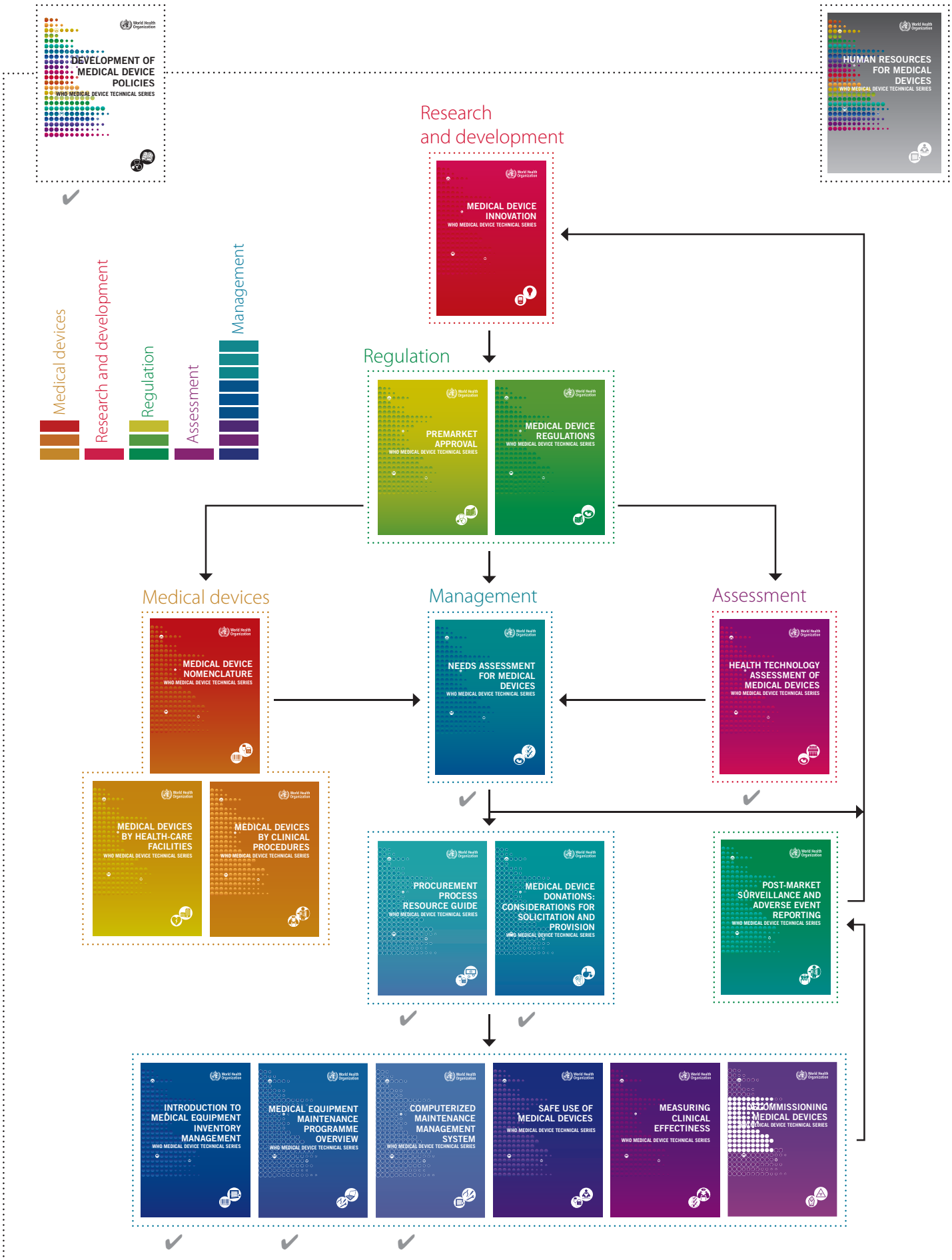
World Health Organization

Needs assessment for medical devices

WHO Medical device technical series

WHO MEDICAL DEVICE TECHNICAL SERIES: TO ENSURE IMPROVED ACCESS, QUALITY AND USE OF MEDICAL DEVICES



✔ Publications available as of June 2011

World Health Organization

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Needs assessment for medical devices

WHO Medical device technical series

WHO Library Cataloguing-in-Publication Data

Needs assessment for medical devices.

(WHO Medical device technical series)

1.Appropriate technology. 2.Equipment and supplies. 3.Technology assessment, Biomedical. I.World Health Organization.

ISBN 978 92 4 150138 5 (NLM classification: WX 147)

Design & layout: L'IV Com Sàrl, Villars-sous-Yens, Switzerland.

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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 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.

One of WHO's strategic objectives is to "ensure improved access, quality and use of medical products and technologies." This objective, together with the World Health Assembly resolution, formed the basis for establishing the Global Initiative on Health Technologies (GIHT), with funding from the Bill & Melinda Gates Foundation. GIHT aims to make core health technologies available at an affordable price, particularly to communities in resource-limited settings, to effectively control important health problems. It has two specific objectives:

- to challenge the international community to establish a framework for the development of national essential health technology programmes that will have a positive impact on the burden of disease and ensure effective use of resources;
- to challenge the business and scientific communities to identify and adapt innovative technologies that can have a significant impact on public health.

To meet these objectives, WHO and partners have been working towards devising an agenda, an action plan, tools and guidelines to increase access to appropriate medical devices. This document is part of a series of reference documents being developed for use at the country level. The series will include the following subject areas:

- policy framework for health technology
- medical device regulations
- health technology assessment
- health technology management
  - needs assessment of medical devices
  - medical device procurement
  - medical equipment donations
  - medical equipment inventory management
  - medical equipment maintenance
  - computerized maintenance management systems
- medical device data
  - medical device nomenclature
  - medical devices by health-care setting
  - medical devices by clinical procedures
- medical device innovation, research and development.

These documents are intended for use by biomedical engineers, health managers, donors, nongovernmental organizations and academic institutions involved in health technology at the district, national, regional or global levels.

Methodology

The documents in this series were written by international experts in their respective fields, and reviewed by members of the Technical Advisory Group on Health Technology (TAGHT). The TAGHT was established in 2009 to provide a forum for both experienced professionals and country representatives to develop and implement the appropriate tools and documents to meet the objectives of the GIHT. The group has met on three occasions. The first meeting was held in Geneva in April 2009 to prioritize which tools and topics most required updating or developing. A second meeting was held in Rio de Janeiro in November 2009 to share progress on the health technology management tools under development since April 2009, to review the current challenges and strategies facing the pilot countries, and to hold an interactive session for the group to present proposals for new tools, based on information gathered from the earlier presentations and discussions. The last meeting was held in Cairo in June 2010 to finalize the documents and to help countries develop action plans for their implementation. In addition to these meetings, experts and advisers have collaborated through an online community to provide feedback on the development of the documents. The concepts were discussed further during the First WHO Global Forum on Medical Devices in September 2010. Stakeholders from 106 countries made recommendations on how to implement the information covered in this series of documents at the country level.[1]

All meeting participants and people involved in the development of these documents were asked to complete a declaration of interest form, and no conflicts were identified.

1 *First WHO Global Forum on Medical Devices: context, outcomes, and future actions* is available at: http://www.who.int/medical_devices/gfmd_report_final.pdf (accessed March 2011)

Definitions

Recognizing that there are multiple interpretations for the terms listed below, they are defined as follows for the purposes of this technical series.

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 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.

2 World Health Assembly resolution WHA60.29, May 2007 (http://www.who.int/medical_devices/resolution_wha60_29-en1.pdf, accessed March 2011).

3 Information document concerning the definition of the term "medical device". Global Harmonization Task Force, 2005 (http://www.ghtf.org/documents/sg1/sg1n29r162005.pdf, accessed March 2011).

Acknowledgements

Needs assessment for medical devices was developed under the primary authorship of Ronald Bauer, Saniplan GmbH, and under the overall direction of Adriana Velazquez-Berumen, WHO, Geneva, Switzerland as part of the Global Initiative on Health Technologies project funded by the Bill & Melinda Gates Foundation.

The document outline was reviewed by Andrew Gammie (Fishtail Consulting Ltd.) and James Wear (consultant), and the draft was reviewed by Jennifer Barragan (WHO), Adham Ismail (WHO), and was edited by Inis Communication.

We would like to thank Aditi A Sharma for assistance in proofreading and Karina Reyes-Moya and Gudrun Ingolfsdottir for administrative support throughout the development of this document.

Declarations of interests

Conflict of interest statements were collected from all contributors to and reviewers of the document. Ronald Bauer declared his employment at Saniplan GmbH, a firm that provides technical assistance and consulting services with the aim to improve the quality and accessibility of health systems and services, and Andrew Gammie his employment at Fishtail Consulting Ltd., a firm that provides advice in the area of medical devices, particularly in developing countries, as remuneration from an organization with an interest related to the subject. None of these declared conflicts influenced the content of the document.

Acronyms and abbreviations

CENETEC	Centro Nacional de Excelencia Tecnológica en Salud (National Center for Health Technology Excellence)
CMMS	computerized maintenance management system
CPG	clinical practice guidelines
GIHT	Global Initiative on Health Technologies
HIV/AIDS	human immunodeficiency virus/acquired immune deficiency syndrome
HTA	health technology assessment
HR	human resources
iHTP	Integrated Healthcare Technology Package
MoH	ministry of health
NGO	nongovernmental organization
PDSA	Plan, Do, Study, Act (prioritization matrix)
SAM	Service Availability Mapping
TAGHT	Technical Advisory Group on Health Technology
UNICEF	United Nations Children's Fund
WHO	World Health Organization

Executive Summary

Needs assessment is a complex process, incorporating a number of variables, that provides decision-makers with the information necessary to prioritize and select appropriate medical devices at a national, regional or hospital level. This document describes and illustrates the objective, the general approach and the process of such a needs assessment. The main section, *Specific approach* (Section 4), demonstrates in seven steps how to identify related needs, consider the requirements of baseline information, analyse the gathered information, appraise the options, and prioritize the specific requirements. Tools are being continuously developed to support this decision-making process, and this document also includes information on useful tools that will help in the execution of these steps.[1]

1 These links are also found in the section *Useful resources*.

1 Introduction

Needs assessment is a process for determining and addressing the gaps between the current situation or condition, and the desired one. It is a strategic activity and a part of the planning process that aims to improve the current performance or to correct deficiencies.

In this particular case, needs assessment is the identification and definition of prioritized requirements with regard to medical devices. A thorough needs assessment includes the potential impact on performance of medical equipment users, and on delivery of services within the context of health system capabilities and service delivery priorities. It takes into account the overall objectives of the institution, existing facilities and infrastructures, long-term plan of use, and human resources (HR) development prior to purchasing a medical device.

It is also critically important that end-users are taken into consideration and are involved in any assessment.

A needs assessment can be performed according to different scenarios and under varying circumstances. It is important to note that this activity is regularly performed as part of an effective medical equipment maintenance programme,[1] and occurs: when updating a medical equipment inventory; when re-evaluating services; and/or when replacing equipment. A needs assessment is also important prior to the construction of any new health facility.

Furthermore, it can be performed at national, regional, local or facility levels.

It should be noted that 'needs assessment of health technology' differs from 'health technology assessment' (HTA). HTA is an instrument to analyse the technical, ethical, social and economical impact, as well as the clinical effectiveness, of a specific technology.[2]

1 Please see *Medical equipment maintenance programme overview* in this technical series for more information.

2 Please see *Health technology assessment of medical devices* in this technical series for more information.

2 Purpose

The main objective of this document is to provide Member States with guidance for a methodological approach, as well as tools and references, and examples to conduct a proper assessment of their current situation and future needs with regard to health technologies – specifically, medical devices – in consideration of their country's health burden and disease data.

Because the characteristics of each Member State vary enormously, this document presents only generic principles. However, the resources and examples shown (or referred to) should enable any country to elaborate or adapt these principles according to their particular needs.

The document can be used for single facilities as well as for a network of facilities, up to national systems (referral systems). The tools referred to in this document do, however, need to be properly selected and appropriately applied. The ultimate goal is for countries to use the tools for integration of prioritized needs into national policies and action plans.

Note: The references and links provided are not intended to be either complete or comprehensive, but rather a selection of documents and tools identified by WHO as sources of information for decision-makers.

3 General approach

The general approach in performing a needs assessment is to examine what is available in the facility, region or country, and to compare it with what *should* be available, considering the particular demand and situation of the catchment area or target group. Part of this process includes looking at locally- and globally-recognized standards. The identified gap specifies the overall need.

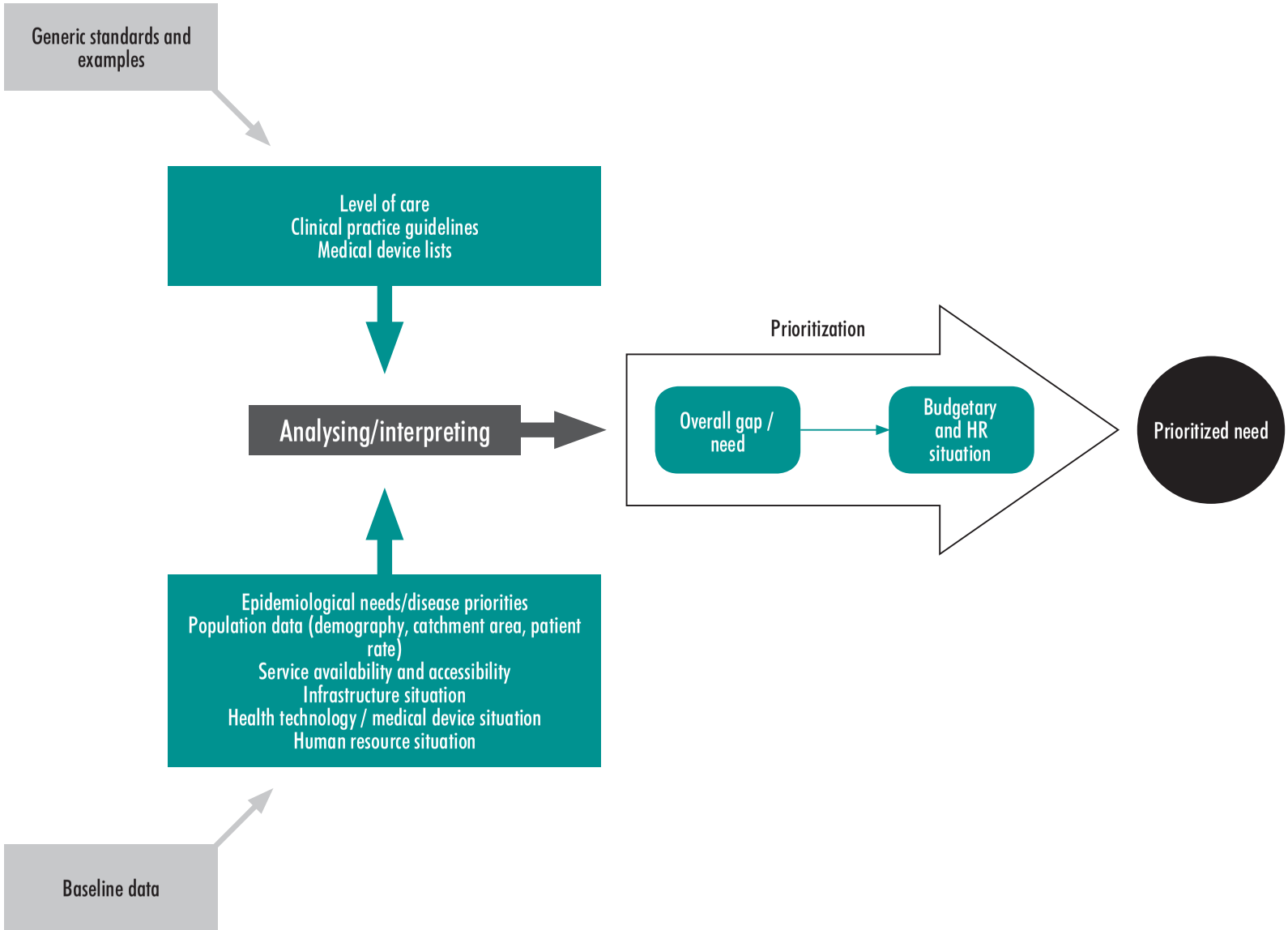
By taking into consideration possible financial and HR restrictions, as well as prioritized epidemiological requirements, a list of the prioritized needs can be established. Table 1 and Figure 1 summarize and visualize the process. Table 1 specifically outlines the questions to be asked, the data required to answer those questions, and the tools available to collect and evaluate the data.

Table 1. General needs assessment approach (process)

	Questions	Data required	Tools[a]	Result
1	What do we want/need in terms of health services?	• Population (target population, catchment area) • Health service provider availability • Epidemiological data	• "Certificate of need" process, see Appendix A • Clinical practice guidelines (CPG) • Survey questionnaires • Standards of level of care • Integrated Healthcare Technology Package (iHTP)	
2	What do we have? (local conditions/ limitations)	• Health service availability • Lists of available medical devices • Human resources availability	• Service Availability Mapping (SAM) questionnaires • Evaluation manuals/tools • Inventory management tool • Computerized maintenance management system (CMMS)	
3	Which standards/ recommended best practices exist that could be applied or adapted?	• Standards/ recommendations for health service delivery coverage (catchment areas) • Standards/ recommendations for medical devices • Standards/ recommendations for human resources required for operation/maintenance/ management of medical equipment	• (essential) Medical device lists; i.e., per facility type and department, or per clinical procedure	
4=3-2	Overall gap:			List of general needs
5	What financial/human resources do we have? (constraints)	• Budget (capital investment and operational) • Human resources		
6=4-5	Prioritized needs:			Prioritized list of needs

[a] Please refer to *Useful resources* and appendices included in this document for more information on these tools.

Figure 1. General needs assessment process



4 Specific approach

Expanding upon the general approach, this section summarizes the seven specific data collection and analysis steps of the needs assessment process. Steps I-III refer to the baseline information collection of health service requirements, health service availability, and health technology. Steps IV and V refer to the specific situation in terms of human resources and finances – and possible respective constraints – of the administration of the facility, region or state. Step VI provides suggestions for analysing and interpreting the results of Steps I-V. Lastly, Step VII briefly discusses the issue of prioritization and option appraisal.

The tables in Steps I-V also summarize what information is to be collected, the data to be considered during the collection process, and the desired result of the process. Due to the cross-cutting nature of the process, the same outcomes may be mentioned in multiple steps.

4.1 Step I: Baseline information on health service requirements

Table 2. Baseline information on health service requirements

Local geographical and public health conditions	Considerations	Result
• Population of target area, including size of the region/area, number and density of population • Major disease burden	• Epidemiological needs (disease priorities) • Population issues (demography / catchment area, patient rate) • CPG/protocols/national or local recommendations • Internationally-recognized standards on diagnosis and treatment of different diseases • Health-care issue prioritization	• Appropriate health service delivery requirements

Complete details on Step I are not provided here, as they are outside the scope of this document and the responsibility of the GIHT. However, Step I remains critically important to address, as it directly refers to the health situation of the target population. WHO has information available at the country level while national ministries of health (MoHs) may have more detailed information.[1]

1 WHO country profiles are available at http://www.who.int/countries/en

4.2 Step II: Baseline information on health service availability

Table 3. Baseline information on health service availability

Service delivery situation	Considerations	Result
• Available services (e.g., maternal and child health, HIV/AIDS, surgical, etc.) • Facilities (e.g., hospitals, clinics, etc.) • Human resources	• Health service availability and accessibility • Opinions on health service delivery from the target population • Opinions on health service delivery from service providers • Facility types, numbers, conditions • Current staffing levels	• Health service availability map (overview) • Facility map

It is important to assess the current situation in order to identify the difference between what is needed and what exists. Taking Table 3 into account, the following questions can be asked to retrieve the relevant information:

- Where is the facility(ies) located?
- Which health services are available at the facility?
- What range of clients does the facility cater to in terms of age, gender, geographical distribution, etc.?
- Which specific needs does the facility (and its services) meet?
- How does the facility receive referrals, and from whom do its referrals come?
- How many clients does the facility see each week/month/quarter/year?
- On average, how long do clients stay at the facility, and what are their reasons for leaving (e.g., drop-out, onward referral, etc.)?
- How many clients each week/month, etc., are referred on to other agencies?
- What is the caseload of staff?
- How many full-time staff does the service employ, and how much time do they have available each week for client appointments?
- Is there any information regarding staff satisfaction or facility-user satisfaction available by way of surveys?
- How do existing clients access the facility (e.g., on foot, by public transportation, etc.)?
- How accessible is the service by public transportation?

Specific tools[1] can further assist in the collection of the appropriate information for this and other steps in the process, including:

- *Service Availability Mapping (SAM)* tool, World Health Organization.
- *Rapid health facility assessment flow chart.* International Health Facility Assessment Network, 2007.

1 Reference information for these tools can be found under *Useful Resources.*

4.3 Step III: Baseline information on medical devices

Table 4. Baseline information on medical devices

Medical device situation	Considerations	Result
• Availability and condition of medical devices (including type, number, location and physical condition) • Status of electrical, water, and waste disposal systems related to medical device use	• Medical equipment inventory including status and condition • Current health technology management infrastructure (or lack thereof)	• Facility map • Medical equipment inventory (quantitative and qualitative) • Outline of health technology management infrastructure

This is the key step in the process with regard to health technology. The main goal is to identify what is available in terms of medical devices and related infrastructure, and their condition. It is important to collect as much detailed and reliable information as possible, because any change, correction or improvement will have a major impact on the financial and human resources, as well as on the environment.

A two-step approach can be followed where the first step is a neutral, quantitative assessment, and the second, a more detailed, qualitative assessment. It is up to the implementer to decide if the second step is desired or necessary.

Taking Table 4 into account, some of the key information to be collected includes the following:

Infrastructure

- type, size, and position of premise and building(s), including the number and type of building(s);
- availability and condition of:
  - water supply, connections and installation (e.g., where does the water come from?, what is the quality?, etc);
  - power supply, electrical connections and installations (e.g., is an emergency generator available?);
  - waste disposal system (e.g., how is waste handled, segregated, and disposed of?).

Medical equipment[1]

- type and number of equipment
- brand name
- model
- year of manufacture
- date of installation
- location (medical department)
- physical condition (in operation/out of order/repairable)
- spare parts required/available for repair
- tools available for inspection, maintenance, and repair
- medical equipment history if available (operation/use time, maintenance/repair).

Health technology management

- Type of existing management structure, including responsibilities.
- Existing policy (if available).

1 Most of this data is collected in an inventory. Please refer to *Introduction to medical equipment inventory management* in this technical series for more details on developing an inventory.

Specific tools[2] can further assist in the collection of the appropriate information for this and other steps in the process, including:

- *Introduction to medical equipment inventory management.* Geneva, World Health Organization, 2011.
- *Computerized maintenance management system.* Geneva, World Health Organization, 2011.
- *Integrated Healthcare Technology Package (iHTP).* World Health Organization.[3]
- *Rapid health facility assessment flow chart.* International Health Facility Assessment Network, 2007.
- *Practical steps for developing health care technology policy.* Brighton, Institute of Development Studies, 2000.
- *Development of medical device policies, strategies and action plans.* Geneva, World Health Organization, 2011.

Additionally, the following are some available tools on internationally or regionally recognized standards that are useful for comparison purposes:

- *Interagency list of essential medical devices for reproductive health.* Geneva, World Health Organization, 2008.
- *Integrated Management for Emergency and Essential Surgical Care (IMEESC) tool kit.* Geneva, World Health Organization.
- *Surgical care at the district hospital.* Geneva, World Health Organization, 2003.
- *Package of essential noncommunicable (PEN) disease interventions for primary health care in low-resource settings.* Geneva, World Health Organization, 2010.
- *Medical devices by health-care facilities* (in preparation). Geneva, World Health Organization, 2011.
- *Medical devices by clinical procedures* (in preparation). Geneva, World Health Organization, 2011.
- *Models and medical equipment guidelines.* Mexico City, Centro Nacional de Excelencia Tecnológica en Salud (CENETEC).
- *Primary health care centres and first referral level hospitals. Planning guide: Equipment and renewable resources.* New York, United Nations Children's Fund, 2005.

2 Reference information for these tools can be found under *Useful Resources.*
3 Tool requires technical support from WHO before use.

4.4 Step IV: Baseline information on human resources

Table 5. Baseline information on human resources

Human resources	Considerations	Result
Qualification and number of human resources required to cover the required health-care demand (as defined by results of Step I)	• Availability, capacity, and capability of current human resources	• Human resource data information (staffing plan) • Education and training map

The minimum information that should be available for collection and assessment is:

- existing posts and job descriptions
- number of vacant posts
- status and availability of:
  - › basic, higher or vocational education
  - › continuous training
  - › on-the-job training
  - › human resources planning.

Further details on Step IV are not provided here, as this is outside the scope of this document and the responsibility of the GIHT. This information should be available at the HR department of your administration.

4.5 Step V: Baseline information on finances

Table 6. Baseline information on finances

Financial situation	Considerations	Result
Capacity to finance overall facility operations, including health services, health technology, and infrastructure (Steps II and III above).	• Financial resources	• Budget

The minimum information that should be available for collection and assessment is:

- budget and expenses from previous periods
- current budget
- system of monitoring/controlling budget.

Further details on Step V are not provided here, as this is outside the scope of this document and the responsibility of the GIHT. This information should be available at the financial department of your administration.

4.6 Step VI: Analysis and interpretation

Once all the information is gathered, it is possible to analyse, interpret and draw conclusions. The analysis and interpretation should be based directly on the information gathered in the manner outlined in previous steps. Therefore, keep in mind that the use of poor methodology in the information-gathering stages will undermine the ability to develop valid interpretations of the situation. In the end, this will affect the quality of the conclusions and resulting recommendations targeting the needs of the population.

Specifically for analysing medical device needs, it is necessary to compare the current inventory list (results of Step III above) with an internationally- or regionally-recognized standard for the type of facility and/or intervention being reviewed, and assess the respective gap. Using spreadsheets in a programme such as Excel can be helpful, but if there is a large amount of data to compare, it may be best to use the inventory section of a CMMS, if available, for such purposes.

The recent WHO background paper entitled: *A stepwise approach to identify gaps in medical devices (availability matrix and survey methodology)*, is a result of the Priority Medical Devices project, and it might be a helpful tool during this stage of the process.

4.7 Step VII: Prioritization and appraisal of options

After having analysed the information gathered in the earlier steps of the needs assessment process, and having drawn conclusions, there should now be a reasonably clear picture of the needs of the target population. Decisions regarding the actions to take will depend on several crucial and closely connected activities. These include:

- **Prioritization:** If there are insufficient resources to meet all the identified needs, it may be necessary to rank them in order to decide which needs should be met first and which will be met later.
- **Option appraisal:** There may be more than one way of meeting the needs identified. Various options should be considered, and the evidence in favour of each should be weighed carefully.
- **Implementation:** When agreement has been reached about how the needs are to be met, an action plan and timetable should be drawn up, including a plan for resource allocation.

In practice, the tasks of prioritization and option appraisal are directly linked. Both must be considered together.

4.7.1 Prioritization

When sufficient resources are not available to meet all the identified needs (which is the case in most circumstances), it is important for prioritization to occur. Prioritization is a strategic process, undertaken by those responsible for the commissioning of services. Those involved in prioritizing should also consider the opinions of service users and service providers regarding how to

prioritize needs. However, they may not always agree, so priority is best given to those areas where they do.

The way in which decisions are made with regard to identified priorities will depend on local circumstances. National priorities and the availability of required resources are often what prompts the needs assessment process. Therefore, the purpose of this step is to determine specifically what should be done, how, and in what order. For example, national and local policy may require that services should be provided for maternal and child health. In this case, the local needs assessment will focus on identifying the specific needs of women/mothers and newborns in the local area, their prioritization, and what is particularly required (in terms of medical devices) in order to render the required services that will allow these priorities to be realized.

4.7.2 Option appraisal

In most cases, there will be more than one way of responding to the needs which have been identified. The options you choose will depend on several factors, including:

- how the needs are prioritized
- what the likely impact of each option will be
- the availability of resources.

Table 7 provides one way of thinking about the options for change following a needs assessment.

Table 7. Plan, Do, Study, Act (PDSA) prioritization matrix

Finances/resources required to implement change	Likely impact of change	
	Low	High
Low	Soft target: Wait	Win: Go!
High	Refrain or Wait	Challenging: Wait

The aim will be to give first priority to actions that will have the highest positive impact on the ability to provide optimal services to the target population, as well as require the fewest additional resources.

At the other extreme, it is better to avoid making changes that are likely to have a low impact but which require a high level of resources. In between are those actions that are likely to have a high impact, but will also demand high resources. In most circumstances, these would not be selected for immediate action either, but rather, considered as long-term options.

Similarly, so called 'soft targets' are those actions requiring few resources but having little impact. It may be tempting/attractive to go ahead with these actions, but they can prove to be a distraction from the more high-impact actions. For this reason, it is usually better to wait until the 'quick wins' have been successfully implemented first.

Hooper and Longworth (2002) suggest that a number of key questions should be addressed when appraising the options and prioritizing the needs following a needs assessment exercise. These questions focus on the issues of impact, changeability, acceptability and resource feasibility, and are adapted here for the application of needs assessment of health technology.

Table 8. Key questions for prioritizing and appraisal of options

Key questions to ask when appraising the options and prioritizing
Impact • Which changes would have the greatest positive impact in meeting needs? • Do the identified needs relate to a local or a national priority (e.g., maternal and child health, HIV/AIDS, etc.)? • What would be the implications of not addressing the needs?
Changeability • Which things can be changed and effectively improved? • What evidence is there of effective interventions? • Can negative impacts be stopped or reduced? • Are there national or local, professional or organizational policies that set out guidelines on what should be done (e.g., national frameworks, national guidance, etc.)?
Acceptability • Which of the options for change are likely to be most acceptable to the health service providers, to the target population, and to the managers? • What might be the 'knock-on' effects, or unintended consequences, of making a change?
Resource feasibility • Which resources are required to implement the proposed changes? • Can existing resources be used differently? • Which resources will be released if ineffective actions are stopped/changed (e.g., proper management of health technology, etc.)? • Are there other resources available which have not been given prior consideration (e.g., income generation of laboratory services, consideration of public-private partnerships, assistance from NGOs, etc.)? • Which of the actions will achieve the greatest impact for the resources used?

4.7.3 Developing an implementation plan

Once priorities and the ways to address these priorities are agreed upon, the next step is to develop an action plan for implementation. An implementation plan should be **realistic, achievable** and **adequately fundable**, while at the same time able to clearly outline the various stages of the implementation process.

It is important that health service providers are included in discussions regarding the implementation plan – and are supportive of it – because at an operational level, they will be directly involved in the implementation and introduction of the agreed changes to existing services.

A good implementation plan includes:

- a statement of the aims and objectives of the planned action, and the specific steps and milestones required to achieve it;
- the names of the individuals responsible for carrying out each part of the plan, what they will do and when, and the skills and training they will need (in particular, with a focus on health technology management, policy and structure);
- details of the resources that will be required (including devices, and if applicable, administrative, managerial, and IT systems), and where they will come from;
- a clear understanding of how the plan will be kept on track, how the implementation of each component of the plan will be measured, and how the relevant people will be kept motivated and involved.

5 Concluding remarks

The needs assessment process is a powerful tool for determining medical device needs at the facility, regional and/or country level. By collecting baseline information and comparing it to a desired standard, the existing gap can be identified.

Determining how to best use the resources available to fill that gap will lead to a prioritization of activities that can eventually lead to a more efficient provision of health services and better quality of care.

6 Useful resources

All URLs accessed 30th March 2011

For these and more resources, please visit the World Health Organization Library Information System (WHOLIS) at http://dosei.who.int, or the e-Documentation centre for WHO Health Technologies/Medical devices at http://hinfo.humaninfo.ro/gsdl/healthtechdocs.

Medical equipment maintenance programme overview. Geneva, World Health Organization, 2011.

Health technology assessment of medical devices. Geneva, World Health Organization, 2011.

Service Availability Mapping (SAM), World Health Organization (http://www.who.int/healthinfo/systems/serviceavailabilitymapping/en).

Rapid health facility assessment flow chart. New York, International Health Facility Assessment Network, 2007 (http://ihfan.org/home/docs/attachments/ms-08-28_flowchart.pdf).

Introduction to medical equipment inventory management. Geneva, World Health Organization, 2011.

Computerized maintenance management system. Geneva, World Health Organization, 2011.

Integrated Healthcare Technology Package (iHTP), World Health Organization (http://www.ihtp.info).

Temple-Bird C. *Practical steps for developing health care technology policy.* Brighton, Institute of Development Studies, 2000.

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Appendix A

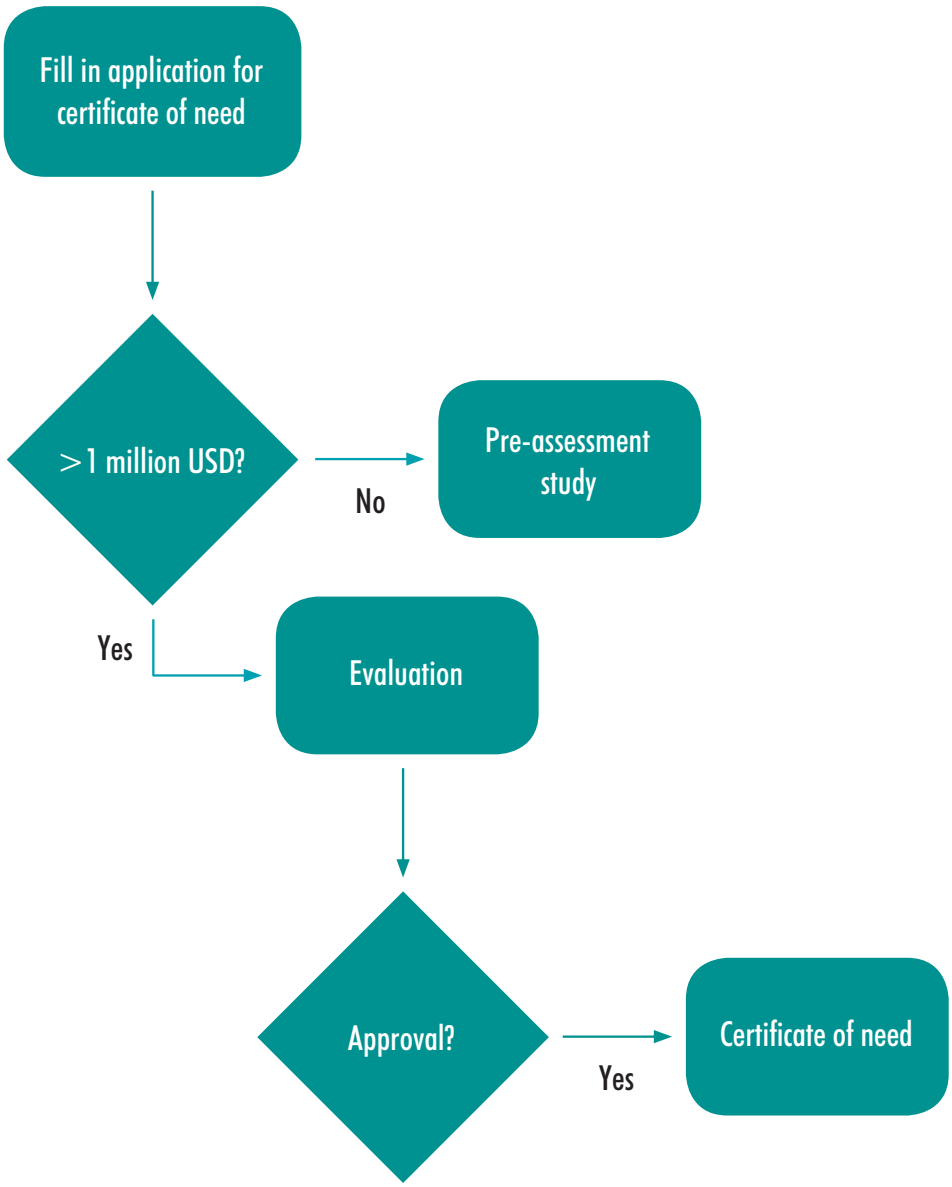
Certificate of need process

The Certificate of Need is a planning tool used to support decision-makers in evaluating investments of highly-specialized and expensive medical equipment, based on technical, epidemiological, and cost-benefit criteria in order to best optimize resources.[1] Many countries do not have this process in place but may be something decision-makers may want to consider. For those countries who have or will implement this process, it is important to take into consideration the following when applying for a certificate of need.

- General Data
  - Place
  - Catchment area
  - Epidemiology information
  - Mortality/morbidity
  - Applicants data.
- Description of need
  - Service characteristics
  - Clinical procedures required
  - Number of referred patients to another site
  - Other available equipment in the area.
- Proposal
  - Medical equipment
  - Staff
  - Infrastructure.
- Resources needed
  - Investment
  - Operational costs
  - Sources of financing.

1 CENETEC definition translated from Spanish (http://www.cenetec.salud.gob.mx/interior/cert_nec.html)

The flow chart below demonstrates the process for obtaining a certificate of need.



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ISBN 978 92 4 150138 5