinea



Country indicators

| | | | | | |
|---------------------------------|-------|---|-----|--------------------------------------|--------------|
| Population (000s)* | 7'321 | Life expectancy at birth (years) ^a | 62 | World Bank income group ^β | Lower-middle |
| Internet users (%) ^γ | 6.5% | Per capita total health expenditure (PPP Int \$) ^δ | 151 | GNI per capita (US\$) ^ε | 2'010 |



National policy on health technology

Health technology (medical device) national policy: Yes, and it is part of the National Health Program/Plan or Policy

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: —

Name of principal institution: Pharmaceutical Services Standards Branch, Department of Health

Web site: <http://www.health.gov.pg/pages/pharmaceutical.htm>



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: — Type: — Use: —

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: —

Web site: —

National level procurement: Yes

Web site: —

DONATIONS

Policy or guideline: Yes

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: Yes, but not publically available

Web site: —

Medical device incorporation comments^λ: —



Inventory and maintenance

Type of inventories available: National Inventory for medical equipment

Comments: –

Medical equipment management unit: Yes

National level = –

Regional level = –

Hospital level = –

Management software: Yes

Software and comments^λ: –



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:

Lists comments^λ: –

Lists available: No

Unit: –

Web site: –

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: For different healthcare facilities and specific procedures

Web site - facilities: –

Web site - procedures: –

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: –

| | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|--------|-----------------------|---------------------------|----------|------------------------------------|



Healthcare facility

| | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 2'600 | n/a | 2600 | 35.513 |
| Health centre | 352 | 325 | 677 | 9.247 |
| District hospital | 89 | n/a | 89 | 1.216 |
| Provincial hospital | 19 | n/a | 19 | 0.260 |
| Regional hospital | 3 | 4 | 7 | 0.096 |



Medical equipment

| | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 0 | 0 | 0 | 0.000 |
| Computerized Tomography Scanner | 1 | 2 | 3 | 0.410 |
| Positron Emission Tomography Scanner | 0 | 0 | 0 | 0.000 |
| Nuclear medicine | 0 | 0 | 0 | 0.000 |
| Mammograph* | 1 | 2 | 3 | 8.511 |
| Linear accelerator | 0 | 0 | 0 | 0.000 |
| Telecobalt unit (Cobalt-60) | 1 | 0 | 1 | 0.137 |
| Radiotherapy | 1 | 0 | 1 | 0.137 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: –

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

Philippines



Country indicators

| | | | | | |
|---------------------------------|--------|---|-----|--------------------------------------|--------------|
| Population (000s)* | 98'394 | Life expectancy at birth (years) ^a | 69 | World Bank income group ^β | Lower-middle |
| Internet users (%) ^γ | 37.0% | Per capita total health expenditure (PPP Int \$) ^δ | 203 | GNI per capita (US\$) ^ε | 3'270 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Bureau of Health Devices and Technology- Department of Health (to be renamed as Center for Device Regulation, Radiation Health and Research-Food and Drug Authority)

Web site: <http://www.doh.gov.ph/bhdt>



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: Bureau of Health Devices and Technology

Web site: <http://www.doh.gov.ph/bhdt>

OTHER: —

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: <http://www.gppb.gov.ph/>

National level procurement: No

Web site: —

DONATIONS

Policy or guideline: Yes

Web site: <http://home.doh.gov.ph>

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: Yes

Web site: <http://home.doh.gov.ph>

Medical device incorporation comments^λ:

The procurement for medical device is part of the National Procurements system of the Philippine Government (see website). Procurement of medical devices can be done at the national level, at the regional level and at the local government units



Inventory and maintenance

Type of inventories available: National inventory only for high cost technologies (such as MRI, CT or PET scanners)

Comments: –

Medical equipment management unit: Yes

National level = 4

Regional level = 0

Hospital level = 0

Management software: No

Software and comments^λ: –



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^α

Lists comments^λ:

Lists available: Yes

Unit: Bureau of Health Devices and Technology(BHDT)- Department of Health (to be renamed as Center for Device Regulation, Radiation Health and Research-Food and Drug Authority)

Web site: –

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: For different healthcare facilities and specific procedures

Web site - facilities: www.doh.gov.ph/licensing/bhfs ; www.doh.gov.ph/files/ao147-04.pdf

Web site - procedures: www.doh.gov.ph/asc_inspectiontool_partIII.general.pdf

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: –

| | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|--------|-----------------------|---------------------------|----------|------------------------------------|

This is part of the requirements in the licensing of health facilities in the Philippines. There is no database yet but the provided list are those which are approved only from 2007 where the BHDT was appointed as the technical arm of the Bureau of Food and Drugs for medical device regulation in the Philippines



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | n/a | n/a | n/a | n/a |
| Health centre | n/a | n/a | n/a | n/a |
| District hospital | 623 | 829 | 1452 | 1.476 |
| Provincial hospital | 38 | 175 | 213 | 0.216 |
| Regional hospital | 50 | 69 | 119 | 0.121 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 4 | 26 | 30 | 0.305 |
| Computerized Tomography Scanner | 21 | 86 | 107 | 1.087 |
| Positron Emission Tomography Scanner | n/a | n/a | n/a | n/a |
| Nuclear medicine | n/a | n/a | n/a | n/a |
| Mammograph* | 8 | 71 | 79 | 13.121 |
| Linear accelerator | 0 | 18 | 18 | 0.183 |
| Telecobalt unit (Cobalt-60) | n/a | n/a | n/a | n/a |
| Radiotherapy | 0 | 18 | 18 | 0.183 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: –

* UNPD as of 1 July 2012 (2013 update)

^α WHO 2012 data

^β WB 2014 classification

^γ WB 2013 data (2014 update)

^δ WHO 2012 data

^ε WB 2013 (2014 update)

n/a not applicable

^λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

Korea, Republic of



Country indicators

| | | | | | |
|---------------------------------|--------|---|------|--------------------------------------|--------|
| Population (000s)* | 49'263 | Life expectancy at birth (years) ^a | 81 | World Bank income group ^β | High |
| Internet users (%) ^γ | 84.8% | Per capita total health expenditure (PPP Int \$) ^δ | 2321 | GNI per capita (US\$) ^ε | 25'920 |



National policy on health technology

Health technology (medical device) national policy: Yes, and it is part of the National Health Program/Plan or Policy

Web site: <http://law.go.kr>

Language(s): Korean

MOH responsible for health technology policy implementation: Division of Pharmaceutical Policy



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Korea Food & Drug Administration

Web site: <http://mw.kfda.go.kr>



National health technology assessment unit

Unit/department: National Evidence-based healthcare Collaborating Agency (NECA)

Web site: www.neca.re.kr



National health technology management units

National health technology unit(s): No

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Nationally developed Use: Not specified

Nomenclature system name: — Web site: <http://kfda.go.kr/index-kfda?mid=92>



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: <http://www.pps.go.kr>

National level procurement: Yes

Web site: <http://www.pps.go.kr>

DONATIONS

Policy or guideline: Yes

Web site: <http://www.kofih.org>

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: —

Web site: —

Medical device incorporation comments^λ:

National and public hospitals Purchases medical equipments according to the generals procurement procedures.



Inventory and maintenance

Type of inventories available: —

Comments: Inventories for medical devices are not managed by government

Medical equipment management unit: Yes

National level = 3

Regional level = —

Hospital level = —

Management software: —

Software and comments^λ: —



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^α:

Lists available: Yes

Unit: HIRA (Health Insurance Review & Assessment Service)

Web site: —

Lists comments^λ:

HIRA is responsible for listing treatment materials for public insurance

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: —

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: —

Web site: —

| | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|--------|-----------------------|---------------------------|----------|------------------------------------|



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | n/a | n/a | n/a | n/a |
| Health centre | 25 | 27'793 | 27818 | 56.469 |
| District hospital | 46 | 1'320 | 1366 | 2.773 |
| Provincial hospital | 31 | 244 | 275 | 0.558 |
| Regional hospital | n/a | 44 | 44 | 0.089 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | n/a | 985 | 985 | 19.995 |
| Computerized Tomography Scanner | 3 | 1740 | 1743 | 35.382 |
| Positron Emission Tomography Scanner | n/a | 155 | 155 | 3.146 |
| Nuclear medicine | 5 | 393 | 398 | 8.079 |
| Mammograph* | 6 | 2408 | 2414 | 402.326 |
| Linear accelerator | n/a | 138 | 138 | 2.801 |
| Telecobalt unit (Cobalt-60) | n/a | 10 | 10 | 0.203 |
| Radiotherapy | n/a | 148 | 148 | 3.004 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ:

Concerning Infrastructure section: Korea, Health Center is down to 29 beds,

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|-------|---|-----|--------------------------------------|--------------|
| Population (000s)* | 190 | Life expectancy at birth (years) ^a | 73 | World Bank income group ^β | Lower-middle |
| Internet users (%) ^γ | 15.3% | Per capita total health expenditure (PPP Int \$) ^δ | 308 | GNI per capita (US\$) ^ε | 3'970 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Ministry of Health, Medical equipment management committee

Web site: <http://moh@health.gov.ws>



National health technology assessment unit

Unit/department: Biomed. Engineering Unit

Web site: <http://www.health.gov.ws/>



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: TTM Hosp. Acting GM

Web site: <http://www.health.gov.ws/>

OTHER: Planning of medical equipment allocation

Unit/department: TTM Hospital Administrator

Web site:

OTHER: Planning of medical equipment allocation/HTA

Unit/department: Ministry of Health Con. Sp. PH Physician

Web site:



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Nationally developed Use: For procurement

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: www.mof.gov.ws

National level procurement: Yes

Web site: —

DONATIONS

Policy or guideline: Yes

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: Yes, but not publically available

Web site: —

Medical device incorporation comments^λ:

For more information refer to the Biomed Engineering Unit



Inventory and maintenance

Type of inventories available: National functional inventory for medical equipment

Comments: —

Medical equipment management unit: Yes

National level = 1

Regional level = —

Hospital level = 1

Management software: No

Software and comments^λ: —



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:

Lists available: Yes, but it is only a recommendation

Unit: Biomedical Engineering Unit

Web site: —

Lists comments^λ:

We have lists of communicable high burden diseases

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: For different healthcare facilities and specific procedures

Web site - facilities: —

Web site - procedures: <http://www.health.gov.ws/>

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: One or more

Web site: <http://www.health.gov.ws/>

| | | | | | | | |
|--------|-----------------------|---|---------------------------|--|----------|--|------------------------------------|
| Types: | Communicable diseases | x | Non-communicable diseases | | Injuries | | Public health emergency situations |
|--------|-----------------------|---|---------------------------|--|----------|--|------------------------------------|



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | n/a | n/a | 0 | 0.000 |
| Health centre | 3 | n/a | 3 | 1.576 |
| District hospital | 6 | n/a | 6 | 3.152 |
| Provincial hospital | 1 | n/a | 1 | 0.525 |
| Regional hospital | 1 | n/a | 1 | 0.525 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 0 | 0 | 0 | 0.000 |
| Computerized Tomography Scanner | 1 | 0 | 1 | 5.253 |
| Positron Emission Tomography Scanner | 0 | 0 | 0 | 0.000 |
| Nuclear medicine | 0 | 0 | 0 | 0.000 |
| Mammograph* | 1 | 0 | 1 | 91.158 |
| Linear accelerator | 0 | 0 | 0 | 0.000 |
| Telecobalt unit (Cobalt-60) | 0 | 0 | 0 | 0.000 |
| Radiotherapy | 0 | 0 | 0 | 0.000 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ:

Concerning Infrastructure section: there are 18 General Practitioner Clinics in the Private sector.

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

Singapore



Country indicators

| | | | | | |
|---------------------------------|-------|---|------|--------------------------------------|--------|
| Population (000s)* | 5'412 | Life expectancy at birth (years) ^a | 83 | World Bank income group ^β | High |
| Internet users (%) ^γ | 73.0% | Per capita total health expenditure (PPP Int \$) ^δ | 2881 | GNI per capita (US\$) ^ε | 54'040 |



National policy on health technology

Health technology (medical device) national policy: Yes

Web site: http://www.hsa.gov.sg/publish/etc/medialib/hsa_library/health_products_regulation/trade_announcements/files.Par.67312.File.dat/Health_Products_Act_2007.pdf

Language(s): English

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: HEALTH SCIENCE AUTHORITY OF SINGAPORE

Web site: www.hsa.gov.sg



National health technology assessment unit

Unit/department: Health Technology Assessment Branch, Ministry of Health

Web site: www.moh.gov.sg



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: Medical Device Branch, Health Sciences Authority

Web site: www.hsa.gov.sg

OTHER: Development of Technical Specifications/HTA

Unit/department: Medical Device Branch, Health Sciences Authority

Web site: www.hsa.gov.sg

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: www.gmdnagency.com



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: No

Web site: —

DONATIONS

Policy or guideline: No

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ: —



Inventory and maintenance

Type of inventories available: None

Comments: –

Medical equipment management unit: No

National level = 0

Regional level = 0

Hospital level = 0

Management software: No

Software and comments^λ: –

Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^α:

Lists available: Yes

Unit: MEDICAL DEVICES BRANCH / HSA

Web site: <http://eservice.hsa.gov.sg/medics/md/mdEnquiry.do?action=getAllDevices>

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: No list available

Web site - facilities: –

Web site - procedures: –

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: –

Lists comments^λ:

A list is available in the form of the Singapore Medical Device Register (SMDR). This shows all approved medical devices in Singapore and provides information on them. It is not a list of recommended devices for procurement.

| | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|--------|-----------------------|---------------------------|----------|------------------------------------|



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 230 | 2'975 | 3205 | 59.223 |
| Health centre | n/a | n/a | n/a | n/a |
| District hospital | n/a | n/a | n/a | n/a |
| Provincial hospital | 11 | 16 | 27 | 0.499 |
| Regional hospital | n/a | n/a | n/a | n/a |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 23 | 19 | 42 | 7.761 |
| Computerized Tomography Scanner | 26 | 22 | 48 | 8.870 |
| Positron Emission Tomography Scanner | n/a | n/a | n/a | n/a |
| Nuclear medicine | n/a | n/a | n/a | n/a |
| Mammograph* | 40 | 45 | 85 | 127.648 |
| Linear accelerator | 14 | 4 | 18 | 3.326 |
| Telecobalt unit (Cobalt-60) | 0 | 1 | 1 | 0.185 |
| Radiotherapy | 14 | 5 | 19 | 3.511 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: –

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

Solomon Islands



Country indicators

| | | | | | |
|---------------------------------|------|---|-----|--------------------------------------|--------------|
| Population (000s)* | 561 | Life expectancy at birth (years) ^a | 69 | World Bank income group ^β | Lower-middle |
| Internet users (%) ^γ | 8.0% | Per capita total health expenditure (PPP Int \$) ^δ | 252 | GNI per capita (US\$) ^ε | 1'600 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: Adhoc EQUIPMENT COMMITTEE



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: No

Name of principal institution: —

Web site: —



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: Unit of procurement

Web site: —

OTHER: —

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: —

National level procurement: Yes

Web site: —

DONATIONS

Policy or guideline: No

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ:

Procurement Unit, Ministry of Health & Medical Service is mainly to do with finance not technical aspect of equipment. The Committee is Adhoc and meet only to allocate equipment base on Departmental requests.



Inventory and maintenance

Type of inventories available: —

Comments: —

Medical equipment management unit: —

National level = —

Regional level = —

Hospital level = —

Management software: No

Software and comments^λ: —

Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^α:

Lists available: No

Unit: —

Web site: —

Lists comments^λ:

Unfortunately there is not lists available for communicable and non communicable diseases, injuries, and public health emergency situations.

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: For different healthcare facilities

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: —

| | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|--------|-----------------------|---------------------------|----------|------------------------------------|



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | n/a | n/a | n/a | n/a |
| Health centre | n/a | n/a | n/a | n/a |
| District hospital | n/a | n/a | n/a | n/a |
| Provincial hospital | n/a | n/a | n/a | n/a |
| Regional hospital | n/a | n/a | n/a | n/a |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | n/a | n/a | n/a | n/a |
| Computerized Tomography Scanner | n/a | n/a | n/a | n/a |
| Positron Emission Tomography Scanner | n/a | n/a | n/a | n/a |
| Nuclear medicine | n/a | n/a | n/a | n/a |
| Mammograph* | n/a | n/a | n/a | n/a |
| Linear accelerator | n/a | n/a | n/a | n/a |
| Telecobalt unit (Cobalt-60) | n/a | n/a | n/a | n/a |
| Radiotherapy | n/a | n/a | n/a | n/a |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: —

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|-------|---|-----|--------------------------------------|--------------|
| Population (000s)* | 105 | Life expectancy at birth (years) ^a | 71 | World Bank income group ^β | Upper-middle |
| Internet users (%) ^γ | 35.0% | Per capita total health expenditure (PPP Int \$) ^δ | 270 | GNI per capita (US\$) ^ε | 4'490 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: No

Name of principal institution: —

Web site: —



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: —

Web site: —

OTHER: Maintenance of equipment

Unit/department: Biomedical engineering

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: Yes

Web site: —

DONATIONS

Policy or guideline: Yes

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: Yes

Web site: —

Medical device incorporation comments^λ: —



Inventory and maintenance

Type of inventories available: National inventory for medical equipment

Comments: –

Medical equipment management unit: Yes

National level = 1

Regional level = 0

Hospital level = 0

Management software: Yes

Software and comments^λ: Equipment Management Systems



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:

Lists comments^λ: –

Lists available: Yes

Unit: Facility and equipment committee together with the Biomedical Engineering Unit of the Ministry of Health

Web site: –

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: No list available

Web site - facilities: –

Web site - procedures: –

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: –

| | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|--------|-----------------------|---------------------------|----------|------------------------------------|



Healthcare facility

| | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 15 | n/a | 15 | 14.242 |
| Health centre | 14 | n/a | 14 | 13.292 |
| District hospital | 3 | n/a | 3 | 2.848 |
| Provincial hospital | 1 | n/a | 1 | 0.949 |
| Regional hospital | n/a | n/a | n/a | n/a |



Medical equipment

| | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 0 | 0 | 0 | 0.000 |
| Computerized Tomography Scanner | 0 | 0 | 0 | 0.000 |
| Positron Emission Tomography Scanner | 0 | 0 | 0 | 0.000 |
| Nuclear medicine | 0 | 0 | 0 | 0.000 |
| Mammograph* | 0 | 0 | 0 | 0.000 |
| Linear accelerator | 0 | 0 | 0 | 0.000 |
| Telecobalt unit (Cobalt-60) | 0 | 0 | 0 | 0.000 |
| Radiotherapy | 0 | 0 | 0 | 0.000 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: –

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|-------|---|-----|--------------------------------------|--------------|
| Population (000s)* | 10 | Life expectancy at birth (years) ^a | 68 | World Bank income group ^β | Upper-middle |
| Internet users (%) ^γ | 37.0% | Per capita total health expenditure (PPP Int \$) ^δ | 433 | GNI per capita (US\$) ^ε | 5'840 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): English

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Ministry of Health

Web site: http://www.tuvaluislands.com/gov_addresses.htm



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: Biomedical Department of Princess Margaret Hospital

Web site: http://www.tuvaluislands.com/gov_addresses.htm

OTHER: Biomedical Technician

Unit/department: Biomedical Department of Princess Margaret Hospital

Web site: http://www.tuvaluislands.com/gov_addresses.htm

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on UMDNS (Universal Medical Device Nomenclature System) Use: —

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: Yes

Web site: —

National level procurement: Yes

Web site: —

DONATIONS

Policy or guideline: Yes

Web site: —

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: Yes, but not publically available

Web site: —

Medical device incorporation comments^λ:

Guidelines on Donations exist, they were nationally developed but there are not publically available



Inventory and maintenance

Type of inventories available: National inventory for medical equipment

Comments: —

Medical equipment management unit: Yes

National level = 1

Regional level = —

Hospital level = —

Management software: No

Software and comments^λ: —



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:

Lists comments^λ: —

Lists available: No

Unit: —

Web site: —

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: —

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: —

| | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|--------|-----------------------|---------------------------|----------|------------------------------------|



Healthcare facility

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | n/a | n/a | n/a | n/a |
| Health centre | 10 | 1 | 11 | 111.381 |
| District hospital | n/a | n/a | 0 | 0.000 |
| Provincial hospital | n/a | n/a | 0 | 0.000 |
| Regional hospital | 1 | n/a | 1 | 10.126 |



Medical equipment

| Medical equipment | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | n/a | n/a | n/a | n/a |
| Computerized Tomography Scanner | n/a | n/a | n/a | n/a |
| Positron Emission Tomography Scanner | n/a | n/a | n/a | n/a |
| Nuclear medicine | n/a | n/a | n/a | n/a |
| Mammograph* | n/a | n/a | n/a | n/a |
| Linear accelerator | n/a | n/a | n/a | n/a |
| Telecobalt unit (Cobalt-60) | n/a | n/a | n/a | n/a |
| Radiotherapy | n/a | n/a | n/a | n/a |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ:

Tuvalu has a draft health technology policy.

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|-------|---|-----|--------------------------------------|--------------|
| Population (000s)* | 253 | Life expectancy at birth (years) ^a | 72 | World Bank income group ^β | Lower-middle |
| Internet users (%) ^γ | 11.3% | Per capita total health expenditure (PPP Int \$) ^δ | 167 | GNI per capita (US\$) ^ε | 3'130 |



National policy on health technology

Health technology (medical device) national policy: No

Web site: —

Language(s): —

MOH responsible for health technology policy implementation: —



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: No

Name of principal institution: —

Web site: —



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): No

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —

OTHER: —

Unit/department: —

Web site: —



Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Nationally developed Use: For procurement

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: No

Web site: —

DONATIONS

Policy or guideline: No

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: No

Web site: —

Medical device incorporation comments^λ: —



Inventory and maintenance

Type of inventories available: National inventory for medical equipment

Comments: An updated complete list of medical equipment does not exist at national level; but at subnational levels and at facility level, health managers maintain their own inventory for various commodities including medical devices.

Medical equipment management unit: No

National level = —

Regional level = —

Hospital level = —

Management software: No

Software and comments^λ: —



Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT:

Lists available: No

Unit: —

Web site: —

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES

OR SPECIFIC PROCEDURES: Lists available: For different healthcare facilities and specific procedures

Web site - facilities: —

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: No list available

Web site: —

| | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|--------|-----------------------|---------------------------|----------|------------------------------------|

Lists comments^λ:

We do not have specifically documented as a guideline. Lists for procedures exist as part of another documents - eg essential drug list, or inventory list of a health facility but not specifically documented as a separate document of guideline on its own.

We do not have any available lists for communicable and non-communicable diseases, injuries, and public health emergency



Healthcare facility

| | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 300 | n/a | 300 | 118.688 |
| Health centre | 37 | 2 | 39 | 15.429 |
| District hospital | 4 | n/a | 4 | 1.583 |
| Provincial hospital | 1 | n/a | 1 | 0.396 |
| Regional hospital | 1 | n/a | 1 | 0.396 |



Medical equipment

| | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 0 | 0 | 0 | 0.000 |
| Computerized Tomography Scanner | 0 | 0 | 0 | 0.000 |
| Positron Emission Tomography Scanner | 0 | 0 | 0 | 0.000 |
| Nuclear medicine | 0 | 0 | 0 | 0.000 |
| Mammograph* | 0 | 0 | 0 | 0.000 |
| Linear accelerator | 0 | 0 | 0 | 0.000 |
| Telecobalt unit (Cobalt-60) | 0 | 0 | 0 | 0.000 |
| Radiotherapy | 0 | 0 | 0 | 0.000 |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ:

Vanuatu is a small island country in the Pacific region with a population of around 250,000; this explains the low level of health facilities available.

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls



Country indicators

| | | | | | |
|---------------------------------|--------|---|-----|--------------------------------------|--------------|
| Population (000s)* | 91'680 | Life expectancy at birth (years) ^a | 76 | World Bank income group ^β | Lower-middle |
| Internet users (%) ^γ | 43.9% | Per capita total health expenditure (PPP Int \$) ^δ | 234 | GNI per capita (US\$) ^ε | 1'740 |



National policy on health technology

Health technology (medical device) national policy: Yes, but is not part of the National Health Program

Web site: —

Language(s): Vietnamese

MOH responsible for health technology policy implementation: Department of Medical Equipment and Construction



Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes

Name of principal institution: Department of Medical Equipment and Construction

Web site: <http://imecd.gov.vn>



National health technology assessment unit

Unit/department: —

Web site: —



National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:

Unit/department: Department of Medical Equipment and Construction

Web site: —

OTHER: Planning of medical equipment allocation

Unit/department: Department of Medical Equipment and Construction

Web site: —

OTHER: Management of medical equipment

Unit/department: Institute of Medical Equipment and Construction

Web site: <http://imecd.gov.vn>



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No

Nomenclature system name: — Web site: —



Medical device incorporation

PROCUREMENT

Policy or guideline: No

Web site: —

National level procurement: Yes

Web site: <http://www.moh.gov.vn/>

DONATIONS

Policy or guideline: —

Web site:—

TECHNICAL SPECIFICATIONS

Technical specifications to support procurement or donations: Yes, but not publically available

Web site: —

Medical device incorporation comments^λ: —



Inventory and maintenance

Type of inventories available: —

Comments: —

Medical equipment management unit: Yes

National level = 6

Regional level = —

Hospital level = —

Management software: No

Software and comments^λ: —

Lists of medical devices

LISTS OF APPROVED MEDICAL DEVICES FOR PUBLIC PROCUREMENT OR REIMBURSEMENT^α

Lists available: No

Unit: —

Web site: —

NATIONAL LISTS OF MEDICAL DEVICES FOR DIFFERENT TYPES OF HEALTHCARE FACILITIES OR SPECIFIC PROCEDURES: Lists available: For different healthcare facilities and specific procedures

Web site - facilities: <http://csdl.thutuchanhchinh.vn/content/download/328488/9195358/file/QD%20437%20nam%202002>

Web site - procedures: —

NATIONAL LIST FOR DISEASES AND SITUATIONS:

Lists available: —

Web site: —

| | | | | |
|--------|-----------------------|---------------------------|----------|------------------------------------|
| Types: | Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations |
|--------|-----------------------|---------------------------|----------|------------------------------------|

Lists comments^λ:

We have enacted list of essential medical devices for decentralized hospitals (provincial hospitals, district-level hospitals and commune-level health stations), specialty hospitals and medical universities. There are but not complete for all general procedures. We have enacted medical device list for procedures which shall be covered by medical insurance only.



Healthcare facility

| | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | n/a | n/a | n/a | n/a |
| Health centre | n/a | n/a | n/a | n/a |
| District hospital | n/a | n/a | n/a | n/a |
| Provincial hospital | n/a | n/a | n/a | n/a |
| Regional hospital | n/a | n/a | n/a | n/a |



Medical equipment

| | Public sector | Private sector | Total | Density per 1,000,000 population |
|--------------------------------------|---------------|----------------|-------|----------------------------------|
| Magnetic Resonance Imaging | n/a | n/a | n/a | n/a |
| Computerized Tomography Scanner | n/a | n/a | n/a | n/a |
| Positron Emission Tomography Scanner | n/a | n/a | n/a | n/a |
| Nuclear medicine | n/a | n/a | n/a | n/a |
| Mammograph* | n/a | n/a | n/a | n/a |
| Linear accelerator | n/a | n/a | n/a | n/a |
| Telecobalt unit (Cobalt-60) | n/a | n/a | n/a | n/a |
| Radiotherapy | n/a | n/a | n/a | n/a |

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments^λ: —

* UNPD as of 1 July 2012 (2013 update)

α WHO 2012 data

β WB 2014 classification

γ WB 2013 data (2014 update)

δ WHO 2012 data

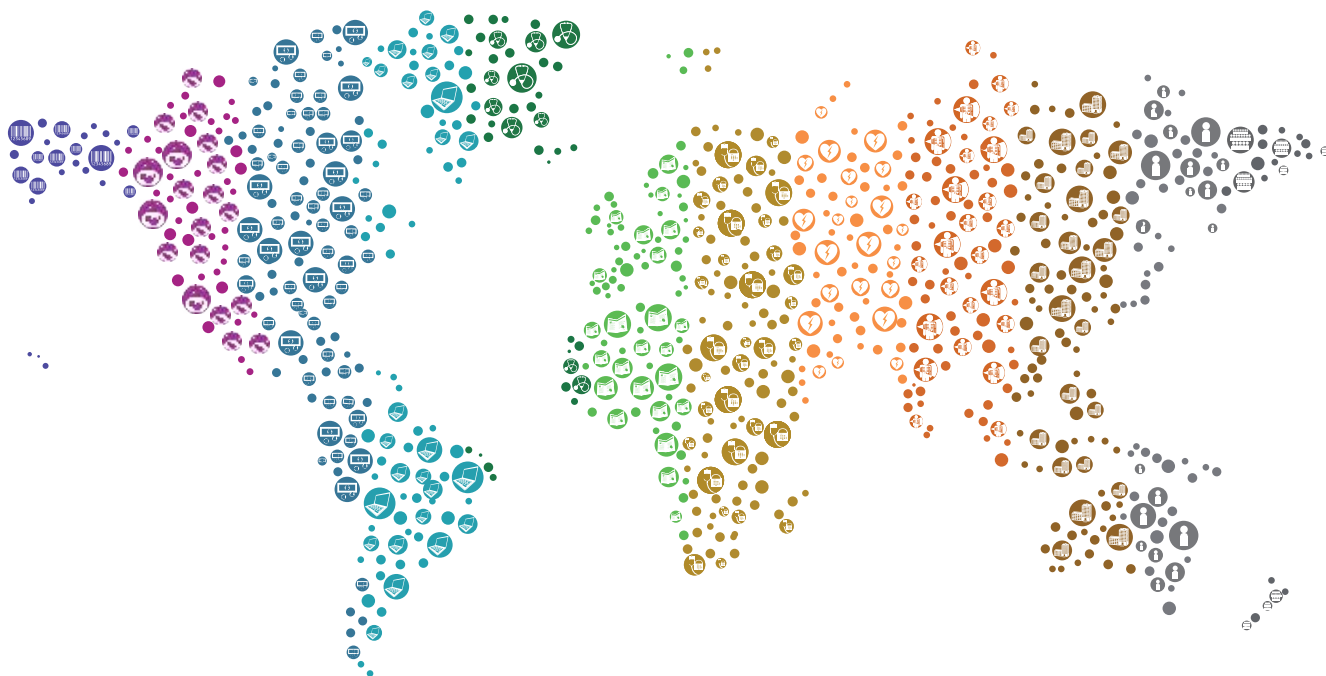
ε WB 2013 (2014 update)

n/a not applicable

λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

Global atlas of medical devices

WHO medical devices technical series



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