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.

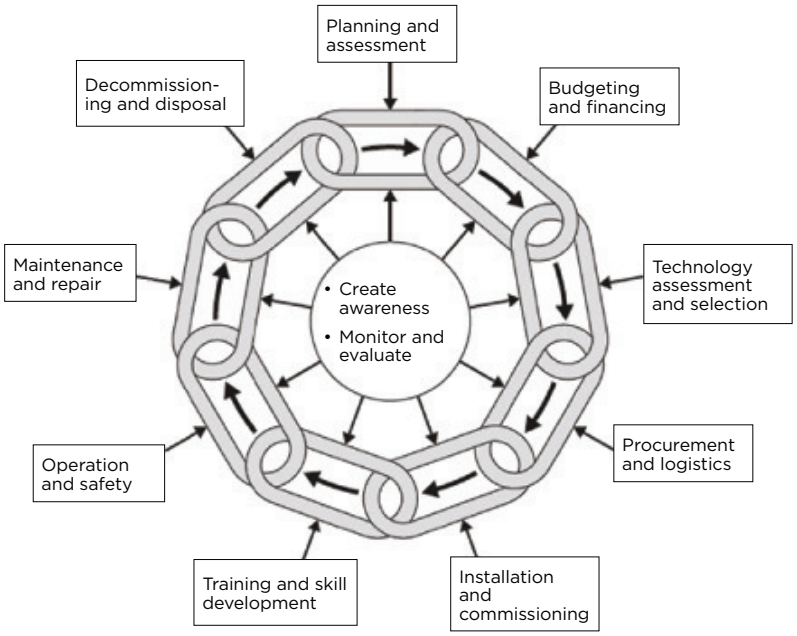

Fig. 3.4-1. Functions in the healthcare technology management cycle[ii]

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[…].*"[i]

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.

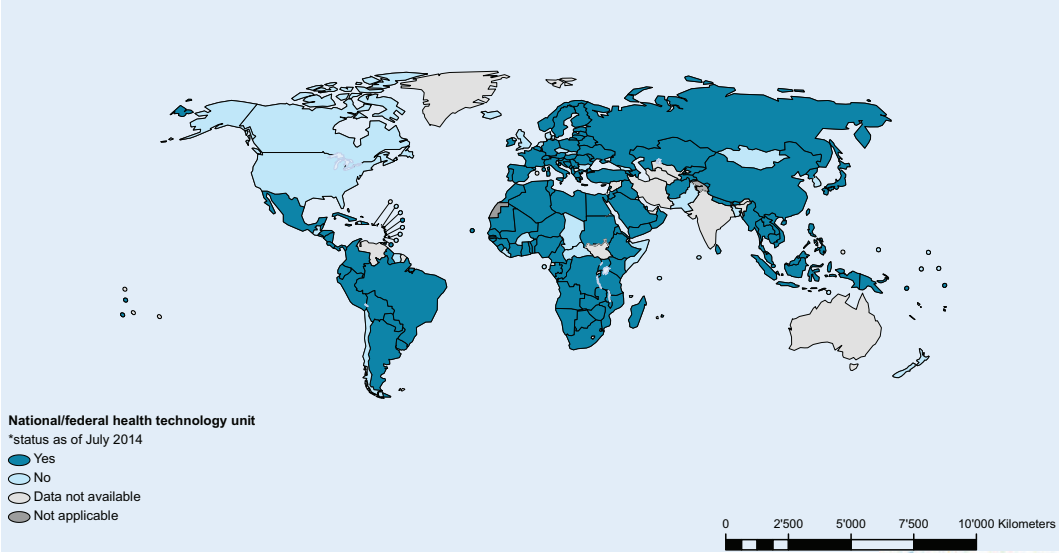

Fig. 3.4-2. Global map showing presence of management units of medical devices at national/federal level

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).

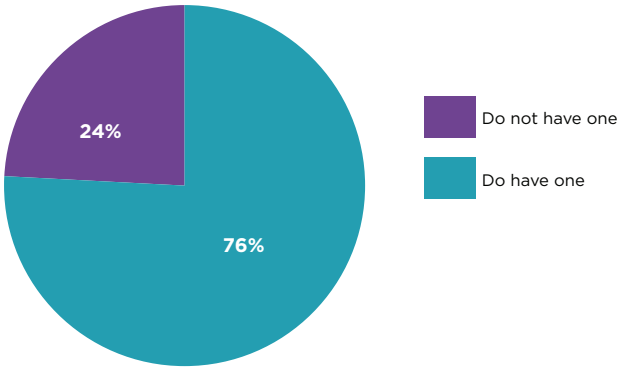

Fig. 3.4-3. Existence of a designated unit within the country's ministry of health that performs health technology management activities

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).

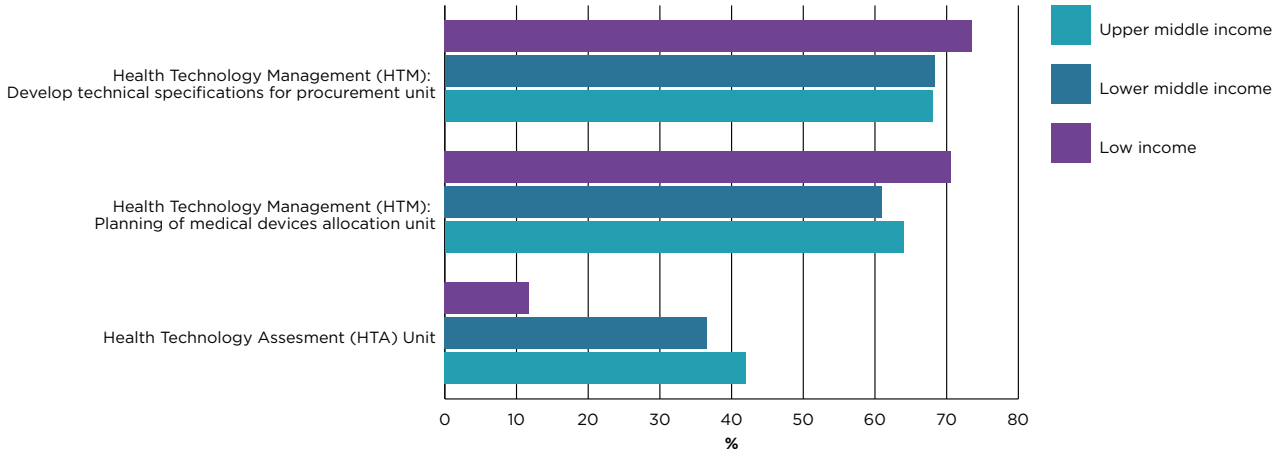

Fig. 3.4-4. Comparison of activities in national health technology management units versus health technology assessment units by income level. High income countries not included because of too few responses.

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.

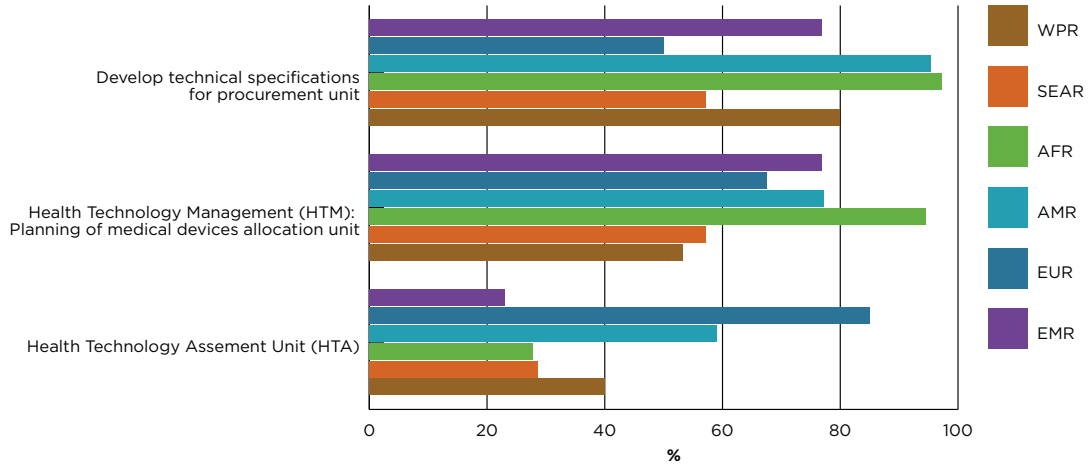

Fig. 3.4-5. Presence of health technology national units within the countries' ministry of health by WHO region. Comparison of HTM (planning of medical device allocation and development of technical specs) vs. HTA units.

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].

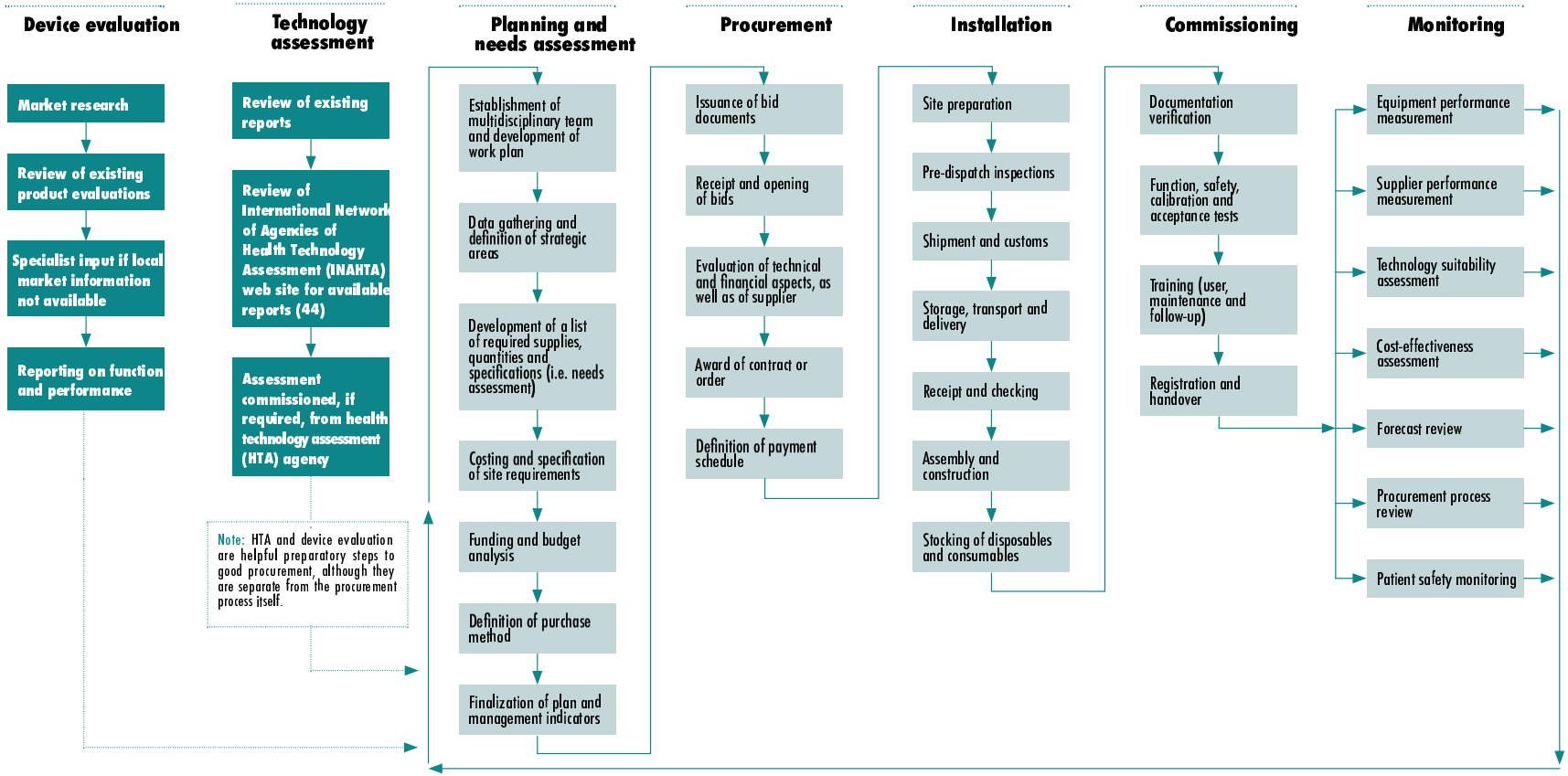

Fig. 3.4-6. Summary flow chart of standard procurement procedures (http://www.who.int/medical_devices/publications/procurement_guide/en/)

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).

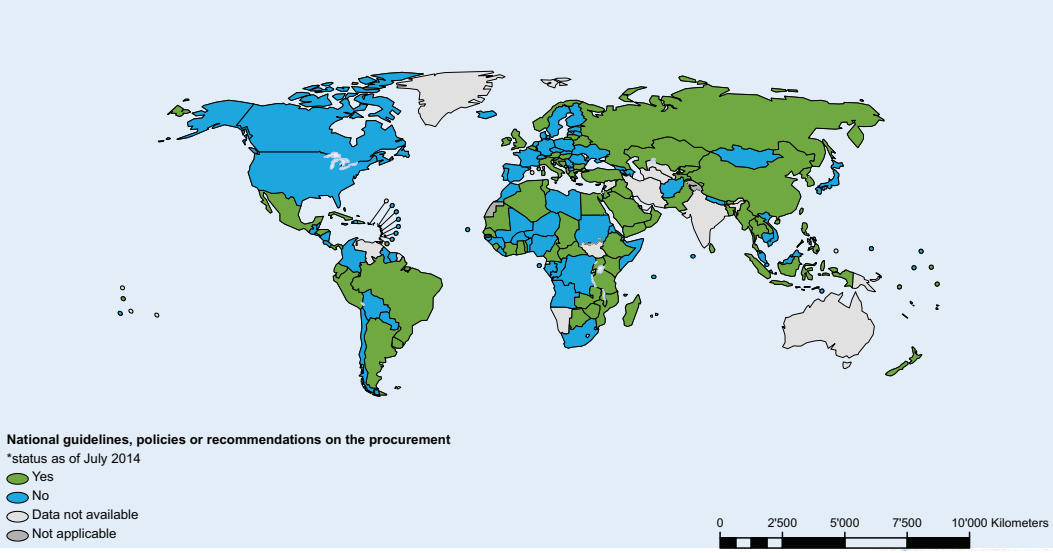

Fig. 3.4-7. National guidelines, policies or recommendations on the procurement of medical devices

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.

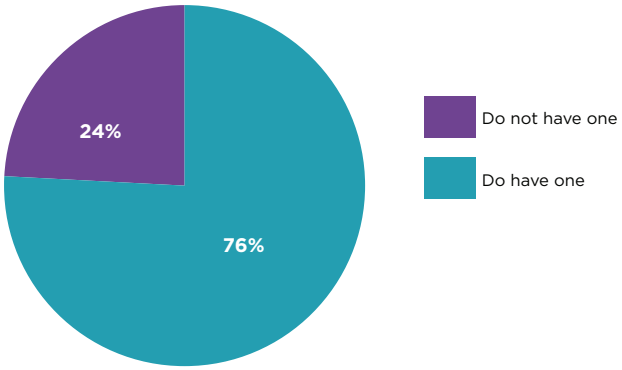

Fig. 3.4-8. Existence of national guidelines, policies, or recommendations on the procurement of medical devices as responded by 172 countries

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.[ix]

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.

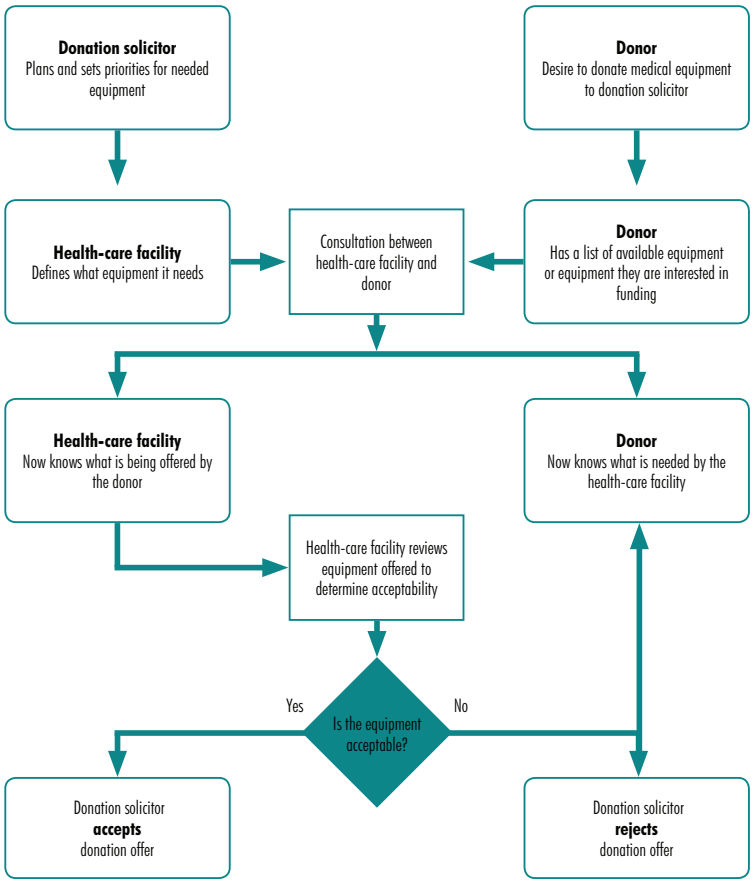

Fig. 3.4-9. Process for soliciting and offering donations of medical equipment (http://www.who.int/medical_devices/publications/med_dev_donations/en/)

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).

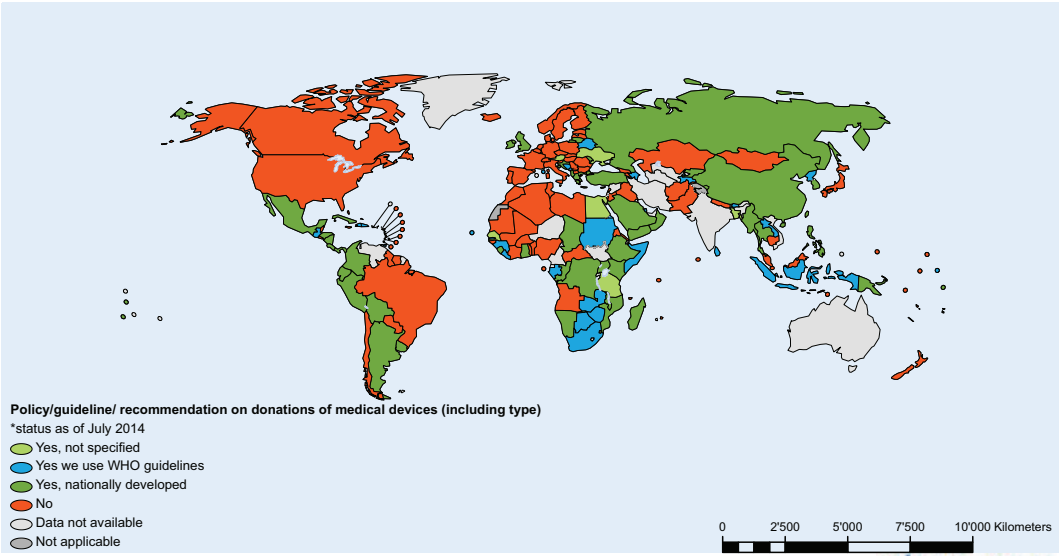

Fig. 3.4-10. Policies, guidelines, or recommendations on donations of medical devices

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.

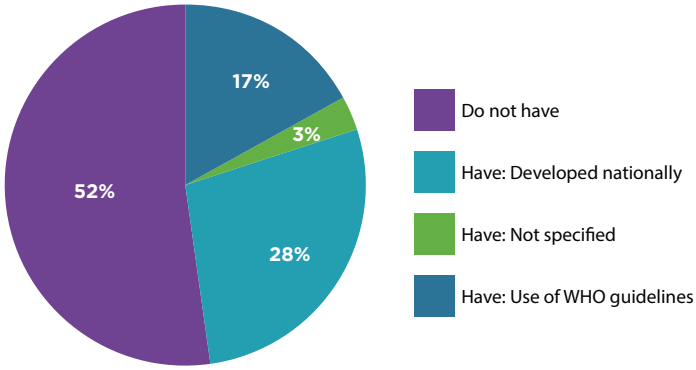

Fig. 3.4-11. Existence of policy, guideline or recommendation on donations for medical devices as responded by 174 countries

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 60601-1-1-1 (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).

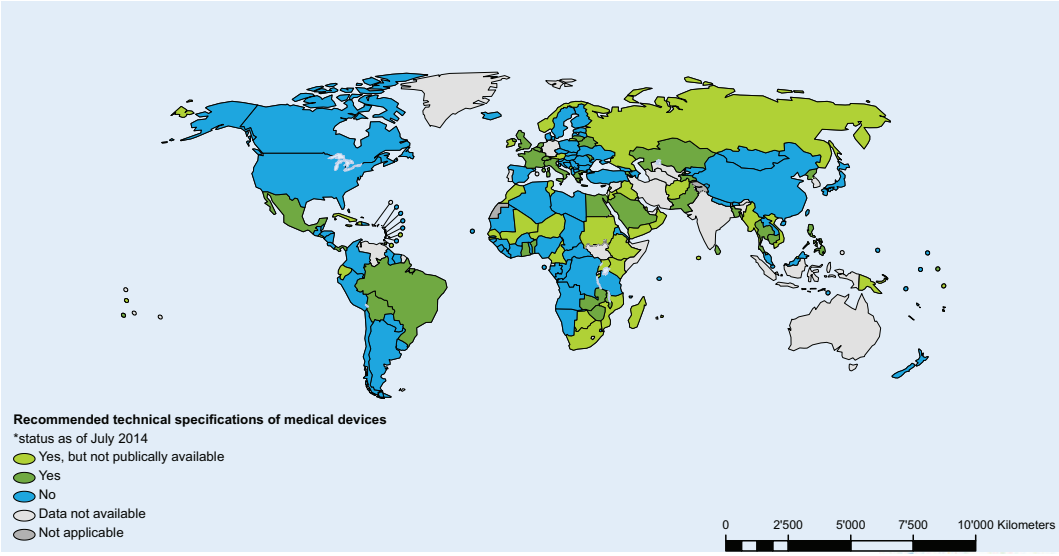

Fig. 3.4-14. Recommended publically available national technical specifications for procurement or donations of medical devices

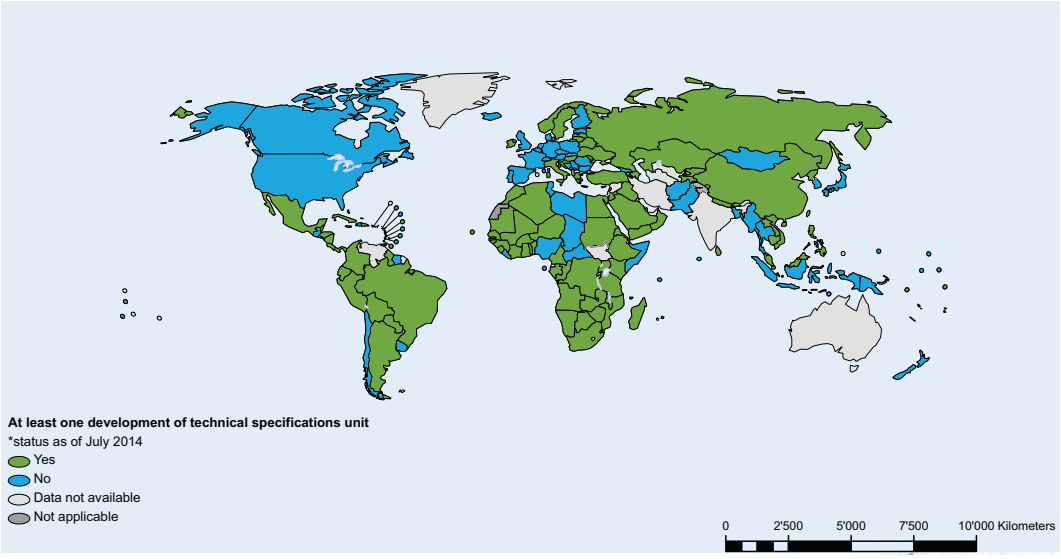

Fig. 3.4-15. Global map showing presence of units responsible for development of technical specifications for procurement purposes at national/federal level

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).

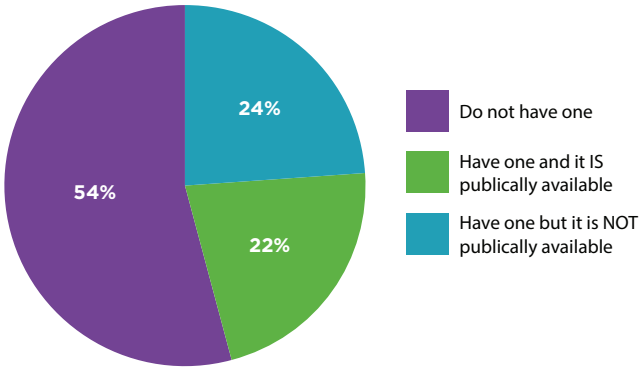

Fig. 3.4-16. Existence and availability of recommended technical specifications of medical devices to support procurement or donations as responded by 169 countries

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.

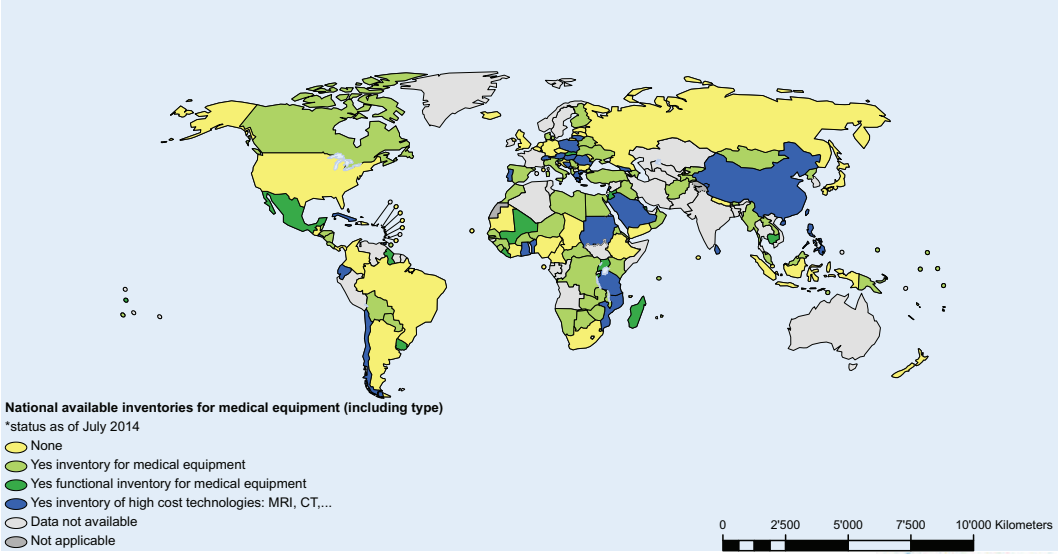

Fig. 3.4-19. National available inventories of medical equipment

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).

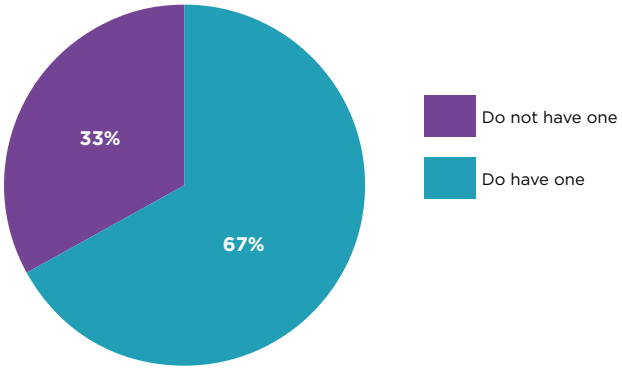

Fig. 3.4-20. Existence of country's available national inventory for medical equipment

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).

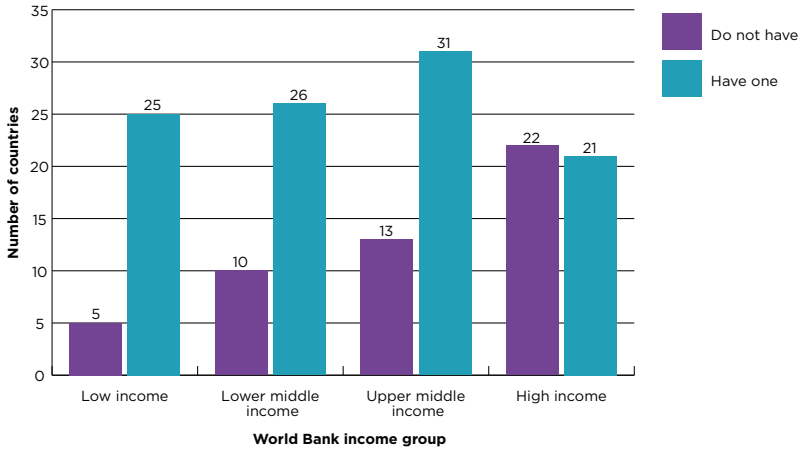

Fig. 3.4-21. Availability of national inventory for medical equipment by income group.

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).

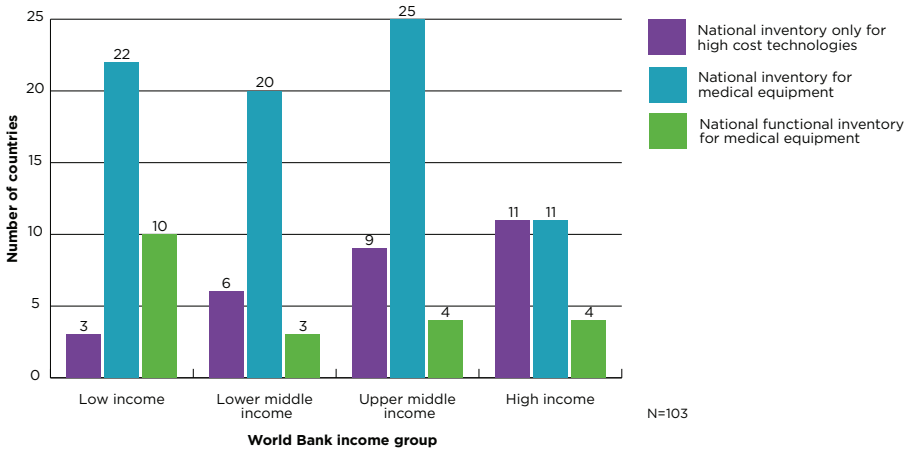

Fig. 3.4-22. Countries with available inventories of medical equipment by type of inventory and World Bank income group

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.

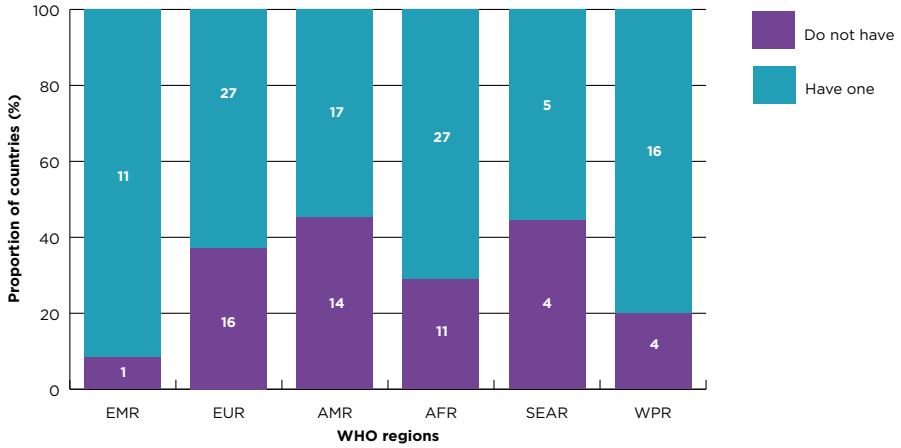

Fig. 3.4-23. Presence of country's medical equipment available inventory by WHO region

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.

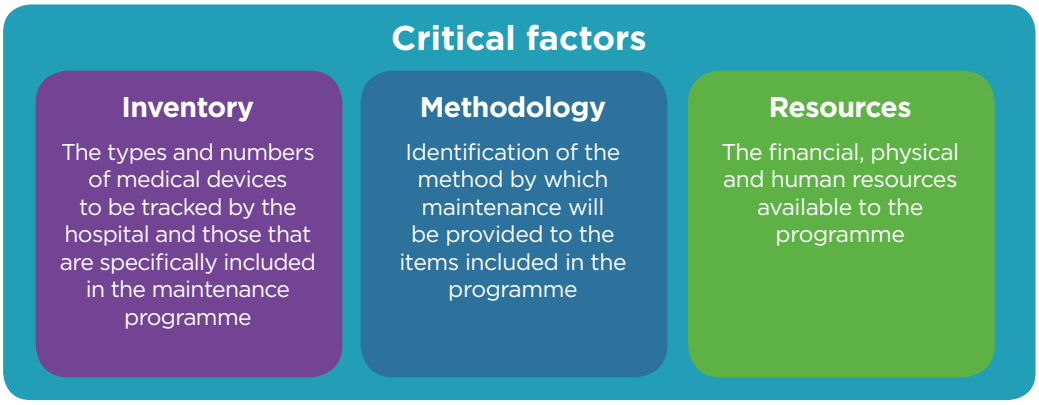

Fig. 3.4-25. Critical factors in planning a maintenance programme

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.

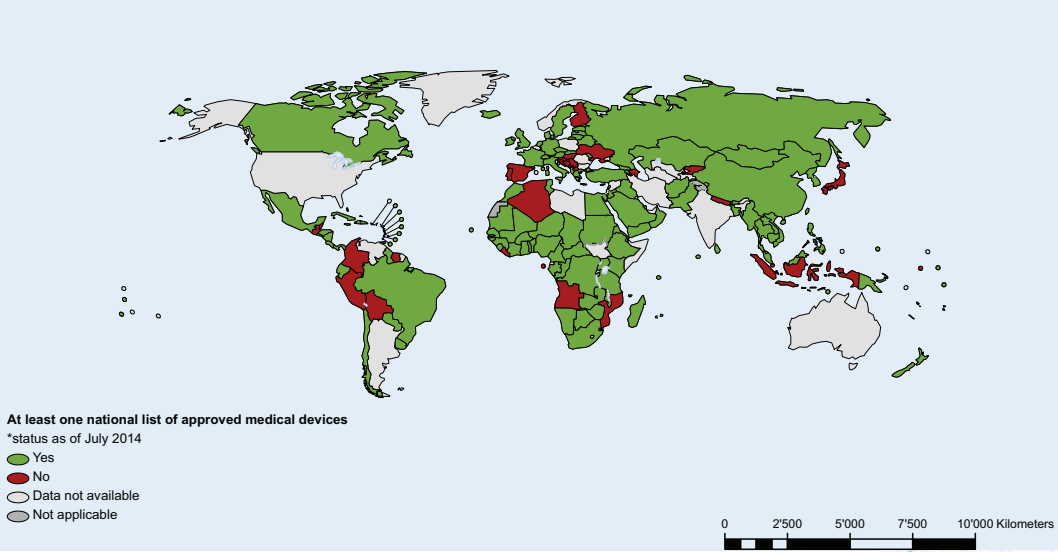

Fig. 3.4-26. Management units for medical equipment with professionally trained biomedical/clinical engineers or technicians

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).

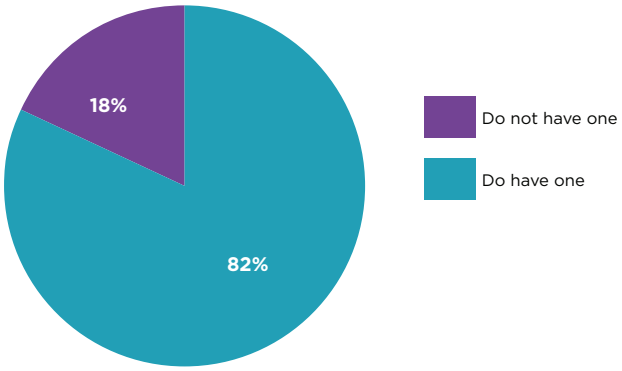

Fig. 3.4-27. Existence of a medical equipment management unit with professionally trained biomedical/clinical engineers or technicians

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).

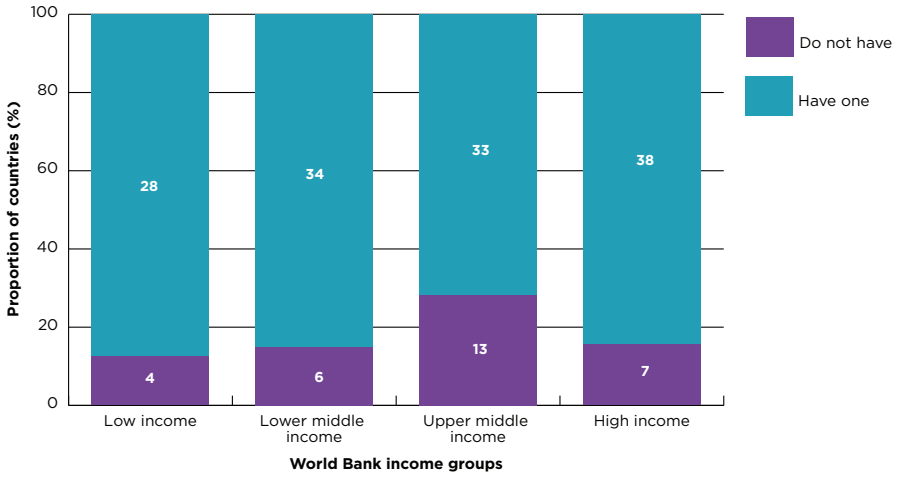

Fig. 3.4-28. Proportion of countries that reported a medical equipment management unit with professionally trained biomedical/clinical engineers or technicians by World Bank income group

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.