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MEDICAL DEVICES: MANAGING THE MISMATCH

An outcome of the Priority Medical Devices project

A stepwise approach to identify gaps in medical devices (availability matrix and survey methodology)

Background Paper 1

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Preface

In 2007, at the request of the Government of the Netherlands, the World Health Organization launched the *Priority Medical Devices (PMD)* project to determine whether medical devices currently on the global market are meeting the needs of health-care providers and patients throughout the world and, if not, to propose remedial action based on sound research.

The project gathered the information required by conducting literature reviews and surveys, and by convening meetings of specialist consultants.

The project addressed various complementary issues:

- the global burdens of disease and disability;
- guidelines on clinical procedures for the management of diseases and disabilities;
- projections of future burdens of disease and disability in the context of demographic trends;
- cross-cutting issues, such as the training of medical device users, medical device design, contextual appropriateness of medical devices, and regulatory oversight;
- catalysts of, and barriers to medical device innovation and research.

The original objective of the *PMD* project was to identify gaps in the availability of medical devices. The findings of the project showed that gaps in the availability of medical devices is not the primary issue, but rather a number of shortcomings spanning several facets of the medical device sphere. This result prompted a change of direction in which the project shifted its focus onto the many shortcomings related to medical devices.

These problems, challenges, and failures amount to a mismatch, rather than a gap, that prevents medical devices from achieving their full public health potential.

The *PMD* project also produced a report *Medical Devices: Managing the Mismatch* aimed at achieving two objectives: the first, to inform national health policy-makers, international organizations, manufacturers and other stakeholders of the factors preventing the current medical device community from achieving its full public health potential; the second, to provide a basis on which all players in the medical device scene can together use the findings and recommendations of the *PMD* project to make public health the central focus of their activities.

This paper is part of a series of documents produced as background material for the *PMD* project report. The following papers are available as part of this series:

❶ A stepwise approach to identifying gaps in medical devices (Availability Matrix and survey methodology)
❷ Building bridges between diseases, disabilities and assistive devices: linking the GBD, ICF and ISO 9999
❸ Clinical evidence for medical devices: regulatory processes focussing on Europe and the United States of America
❹ Increasing complexity of medical devices and consequences for training and outcome of care
❺ Context dependency of medical devices
❻ Barriers to innovation in the field of medical devices
❼ Trends in medical technology and expected impact on public health
❽ Future public health needs: commonalities and differences between high- and low-resource settings

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Executive summary

Few data exist on the availability and use of medical devices to treat disease and to assist people with disabilities. While access to pharmaceuticals has been studied at length, this has not been the case with medical devices.

The *Priority Medical Devices (PMD)* project aims at identifying the need for medical devices in 15 high-burden diseases, diseases which account for almost two-thirds of the global burden of disease.

The first part of this document outlines the methodology used to identify gaps between the need for and the availability of medical devices. The second part reveals the results of two surveys conducted both at country and specialist level.

The *PMD* project used a stepwise approach to identify the gaps between the need for and the availability of medical devices. Matrix development consists of mapping medical devices for high-burden diseases or disabilities according to the Global Burden of Disease and Risk Factors *(1)*. Medical devices used to prevent, diagnose, treat and assist the patient at all stages of the disease/disability were then extracted from the relevant published clinical guidelines. This resulted in the creation of the Availability Matrix: a proposed listing of medical devices relevant to the 15 high-burden diseases based on the clinical guidelines for these diseases.

One of the first gaps identified by the *PMD* project is that medical devices listed in clinical guidelines are not specific, nor do they include an all-inclusive list of medical devices needed to perform a clinical protocol. In addition, medical devices within these guidelines are not described according to a standardized nomenclature and classification system. Moreover, in regard to relevant medical devices, it was very clear that the information provided by clinical guidelines is currently much too unspecific to enable coding or direct compatibility with a single nomenclature system.

Furthermore, clinical guidelines do not generally include reference to medical devices for use in prevention of or rehabilitation from conditions. In order to map assistive devices as part of the *PMD* project, the selected diseases have been linked to functioning through a core set[1] for each of the diseases listed.

There are numerous limitations and assumptions in the Availability Matrix. Firstly, the assumption is made that the clinical guidelines used are evidence-based, and that they include the important medical devices needed in the management of the respective disease. Secondly, due to the specific disease approach used in the creation of the Availability Matrix, medical devices for general use (such as hospital beds, operating lamps, sterilizers, etc.) are not covered, as they are rarely considered or emphasized as part of the overall disease management process.

The second part of this document indicates the results of two surveys that were completed, based on the methodology developed by the *PMD* project. The first survey was sent out to six countries (four of which responded) from different continents. Countries were selected based on their Human Development Index (HDI), a measure of a country's developing or developed status. The use of medical devices was assessed in three areas encompassing primary, secondary and tertiary health-care levels: 1) in the management of diabetes, as an example of a noncommunicable disease; 2) in tuberculosis (TB), as an example of an infectious disease; and 3) in injury sustained following a road traffic accident, as an example of where early intervention could prevent long-term disability.

The second survey was sent out to specialists in the 15 diseases in order to provide another perspective from which to assess the gaps in the use of medical devices. The specialist survey was adapted from the country survey. It contained questions on each of 15 high-burden diseases. Questions about the health care system were replaced by a single question on the context to which the disease specialist would be referring: low-, medium- or high-resource setting (as per HDI level). The medical devices needed in the management of each disease were listed in the questionnaire. The survey was sent directly to specialists.

The results indicated that of the devices being used, most are being used at the tertiary health-care level; medical device use at the secondary and primary levels was not as prevalent. In addition, the results suggested that diagnostic and therapeutic medical devices are more frequently used than assistive medical devices, and that countries with low HDI tend to have the lowest use of medical devices. Moreover, technical information and training appear to be often unavailable in countries with low HDI.

The specialist survey reinforced the country survey's findings. Gaps between need and availability of devices were found to be greatest in low-income settings. A lack of assistive devices was also clearly indicated (except for wheelchairs and crutches). In addition, low-income settings seem to have a dearth of technical information – for procurement, maintenance and repair and daily use of medical devices.

In conclusion, countries or contexts with low HDI scores consistently exhibited the greatest gaps in availability of medical devices. Responses consistently cite an

1 A core set is a selection of classes representing relevant aspects in the functioning of people with a specific disease or health problem, based on The International Classification of Functioning, Disability and Health (ICF).

associated lack of availability of various kinds of technical information (e.g. procurement, maintenance and repair and daily use), which highlights the relevance of this issue.

With due caution, the following can be said about the pattern of gaps that emerged: GAP scores, the availability of technical information, information materials and training opportunities, all appear to be part of a larger problem. A general lack of many assistive devices is also indicated as a recurring issue.

These two surveys show the potential of the *PMD* methodology. The survey methodology could be used in the future to identify gaps on use and availability of medical devices and related materials. However, future surveys will need to be adapted to use standardized terminology regarding medical devices.

The Availability Matrix: a methodology to map medical devices to high-burden diseases

Introduction

The *Priority Medical Devices (PMD)* project relates the need for medical devices to 15 high-burden diseases. Together these diseases account for an estimated two-thirds of the global burden of disease (GBD).

The first step in this project was to map the high-burden diseases/disabilities according to the *Global Burden of Disease and Risk Factors (1)*. The second step was the selection of the relevant clinical guidelines developed to describe the management of these diseases/disabilities. On this basis, clinical procedures and medical devices are extracted to fill the Availability Matrix. This method allows the identification of medical devices recommended for the management of a specific disease in clinical practice mentioned in the clinical guideline. The assumption is made that clinical guidelines are evidence-based and list the most relevant medical devices needed in the management of the diseases.

Creation of the Availability Matrix

Selection of diseases and disabilities

The *Global Burden of Disease and Risk Factors* describes the top 15 causes of death and disability (referred to as disability-adjusted life years, DALYs) in 2002 *(1)*. These are combined with projections and trends for 2030 (Table 1) *(2)*. The list of so-called 'high-burden' diseases is composed of the top 15 causes of death and DALYs for 2001.

Matrix development: The example of Tuberculosis

Table 2 shows the Availability Matrix for Tuberculosis (TB). The cells 'GBD code' and 'GBD cause' are adapted from the *Global Burden of Disease and Risk Factors (1)*. The matrix cell 'case definition' defines the inclusion criteria for each disease/disability and is taken from table 3A.5 of the Global Burden of Disease and Risk Factors *(1)*. Medical devices are categorized as preventive, diagnostic, therapeutic and assistive devices, according to the stages of health care. For these four subcategories, a distinction is made between medical devices for general use (e.g. stethoscope, thermometer) and disease-specific medical devices, listed in the Availability Matrix. Further distinction between these subcategories is not relevant for the purposes of the Availability Matrix, since the categories are only meant to provide an overview of the most relevant medical devices in the management of a disease or condition, and are not intended to create an all-inclusive list.

Table 1. Fifteen causes of death and DALY's in 2002 and 2030[a]

	Causes of death		Causes of DALY's	
Rank	Globally 2002	Globally 2030	Globally 2002	Globally 2030
1	Ischemic heart disease	Ischemic heart disease	Perinatal conditions	HIV/AIDS
2	Cerebrovascular disease	Cerebrovascular disease	Lower respiratory infections	Unipolar depressive disorders
3	Lower respiratory infections	HIV/AIDS	HIV/AIDS	Ischemic heart disease
4	HIV/AIDS	COPD[b]	Unipolar depressive disorders	Road traffic accidents
5	COPD[b]	Lower respiratory infections	Diarrhoeal diseases	Perinatal conditions
6	Perinatal conditions	Trachea, bronchus and lung cancers	Ischemic heart disease	Cerebrovascular disease
7	Diarrhoeal diseases	Diabetes mellitus	Cerebrovascular disease	COPD[b]
8	Tuberculosis	Road traffic accidents	Road traffic accidents	Lower respiratory infections
9	Trachea, bronchus, lung cancers	Perinatal conditions	Malaria	Hearing loss, adult onset
10	Road traffic accidents	Stomach cancer	Tuberculosis	Cataracts
11	Diabetes mellitus	Hypertensive heart disease	COPD[b]	Diabetes mellitus
12	Malaria	Self inflicted injuries	Congenital anomalies	Diarrhoeal diseases
13	Hypertensive heart disease	Nephritis and nephrosis	Hearing loss, adult onset	Violence
14	Self inflicted injuries	Liver cancers	Cataracts	Self inflicted injuries
15	Stomach cancer	Colon and rectum cancers	Violence	Malaria

a Pls supply footnote (cannot find it in the Word doc).
b COPD: Chronic Obstructive Pulmonary Disease.
Sources: World Health Organization *(1)* and Mathers *(2)*.

Selection of clinical guidelines

The matrix contains clinical procedures and medical devices that are extracted from clinical guidelines, from the World Health Organization (WHO) or from the National Guideline Clearinghouse (NGC) database[1].This database was selected because it requires authors to disclose any financial support (and hence any possible conflicts of interest). Guidelines were selected separately for all diseases and included when the guideline title referred to the disease. All mentioned medical devices or techniques that involve medical devices are included in the matrix. These constitute a baseline of medical devices needed to manage the disease. Only guidelines published after the year 2000 were included.

Guidelines were selected only if there was no declared conflict of interest. The NGC states that the guidelines in their database

1 www.guideline.gov (accessed on 8 February 2010).

Table 2. Availability Matrix: example of tuberculosis

GBD code	GBD cause	Case definition	Clinical procedure	Medical device							
				Preventive		Diagnostic		Therapeutic		Assistive	
				General	Specific	General	Specific	General	Specific	General	Specific
U003	Tuberculosis	Cases refer to individuals with clinical tuberculosis, normally pulmonary sputum culture positives and extra-pulmonary cases	Management of HIV sero-negative/ positive cases (pulmonary TB) Management of extrapulmonary TB	X-ray		, microscope and laboratory equipment	Equipment to obtain diagnostic specimens, culture test and facilities, sputum smear test, tuberculin test	Surgical equipment (late complications)			

Source: ***Treatment of tuberculosis: guidelines for national programmes.*** Geneva, World Health Organization, 2003. *(??)*.

are evidence-based. The assessment of the quality of guidelines is outside the scope of the *PMD* project.

At the start of the project in May 2007, no WHO guidelines were available for 'lower respiratory infections', 'malignant neoplasms', 'unipolar depressive disorders', 'cataracts', 'ischemic heart disease', 'cerebrovascular disease' and 'chronic obstructive pulmonary disease'. Where no WHO clinical guideline was available, guidelines from the NGC database were used. Guidelines from the NGC database usually relate to high-resource settings. Table 3 lists the sources of the guidelines used.

Table 3 contains a list of the selected guidelines and the organizations that published them. Most guidelines are written for a specific level of care (primary, secondary or tertiary) and context (low-, medium- or high-resource settings). The level of health care is indicated in the guideline and listed in the table below, as is the setting (low- or high-resource setting). Prioritization of the health-care level was not completed in this project.

In the event that several guidelines for a specific disease were found for treatment at the same level of care (e.g. several WHO guidelines are available for tuberculosis), the most generally applicable one was selected.

Methodology of extracting medical devices from the clinical guidelines

The *PMD* project used data on medical devices extracted from clinical guidelines by two independent reviewers. Each reviewer independently scored the guidelines. Where interpretations differed, a specialist in the specific disease area was consulted who had the final word.

The medical devices for each disease are listed in the Availability Matrix.

Nomenclature and classification

Medical devices in clinical guidelines are not described according to a standard nomenclature and classification system. In order to generically identify medical devices, a single nomenclature and classification system would be beneficial. There are three major nomenclature and classification systems available worldwide, the Global Medical Device Nomenclature system[1] (GMDN), the Universal Medical Device Nomenclature System[2] (UMDNS) and the Assistive Products for Persons with Disability – Classification and Terminology (ISO 9999:2007). The ISO 9999:2007 is specifically applicable to assistive products.

The *PMD* project investigated existing coding systems of medical device nomenclatures and the link to clinical guidelines. It was discovered that clinical guidelines are not generally intended to provide a coded list of all medical devices needed to carry out a clinical protocol. It was also clear that the information provided by clinical guidelines is currently much too unspecific to enable coding with a single nomenclature system. It would be desirable to have a complement to clinical guidelines that has a protocol describing in a standardized manner and in much greater detail the devices needed, thus facilitating correct procurement of appropriate medical devices.

Assistive medical devices

Assistive (medical) devices are used to maintain or enhance the functioning and minimize the disability of the person using them, rather than to cure a disease or condition. The International Classification of Functioning, Disability and Heath (ICF) *(3)* is applicable to all people irrespective of the origin of their disability. This is important since a large part of the population using assistive (medical) devices may not be receiving treatment for a disease, but rather are being supported in terms of functioning (e.g. a person using a cane).

The ICF allows for the description of the degree of functioning and disability, although it is not a measurement instrument. Thus, the ICF is a classification system complementary to the International Statistical Classification of Diseases and Related Health Problems (ICD), on which the GBD is based *(4)*.

Assistive medical devices are generally not mentioned in clinical guidelines either. Therefore, a separate approach was used to map the medical devices needed for persons afflicted with disabilities related to high-burden diseases. It is described in detail in another background paper of the *PMD* project: Building bridges between diseases, disabilities, and assistive devices: linking the GBD, ICF and ISO 9999 *(5)*.

1 http://www.gmdnagency.com/?id=nom (accessed 8 February 2010)
2 https://www.ecri.org/Products/Pages/UMDNS.aspx (accessed 8 February 2010)

Table 3. Guidelines used for this report[a]

GBD code	GBD cause/ sequelae	Source guideline	Guideline title	Publication year	Settings
U003	Tuberculosis[b]	WHO	Treatment of tuberculosis: guidelines for national programmes	2003	Primary, secondary and tertiary care, low/ medium resource
U009	HIV/AIDS[c]	WHO	Antiretroviral therapy for HIV infection in adults and adolescents: recommendations for a public health approach	2006	Primary, secondary and tertiary care, low/ medium (/high) resource
U010	Diarrhoeal diseases	USAID, UNICEF, WHO	Diarrhoeal treatment guidelines for clinic-based healthcare workers	2005	Clinic and home, low resource
U020	Malaria	WHO	Guidelines for the treatment of malaria	2006	Primary care, low/ medium resource
U039	Lower respiratory infections[d]	Scottish Intercollegiate Guidelines Network	Community management of lower respiratory tract infections in adults, a national clinical guideline	2002	Primary care, high resource
U049,U050, U051, U052	Perinatal conditions: Low birth weight, birth asphyxia and birth trauma, other perinatal conditions[e]	WHO	Managing newborn problems: a guide for doctors, nurses and midwives	2003	Inside and outside hospital, low (/medium) resource
U067	Malignant neoplasms[f]	Scottish Intercollegiate Guidelines Network	Management of patients with lung cancer: a national clinical guideline	2005	Primary, secondary and tertiary care, high resource
		Scottish Intercollegiate Guidelines Network	Management of oesophageal and gastric cancer: a national clinical guideline	2006	Primary, secondary and tertiary care, high resource
U079	Diabetes mellitus[g]	WHO	Guidelines for the prevention, management and care of diabetes mellitus	2006	Primary, secondary and tertiary care, low/medium/high resource
U082	Unipolar depressive disorders[h]	National Institute for Health and Clinical Excellence	Depression: management of depression in primary and secondary care	2007	Primary and secondary care, high resource
U100	Cataracts[i]	Philippine Academy of Ophthalmology	Clinical practice guideline for the management of cataract among adults	2001, updated 2005	Primary, secondary and tertiary care, medium resource
U102	Hearing loss, adult onset	WHO	Primary ear and hearing care training resource, advanced level	2006	Primary care, low resource
U107	Ischemic heart disease[i,k]	Veterans Health Administration, Department of Defense, USA	VA/DoD clinical practice guideline for the management of ischemic heart disease	2003	Primary and secondary care, high resource
U108	Cerebrovascular disease[l]	Stroke Foundation New Zealand	Life after stroke: New Zealand guideline for management of stroke, best practice evidence-based guideline	2003	Primary, secondary and tertiary care, high resource
U112	Chronic obstructive pulmonary disease	National Collaboration Centre for Chronic Conditions	National clinical guideline on management of chronic obstructive pulmonary disease in adults in primary and secondary care	2004	Primary and secondary care, high resource
U150	Road traffic accidents[m,n,o]	WHO	Guidelines for essential trauma care	2004	Hospital, low/medium/high resource

a WHO and NGC databases were consulted early 2008. Since then, some guidelines may have been updated. It is noteworthy that the NGC database makes reference to several other databases.
b Since no distinction is made in the guideline between HIV seronegative and seropositive cases, no distinction is made in the matrix.
c A distinction is made in AIDS stages 1, 2, 3 and 4 in the guideline; the clinical procedure describes the diseases comprised by these stages.
d Since no distinction is made between the management of 'episodes' and 'chronic sequelae' in the guideline, the two case definitions are merged together.
e The category 'perinatal conditions' is part of the top 10 diseases and disabilities. However, this category does not exist in Table 3A.5 of the GBD. The conditions that resemble perinatal conditions most closely are the subcategories 'low birth weight', 'birth asphyxia and birth trauma', and 'other perinatal conditions'. They are all part of the category 'conditions arising during the perinatal period' in Table 3A.2 and are therefore merged into one GBD cause. 'Other perinatal conditions' are not specified in table 3A.5 and therefore not taken into consideration in the matrix.
f Since Table 3A.5 only refers to 'malignant neoplasms' in general and not to specific types of cancer, this general GBD cause was included in the matrix. However, only the subgroups 'trachea, bronchus and lung cancer' and 'stomach cancer' are forms of cancer that represent a top 10 burden of disease. Therefore, the selected clinical guidelines only discuss lung cancer and gastric cancer and not malignant neoplasms in general. For stomach cancer, the only available general guideline in the NGC database is a clinical guideline on gastric and oesophageal cancer. However, the chapters on oesophageal cancer were not used in the matrix.
g The case definitions as mentioned in Table 3A.5 under 'diabetes mellitus' describe the clinical procedures for the management of diabetes and its secondary effects. Therefore, the case definitions are placed in the cell 'clinical procedure'. Although nephropathy is not mentioned as a GBD sequelae in Table 3A.5, this secondary effect of diabetes was mentioned in the guideline and therefore added to the matrix. The case definitions 'diabetic foot' and 'amputation' were merged into one cell, since they are strongly interrelated and treated as one subject in the guideline.
h No strict distinction was made in the guideline between 'dysthymia', 'mild', 'moderate' and 'severe' major depressive episodes; therefore, the four subcategories were merged together.
i No strict distinction is made in the guideline between 'low vision' and 'blindness'; therefore, both case definitions are mentioned in the matrix under one clinical procedure.
j For ischaemic heart diseases, a WHO guideline is also available (***Prevention of recurrent heart attacks and strokes in low and middle income populations*** , WHO, 2003). The reason for not using this guideline in the matrix is that it only focuses on the prevention of heart attacks instead of management, and only very few medical devices are mentioned.
k Since no strict distinction is made between the subcategories 'acute myocardial infarction', 'angina pectoris' and 'congestive heart failure' in the guideline, only one clinical procedure is mentioned in the matrix that describes all three subcategories.
l The category 'cerebrovascular disease' includes the subcategories 'first ever stroke cases' and 'long term stroke survivors'. In the guideline, no strict distinction between both subcategories is made; therefore no distinction is made in the matrix.
m 'Road traffic accidents' are part of the 'injuries' category. However, only the subcategory 'road traffic accidents' is one of the top 10 diseases with the highest disease burden. Therefore, only this subcategory was included in the matrix and not the 'injuries' group in general.
n ***Surgical care at the district hospital*** (WHO, 2003), is a practical resource for individual practitioners. Medical devices for general use are part of the surgical procedures described.
o The WHO generic essential emergency equipment list: the guide to anaesthetic infrastructure and supplies (WHO, 2003) and the Needs assessment and evaluation form for resource limited health-care facility (WHO, 2004) are available at http://www.who.int/surgery/publications/imeesc/en/index.html.

Limitations

Clinical guidelines often do not describe specific care pathways and protocols, nor do they list specific medical devices needed in the treatment of a particular disease. In some cases, the clinical procedure is mentioned in general terms (e.g. oral examination) without mentioning the specific medical devices used in this procedure. In such cases, the exam name is listed in the matrix followed by 'equipment' (e.g. oral examination equipment).

The methodology used clinical guidelines that are specific to a single disease or category of diseases, and these guidelines do not include a comprehensive list of medical devices used in treatment. General medical devices like sterilizers, hospital beds, surgical drapes, needles and syringes etc. are not typically included.

In addition, any specific published guideline generally applies to a specific context, which means it may or may not be applicable to other settings (e.g. a guideline may be applicable in a high-resource setting but not relevant or feasible in a low-resource setting).

References

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4. Ustün TB et al. *WHO's ICF and Functional Status Information in health records. Health Care Financing Review*, 2003, 24(3): 77–88.

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The Availability Matrix

GBD code	GBD cause	Case definition	Clinical Procedure	Medical device							
				Preventive		Diagnostic		Therapeutic		Assistive	
				General	Specific	General	Specific	General	Specific	General	Specific
U003	Tuberculosis	Cases refer to individuals with clinical tuberculosis, normally pulmonary sputum culture positives and extra-pulmonary cases	Management of HIV sero-negative/positive cases (pulmonary TB)			X-ray, microscope and laboratory equipment	Equipment to obtain diagnostic specimens, culture test and facilities, sputum smear test, tuberculin test	Surgical equipment (late complications)			
			Management of extrapulmonary TB								

Source: ***Treatment of tuberculosis: guidelines for national programmes.*** Geneva, World Health Organization, 2003.

GBD code	GBD cause	Case definition	Clinical Procedure	Medical device							
				Preventive		Diagnostic		Therapeutic		Assistive	
				General	Specific	General	Specific	General	Specific	General	Specific
U009	HIV/AIDS	HIV seropositive, not yet progressed to AIDS	Management of HIV seropositive progressed or not progressed to AIDS	Condom	Condom	Weighing scale, laboratory equipment to collect specimens, serology tests (HBV, HCV, TB, syphilis), microbiology and culture tests for diagnosis of other co-infections and opportunistic diseases, pregnancy test	Laboratory equipment to perform CD4 count, India ink, Gram stain, ZN stain	Pregnancy test, laboratory equipment to perform full chemistry panel test (ALT, other liver enzymes, renal function, glucose, lipids, amylase, lipase, lactate, serum electrolytes)	Laboratory equipment to perform CD4 count or TLC Laboratory equipment to perform WBC, Hgb count Viral load test (plasma HIV-1 RNA level measurement)	—	—
		HIV seropositive and progressed to AIDS in stage 1 (asymptomatic)	Management of lymphadenopathy			Histology test			Laboratory equipment to perform CD4 count or TLC Laboratory equipment to perform WBC, Hgb count Viral load test (plasma HIV-1 RNA level measurement)		
		HIV seropositive and progressed to AIDS in stage 2 (mild)				Weighing scale, tape measure. Laboratory equipment to perform culture of suitable body fluid Fungal culture of nail					
		HIV seropositive and progressed to AIDS in stage 3 (advanced)	Management of weight loss, chronic diarrhoea, persistent fever, pulmonary TB, severe bacterial infections, unexplained anaemia, neutropenia, chronic thrombocytopenia			Weighing scale, tape measure Stool test on pathogens Laboratory equipment to perform blood culture, ZN stain, malaria slide Chest X-ray Sputum smear test or histology of lung biopsy Equipment for isolation of bacteria from appropriate clinical specimens Laboratory tests for measurement Hbg, white blood cells, platelet count		Pregnancy test, laboratory equipment to perform full chemistry panel test (ALT, other liver enzymes, renal function, glucose, lipids, amylase, lipase, lactate, serum electrolytes)			

GBD code	GBD cause	Case definition	Clinical Procedure	Medical device							
				Preventive		Diagnostic		Therapeutic		Assistive	
				General	Specific	General	Specific	General	Specific	General	Specific
U009	HIV/AIDS	HIV seropositive and progressed to AIDS in stage 4 (severe)	Management of HIV wasting syndrome, ***Pneumocystis*** pneumonia, recurrent bacterial pneumonia, HSV infection, oesophageal candidiasis, extrapulmonary TB, kaposi sarcoma, CMV disease Central nervous system toxoplasmosis, HIV encephalopathy, extrapulmonary cryptococcosis, non-TB mycobacteria infection, progressive multifocal leukoencephalopathy, cryptosporidiosis, mycosis, septicaemia, lymphoma, cervical carcinoma, leishmaniasis, nephropathy			Weighing scale, tape measure, blood culture tests, malaria slide, chest X-ray Laboratory equipment to perform cytology (with immunofluorescent microscopy of induced sputum or BAL) or histology of lung tissue. Culture or antigen test for proving bacterial pneumonia Culture or DNA (by PCR) of HSV or cytology/histology Equipment to perform endoscopy/ bronchoscopy or microscopy/ histology Equipment to perform isolation of ***M. Tuberculosis*** and histology or chest X-ray Equipment for CMV histology or demonstrate CMV in CFS by culture or PCR Laboratory test for toxoplasma antibody, CT or MRI scans. Laboratory equipment for isolation of ***Cryptococcus neoformans*** or cryptococcal antigen test (CRAG) on CSF/blood		Pregnancy test, laboratory equipment to perform full chemistry panel test (ALT, other liver enzymes, renal function, glucose, lipids, amylase, lipase, lactate, serum electrolytes)			

AFB, acid-fast bacilli; ALT, alanine aminotransferase; BAL, bronchoalveolar lavage; CBC, complete blood count; CMV, Cytomegalovirus; CSF, cerebrospinal fluid;CT, computerized tomography; Hgb, haemoglobin; HBV, hepatitis B virus; HCV, hepatitis C virus; HPV, human papiloma virus; HSV, herpes simplex virus; MRI, magnetic resonance imaging; PCP, pneumocystis carnii pneumonia; PCR, polymerase chain reaction; TLC, total lymphocyte count; TB, tuberculosis; WBC, whole blood count; ZN, Ziehl-Nielsen.
Source: ***Antiretroviral therapy for HIV infection in adults and adolescents: recommendations for a public health approach.*** Geneva, World Health Organization, revision 2006.

GBD code	GBD cause	Case definition	Clinical Procedure	Medical device							
				Preventive		Diagnostic		Therapeutic		Assistive	
				General	Specific	General	Specific	General	Specific	General	Specific
U010	Diarrhoeal diseases	Episodes of diarrhoea including acute watery diarrhoea, persistent diarrhoea, and dysentery. Deaths of children with both measles and diarrhoea or both lower respiratory infection and diarrhoea are not included in estimates of diarrhoea mortality	Management of diarrhoea and dehydration	—	—	Weighing scale, thermometer	—	Cooling cloths, fan, intravenous drips, nasogastric tube	—	—	—

Source: ***Diarrhoea treatment guidelines for clinic-based healthcare workers.*** New York /Geneva, USAID/Unicef/World Health Organization, January 2005.

GBD code	GBD cause	Case definition	Clinical Procedure	Medical device							
				Preventive		Diagnostic		Therapeutic		Assistive	
				General	Specific	General	Specific	General	Specific	General	Specific
U020	Malaria	Infectious disease caused by protozoa of the genus Plasmodium Episodes: attacks of chills, fever, and sweating due to Plasmodium infection Anaemia: Defined using WHO criteria for mild to very severe anaemia Neurological sequelae: includes haemiplegia, aphasia, ataxia, and cortical blindness	Management of malaria	—	—	Thermometer, light microscope, blood slide and sample equipment, PCR technology, laboratory tests (stick test for blood glucose, levels of haematocrit/haemoglobin, plasma bicarbonate, renal function, venous lactate, parasitaemia, blood count) and equipment to perform tests, weighing scale, blood gas and pH measurement equipment	Rapid diagnostic test (HRP2 test)	Equipment for measuring blood/ plasma levels of antimalarial medicines, intravenous lines and infusion pump, tepid sponge, fan, electrocardiographic monitoring, haemofiltration/ dialysis (if unavailable peritoneal dialysis), equipment for maintaining airway pressure (positive pressure ventilator), breathing and circulation, urinary sodium test, intravenous cannula, lumbar puncture needle, tube, cooling blanket	—	—	—

HRP2, histidine rich protein 2; PCR, polymerase chain reaction.
Source: ***Guidelines for the treatment of malaria.*** Geneva, World Health Organization, 2006.

GBD code	GBD cause	Case definition	Clinical Procedure	Medical device							
				Preventive		Diagnostic		Therapeutic		Assistive	
				General	Specific	General	Specific	General	Specific	General	Specific
U039	Lower respiratory infections	Episodes of lower respiratory infection and chronic sequelae: includes bronchiectasis and impaired lung function as measured by a decrease in forced expiratory volume	Management of lower respiratory tract infections in adults	—	—	Blood pressure meter, thermometer, stethoscope, chest X-ray	Spirometer, pulse oximeter, laboratory equipment for sputum culture, Gram stain, C-reactive protein blood test	—	—	—	—

Source: ***Community management of lower respiratory tract infections in adults, a national clinical guideline.*** Scottish Intercollegiate Guidelines Network, 2002.

GBD code	GBD cause	Case definition	Clinical Procedure	Medical device							
				Preventive		Diagnostic		Therapeutic		Assistive	
				General	Specific	General	Specific	General	Specific	General	Specific
U049, U050, U051 and U052	Perinatal conditions: Low birth weight, birth asphyxia and birth trauma, other perinatal conditions	Birth weight below 2500g, including small-for-gestational-age infants and premature infants (all developmental sequelae due to low birth weight have been clustered into one outcome, which includes cerebral palsy, mental retardation, epilepsy, hearing loss and vision loss	Maintaining normal body temperature	—	—	Thermometer	—	—	Radiant warmer, incubator		—
		Feeding and fluid management				Weighing scale, laboratory equipment for measurement of blood glucose, stethoscope		Gastric tube, syringe, infusion set, micro dropper, needle, drapes, blade, cord tie or suture, forceps, gauze bandage,		Splints	
		Oxygen therapy				Thermometer		Nasal prongs, nasal catheter, oxygen supply device and pulse oximeter, face mask, self-inflation resuscitation bag, suction apparatus, IV line, gastric tube	Head box, incubator		
		Taking blood samples and lumbar puncture				Laboratory equipment for measurement of blood glucose, haemoglobin, serum bilirubin, serologic test for syphilis, butterfly set, syringe and needle, blood collection tubes, lancet, capillary tube, spinal needle or intravenous needle, laboratory equipment for testing cerebrospinal fluid sample on cell count, Gram stain, equipment for culture and sensitivity testing		Drapes. Bandages			
		Treatment of jaundice				Laboratory equipment for measurement of haemoglobin, serum bilirubin, Coombs test, butterfly set, syringe and needle, blood collection tubes, thermometer		Phototherapy lights	Incubator	Eye patches	
		Assessing growth				Weighing scale					
		Transfer and referral				Stethoscope, thermometer		Resuscitation face mask, self-inflation resuscitation bag, suction apparatus, oxygen supply device and oximeter, nasal prongs/ nasal catheter, gastric tube, IV infusion set, butterfly set or cannula, syringes and needles	Head box		

Source: ***Managing newborn problems: a guide for doctors, nurses and midwives.*** Geneva, World Health Organization, 2003.

GBD code	GBD cause	Case definition	Clinical Procedure	Medical device							
				Preventive		Diagnostic		Therapeutic		Assistive	
				General	Specific	General	Specific	General	Specific	General	Specific
U067	Malignant neoplasms	Trachea, bronchus and lung cancer	Management of non-small cell lung cancer	—	—	TChest X-ray, laboratory equipment for histology and cytology, CT, PET, ultrasound guided FNA equipment, scanner, bronchoscope, MRI scan, equipment to perform fluoroscopy, biopsy needle	Mediastinoscope, thoracoscope	Tube, intravenous infusion equipment, Nd-YAG laser, stent, radiotherapy equipment, electrocautery, cryotherapy, and photodynamic therapy equipment	Video-assisted thoracic surgery equipment, wedge resection equipment, lobectomy and pneumonectomy equipment, extended resection equipment		—
		Stomach cancer	Management of gastric cancer			X-ray, biopsy equipment, laboratory equipment for histology and cytology, CT, EUS, FNA equipment, MRI, bronchoscope	Flexible upper GI-endoscope, laparoscope	Endotracheal tube, photodynamic therapy equipment, laser	Gastrectomy surgical equipment, lymphadenectomy surgical equipment, equipment to perform EMR	Enteral stent, equipment to perform laparoscopic bypass or gastric outlet stenting, intravenous infusion equipment, nasogastric tube, PEG tube, RIG tube	

CT, computerized tomography; EMR, endoscopic mucosal resection; EUS, endoscopic ultrasound; FNA, fine needle aspiration; GI, gastrointestinal; MRI, magnetic resonance imaging; PEG, percutaneous endoscopic gastrostomy; PET, positron emission tomography; RIG, radiological inserted gastrostomy.
Sources: ***Management of patients with lung cancer: a national clinical guideline.*** Edinburgh, Scottish Intercollegiate Guidelines Network, 2005. ***Management of oesophageal and gastric cancer: a national clinical guideline.*** Edinburgh, Scottish Intercollegiate Guidelines Network, 2006.

GBD code	GBD cause	Case definition	Clinical Procedure	Medical device							
				Preventive		Diagnostic		Therapeutic		Assistive	
				General	Specific	General	Specific	General	Specific	General	Specific
U079	Diabetes Mellitus	Cases of DM	Management of venous plasma concentration of 11.1 mmol/L 2 h after a 75 g oral glucose challenge	Tape measure, weighing scale, blood pressure meter, diagnostic tests on metabolic syndrome, screening tests for diabetic dyslipidaemia	—	Tape measure, weighing scale, blood pressure meter, cardiovascular examination devices, equipment for chemistry panel, fasting lipid profile test, urinalysis equipment, thyroid stimulating hormone test, ECG	OGTT, blood glucose measuring test, urine glucose measuring test, HBA1c measuring test, autoimmune marker tests (HLA type, ICA, anti-GAD)		HBA1c measuring test, whole blood and plasma glucose measuring equipment (FPG), self-monitoring blood glucose device		—
		Atherosclerosis	Management of atherosclerosis due to diabetes			Screening tests for risk factors for macrovascular disease					
		Diabetic Foot and Amputation	Management of chronic or recurring diabetic foot ulcers, Surgical elimination of the lower extremity or part of it			Tuning fork, monofilament, Doppler ultrasonography, arteriography		Angioplasty, surgical instruments		Specially fitted shoes, plantar support	
		Neuropathy	Management of reflexes and vibration loss; damage and dysfunction of sensory, motor, or autonomic nerves			Reflex hammer, tuning fork, monofilament					
		Retinopathy-blindness	Management of microaneurysms or eye blood vessel damage and Management of blindness			Ophthalmoscope (coupled with biomicroscope), visual acuity test, non-mydriatic camera		Laser and surgical equipment			
		Nephropathy	Management of renal failure due to diabetes			Urinary microalbumin test, serum creatinine test, serum lipids test, creatinine clearance test		Dialysis equipment, kidney transplantation equipment			

Anti-GAD, antibodies to glutamic acid decarboxylase; DM, Diabetes Mellitus; ECG, electrocardiogram; FPG, fasting plasma glucose test; HLA, human leukocyte antigen; ICA, islet-cell cytoplasmic antibodies; OGTT, oral glucose tolerance test.
Source: ***Guidelines for the prevention, management and care of diabetes mellitus.*** Geneva, World Health Organization, 2006.

GBD code	GBD cause	Case definition	Clinical Procedure	Medical device							
				Preventive		Diagnostic		Therapeutic		Assistive	
				General	Specific	General	Specific	General	Specific	General	Specific
U082	Unipolar depressive disorders	Mild, moderate and severe major depressive episodes and dysthymia case with no concurrent major depressive episode	Management of depression in primary and secondary care	—	—	Stethoscope, blood pressure meter	—	ECG	Computerized cognitive behavioural therapy, electroconvulsive therapy machine (ECT)		—

Source: ***Depression: management of depression in primary and secondary care.*** London, National Institute for Health and Clinical Excellence, 2007.

GBD code	GBD cause	Case definition	Clinical Procedure	Medical device							
				Preventive		Diagnostic		Therapeutic		Assistive	
				General	Specific	General	Specific	General	Specific	General	Specific
U100	Cataracts	Cases of senile cataract causing progressive visual impairment	Management of low vision or blindness	—	—	Visual acuity measuring equipment, funduscope, pinhole test, slit-lamp biomicroscope, tonometer, lacrimal apparatus irrigation (LAI) test equipment	Equipment for measuring contrast and glare sensitivity, keratometer, biometer	Surgical equipment, equipment to perform phacoemulsification or manual phacofragmentation, suction devices	Equipment to perform extracapsular cataract extraction (ECCE), intraocular lens	Spectacles, contact lenses	—
		Low vision: corrected visual acuity in the better eye of less than 6/18 but better than or equal to 3/60									
		Blindness: corrected visual acuity in the better eye of less than 3/60									

LAI, lacrimal apparatus irrigation; ECCE, extracapsular cataract extraction.
Source: ***Clinical practice guideline for the management of cataract among adults.*** Manila, Philippine Academy of Ophthalmology, 2001 and updated 2005.

GBD code	GBD cause	Case definition	Clinical Procedure	Medical device							
				Preventive		Diagnostic		Therapeutic		Assistive	
				General	Specific	General	Specific	General	Specific	General	Specific
U102	Hearing loss, adult onset	Cases of adult-onset hearing loss due to ageing or noise exposure; excludes hearing loss due to congenital causes, infectious diseases, other diseases, or injuries	Management of mild, moderate and severe hearing loss	—	Hearing protector	Biopsy needle, autoclave	Otoscope, tuning fork, Barany noise box, electrodes for ABR test, headphones for VRA, tympanometer	Suction tip and pump, intravenous infusion equipment, surgical equipment, syringe, cotton wool mop, sterile gauze	Grommet (ventilation tube)	—	Earplugs, cochlear implant, body-worn hearing aid, behind-the-ear hearing aid
		Mild hearing loss, untreated: hearing threshold level in the better ear is 41-60 dBHTL (averaged over 0.5,1,2,4 kHz), person does not use a hearing aid									
		Moderate hearing loss, treated: Hearing threshold level in the better ear is 41-60 dBHTL (averaged over 0.5,1,2,4 kHz); person uses a hearing aid									
		Severe hearing loss, untreated and treated: Hearing threshold level in the better ear is 61 dBHTL or more (averaged over 0.5,1,2,4 kHz); person does not use a hearing aid or uses a hearing aid									

ABR, auditory brain stem response; dBHTL, decibel hearing threshold level; VRA, visual reinforcement audiometry.
Source: ***Primary ear and hearing care training resource, advanced level.*** Geneva, World Health Organization, 2006.

GBD code	GBD cause	Case definition	Clinical Procedure	Medical device							
				Preventive		Diagnostic		Therapeutic		Assistive	
				General	Specific	General	Specific	General	Specific	General	Specific
U107	Ischaemic heart disease	Definite and possible episodes of acute myocardial infarction according to MONICA study criteria	Management of ischaemic heart disease	—	—	Stethoscope, blood gases measuring equipment, blood pressure meter, finger pulse oximeter, laboratory equipment for the measurement of lipid profile, complete blood count, renal function, electrolytes, fasting glucose, liver function, thyroid function and drug screening, ECG, cardiac monitor, PET, SPECT, MRI, EBCT, chest X-ray	Laboratory equipment for the measurement cardiac enzymes/ biomarkers, INR and APTT. Coronary arteriography equipment, equipment to perform contrast angiography, 2D cardiac ultrasound, RNVG, equipment for exercise/ cardiac stress test (treadmill or cycle ergometer)	Intravenous infusion equipment, oxygen mask, nasal prongs, mechanical ventilator, cardiac catheterization	Surgical equipment for a PCI, surgical equipment for a CABG, stent, pacing electrode, advanced cardiac life support equipment (defibrillator), balloon catheter, biventricular pacemaker, implantable cardioverter-defibrillator	—	—
		Cases of clinically diagnosed angina pectoris or definite angina pectoris according to Rose questionnaire									
		Congestive heart failure: mild and more severe (Killip scale k2–k4)									

APTT, activated partial thromboplastin time; CABG, coronary artery bypass graft, EBCT, electron beam computed tomography; ECG, electrocardiogram; INR, international normalized ratio, MRI, magnetic resonance imaging; PCI, percutaneous coronary intervention; PET, positron emission tomography; RNVG, radionucleotide ventriculography; SPECT, single photon emission computed tomography.
Source: ***VA/DoD clinical practice guideline for the management of ischemic heart disease.*** Washington DC, Veterans Health Administration, Department of Defense, 2003.

GBD code	GBD cause	Case definition	Clinical Procedure	Medical device							
				Preventive		Diagnostic		Therapeutic		Assistive	
				General	Specific	General	Specific	General	Specific	General	Specific
U108	Cerebrovascular disease	First-ever stroke cases: management of first ever stroke according to WHO definition; includes subarachnoid haemorrhage, but excludes transient ischaemic attacks, subdural haematoma, and haemorrhage or infarction due to infection or tumour	Management of stroke	—	—	CT, blood glucose test, ECG, blood pressure meter, thermometer, chest X-ray, laboratory equipment for serum electrolytes, serum urea, creatinine, complete blood count, erythrocyte sedimentation rate, bleeding time, prothrombin time, activated partial thromboplastin time, transcranial Doppler imaging equipment, ultrasound, digital subtraction cerebral angiography equipment, catheter, MRI	Video fluoroscopy equipment	Intravenous/ intra-arterial infusion set, shunt, oxygen mask and supply devices, ventricular drain, stent	Surgical decompression and evacuation devices, osmotherapy equipment, surgical equipment for intracerebral haematomas removal, surgical equipment to perform carotid endarterectomy, angioplasty and stenting, surgical equipment for an extracranial-intracranial bypass	Catheter, incontinence products, wheelchair, compression stockings	—
		Long-term stroke survivors: management of persons who survive more than 28 days after first-ever stroke									

ECG, electrocardiogram; CT, computerized tomography; MRI, magnetic resonance imaging.
Source: ***Life after stroke: New Zealand guideline for management of stroke.*** Wellington, Stroke Foundation New Zealand, 2003.

GBD code	GBD cause	Case definition	Clinical Procedure	Medical device							
				Preventive		Diagnostic		Therapeutic		Assistive	
				General	Specific	General	Specific	General	Specific	General	Specific
U112	Chronic Obstructive Pulmonary Disease (COPD)	Chronic (stable) airways obstruction with FEV1 < 1 litre (corresponding to symptomatic disability	Management of chronic obstructive pulmonary disease	—	—	Blood gas analysing equipment, chest X-ray, chest CT, ECG, MRI, blood count test, lab equipment for sputum microscopy culture, blood culture, full blood count, electrolytes, weighing scale	Spirometer, 1-antitrypsin deficiency screening test, pulse oximeter, carbon monoxide transfer test	Endotracheal tube, surgical equipment to perform bullectomy, LVRS and lung transplantation, non-invasive ventilator, face mask, drain	Invasive mechanical ventilation equipment, large volume spacer, nebulizer, positive expiratory pressure masks	Nasal cannulae	Long-term oxygen supply equipment (oxygen concentrator), ambulatory oxygen equipment

CT, computerized tomography; ECG, electrocardiogram; FEV1, forced expiratory volume during the first second; LVRS, lung volume reduction surgery; MRI, magnetic resonance imaging.
Source: ***Chronic obstructive pulmonary disease. National clinical guideline on management of chronic obstructive pulmonary disease in adults in primary and secondary care.*** National Collaboration Centre for Chronic Conditions. Thorax, 2004, 59(Suppl 1): S1–S232.

GBD code	GBD cause	Case definition	Clinical Procedure	Medical device							
				Preventive		Diagnostic		Therapeutic		Assistive	
				General	Specific	General	Specific	General	Specific	General	Specific
U150	Road traffic accidents	Includes crashes and pedestrian injuries due to motor vehicles	Airway management	—	—	Laryngoscope, fibre-optic endoscope, transilluminator, equipment for capnography	Oesophageal detector device (bulb, syringe or electric)	Tongue depressor, suction device, suction catheter, suction tubing, stiff suction tip, bag-valve-mask, Magill forceps	Basic trauma pack Equipment to perform basic oral/ nasal airway management, endotracheal tube with tube connector, needle/surgical cricothyroidotom		
			Management of respiratory distress			Stethoscope, pulse oximeter	Arterial blood gas measurements	Oxygen supply equipment, face mask with tubing, nebulization mask, venture mask, needle and syringe, chest tubes, bag-valve-mask or mechanical ventilator	Basic trauma pack, nasal cannulae and prongs, underwater seal drainage bottle, needle and tube thoracotomy		
			Management of shock			Clock, stethoscope, blood pressure cuff, electronic cardiac monitor, laboratory facilities for measurement of electrolytes, arterial blood gasses, haematocrit, haemoglobin, creatinine, glucose, lactate, thermometer, weighing scale, fluid warmers	Central venous pressure monitor, pulmonary capillary wedge pressure monitor	Gauze and bandages, intravenous infusion set, equipment for central venous infusion (central lines), urinary catheter, nasogastric tube, equipment to perform splinting, equipment for blood transfusion	Arterial tourniquet, intraosseous needle and lines, right-heart catheterization, deep interfascial packing		
			Management of head injury			Torch, CT scan	Intracranial pressure monitoring	Operating theatre equipment, surgical equipment (to perform craniotomy, craniectomy, treatment of intracerebral haematoma), ventilator, equipment for nasogastric feeding	Equipment to maintain cerebral perfusion and oxygenation, cerebrospinal fluid drains		
			Management of neck injury			Contrast radiography, endoscope, angiography		Operating theatre equipment, surgical equipment	Packing, balloon catheter tamponade		
			Management of chest injury			Stethoscope, pulse oximeter	Arterial blood gas measurements	Operating theatre equipment, chest tubes, oxygen supply equipment, equipment to perform anaesthesia, equipment for rib and intrapleural block	(Pulmonary) Thoracotomy equipment, prosthetic graft, pulmonary resection equipment		
			Management of abdominal injury			Blood pressure cuff, stethoscope, ultrasound, CT scan	Diagnostic peritoneal lavage equipment, abdominal tap equipment	Operating theatre equipment	Laparotomy equipment		
			Management of extremity injury			X-ray, image intensification equipment		Surgical equipment, implants, amputation equipment, equipment to perform splinting, splint, sling	External fixation equipment (pins and plaster), equipment for irrigation and debridement of wounds, fasciotomy	Immobilization device, wrapping device, fixation device	Spine board
			Management of spinal injury			X-ray, CT scan, MRI scan		Surgical equipment	Cervical spine traction device	Immobilization devices (spine board)	Cervical spine brace (halo device)
			Management of burns and wounds					Sterile dressing material, surgical equipment	Dermatome, equipment to perform escharotomy, skin grafting, splinting, reconstructive surgery	Splints	
			Rehabilitation			Electromyograph					Splints, prostheses

CT, computerized tomography; MRI, magnetic resonance imaging.
Source: ***Guidelines for essential trauma care.*** Geneva, World Health Organization, 2004.

PMD survey methodology: discovering gaps in the use of medical devices

Introduction

The second part of this paper discusses the methodology employed in two surveys, one directed to stakeholders in six countries, and the other sent to specialists in 15 high-burden diseases, as outlined in the *Global Burden of Disease* (GBD) project *(1)*. The aim of the survey was to incorporate perceived needs from different stakeholders and considers socio-demographic factors to map gaps in the current supply of medical devices.

To be valid, the survey methodology needs to be sensitive to differences in availability (or use) of medical devices. The hypothesis is that there is a difference in health-care levels and in level of development, expressed as scores from the Human Development Index (HDI). The hypothesis is that gaps in access and availability of medical devices to treat the 15 diseases were expected to be greater in low- and middle-income countries than in high-income countries. The sensitivity is tested by including questions on the use of devices at various health-care levels and by performing the survey in different settings .

Questions were developed to collect data on each of the 15 diseases. Common points between each disease questionnaire included the following: distinguishing between diagnostic, therapeutic and assistive devices; questions on medical devices for general (non-disease specific) use (e.g. hospital beds); the appropriate use of medical devices, that is, questions about the management and availability of technical information, communication materials and training opportunities of medical devices, during various stages of the device's life-cycle (e.g. at time of procurement and daily use); and questions about the future needs locally (regionally) that respondents felt were important.

The contents of the surveys and their results are discussed below.

The country survey: a methodology to identify the gaps in the availability of medical devices in the management of high-burden diseases

The objective of the survey was to develop a generic methodology to identify the gaps in the availability of medical devices in the management of high-burden diseases. Two questions regarding the survey were posed:

1. Is the questionnaire accurately identifying gaps in the availability of medical devices?
2. Does the questionnaire reflect the expected differences associated with different HDI levels?

Methodology

Six countries from three continents were selected. The assumption was made that in developing countries the gaps in the availability of medical devices would be greater than in more industrialized countries. Therefore, industrialized countries were not included in the country survey. Selection of countries was made according to HDI level[1].

An HDI index below 0.5 is defined as low development. Three countries in Africa with different populations were chosen: country A (between 10 and 20 million inhabitants), country E (more than 100 million inhabitants), and country F (between 30 and 50 million inhabitants). Two countries were chosen because of their spending on health care: Country B from Asia (spends around 2% of its gross domestic product on health care) and Country C from Latin America (spends around 6% of its gross domestic product on health care and has a relatively high HDI). Country D (1.3 billion inhabitants) was also selected from Asia.

Three of the 15 diseases were used. Diabetes was chosen as an example of a noncommunicable disease, TB as an infectious disease and road traffic accidents as a condition for which early intervention could prevent long-term disability. Questions also assessed the health-care level (primary, secondary or tertiary) in which devices were in use or lacking.

Survey

The survey consisted of a questionnaire, which asked about medical devices present in the clinical guidelines for treating the three conditions under review. Guidelines developed either by WHO or from the National Clearinghouse database (NGC) were used in the survey. The questionnaire consisted of the following sections:

1. General questions on the organization of the health-care system in the respondents' country (e.g. on the presence of quality-control systems).
2. Questions on discrepancies between the need for, and availability of medical devices used in the management of diabetes.
3. Same as above for TB.
4. Same as above for road traffic accidents.
5. 5Questions on medical devices used daily (e.g. hospital beds).
6. General questions on future developments of diseases and the devices needed in their treatment. This section also queried opinions on emerging high-impact diseases/conditions over the next five years, and which medical devices would be needed in their management. In addition, respondents were invited to give feedback on the survey itself and/or the procedure.
7. Qualitative questions, mostly related to other questions in the survey.

The questionnaire was converted into a web-based questionnaire, hosted by Question Pro™, an organization based in Seattle, USA. It was distributed through the WHO Representatives in the selected countries. The Representatives were asked to contact their respective Ministry of Health as well as several medical associations in each country to invite them to participate in the survey.

Scoring

The questionnaire was designed to produce quantitative information on discrepancies between the actual availability and use of medical devices and those indicated by the clinical guidelines. A gap was defined as the difference between the need for medical devices as described in the clinical guidelines and actual availability.

For questions about management procedures, diagnostic, therapeutic and assistive medical devices, respondents were asked to indicate the health-care levels in which the device was used. The respondents could select more than one level. 'No' was the default option. Options that could be ticked were 'yes' or 'NA' (not applicable). The option 'NA' served as a possibility to cover for 'No, not in use at all levels'. Questions about information and communication leaflets could not be scored according to health level, due to technical constraints of the web-based survey.

Results

Four of the six countries responded. No constraints in completing the questionnaire were reported. Country A and Country B responded via the Internet. Country D and Country C responded via hard copy. The responses of Country A, Country B and Country C were each received as a single response. Responses from Country D differed. The completed survey consisted of 22 questionnaires, one having been filled out completely, and the others having been completed partially by 21 different country officials. To be able to report on the countries consistently, the 22 responses from country D were amalgamated into one response.

1 For more information about the HDI, see: http://hdr.undp.org/en/statistics/ (accessed 8 February 2010).

Use of clinical procedures in the management of the three conditions surveyed

Use of clinical procedures in the management of diabetes, TB and road traffic accidents is the first section dealt with by the survey. Figure 1 shows the results by country and health-care level.

Figure 1 shows that at the tertiary health-care level, all procedures are in use for all three conditions, except for TB in Country B. At the primary health-care level, only Country C and Country D report some procedures in use, whereas at the secondary level of care, all countries offer some procedures.

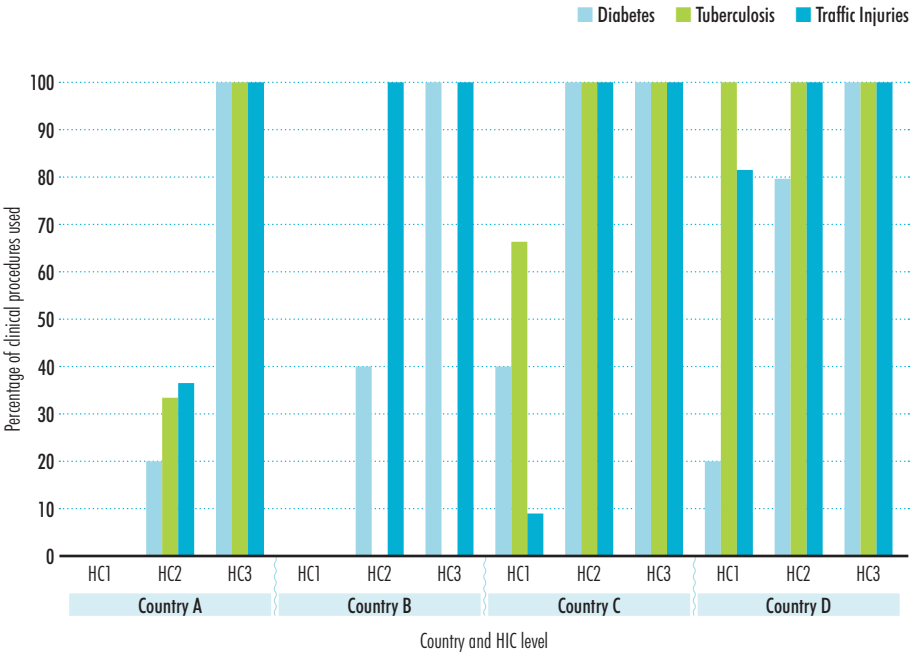
Figures 2a–c show the percentage of countries responding positively to the use of diagnostic, therapeutic and assistive medical devices for the three selected conditions.

Figures 2a and 2c show that the use of diagnostic and therapeutic medical devices for road traffic accidents and diabetes are related to the health-care levels in a similar way. In all four countries almost all devices are reportedly being used in the tertiary health-care level. The primary health-care level shows again the fewest numbers of devices in use, while the secondary health-care level shows more devices are employed. The use of diagnostic and therapeutic devices for TB in the four countries differs. All devices are reported to be in use at the tertiary health-care level, while those at the primary and secondary levels show use is only slightly less frequent.

The reported use of assistive devices for TB shows a similar pattern of use as for road traffic accidents. Figures 2a–c show that assistive devices are in use at the tertiary health-care level in all countries, but for the other health-care levels, only two countries report their use at primary and secondary health-care level.

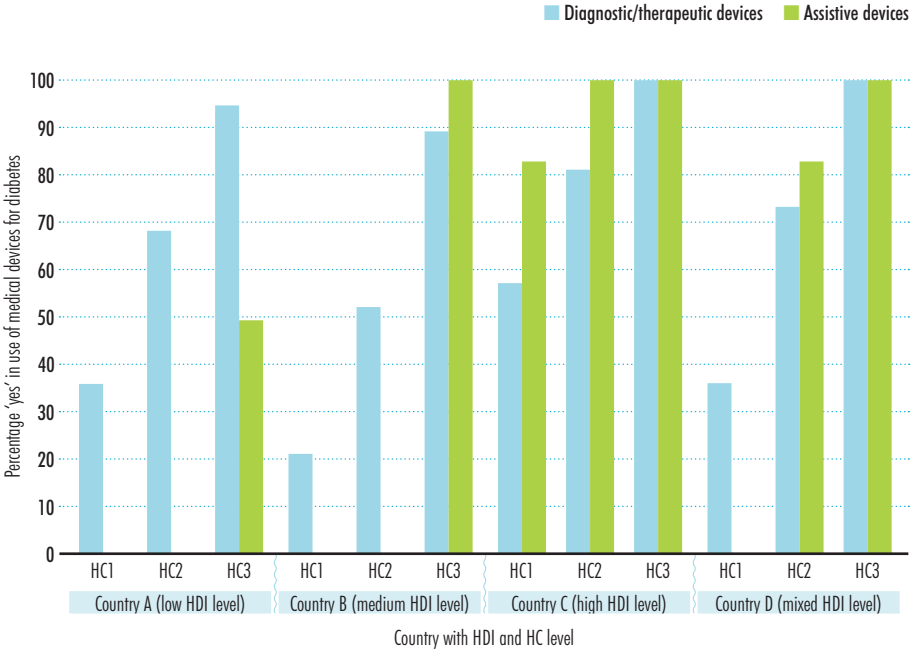
For diabetes, all 4 countries are consistent in reporting assistive devices to be in use at the tertiary level. Country C is the only country reporting a large percentage of assistive devices at all health-care levels.

Figure 1. Percentage of clinical procedures by country and by health-care levels[a]



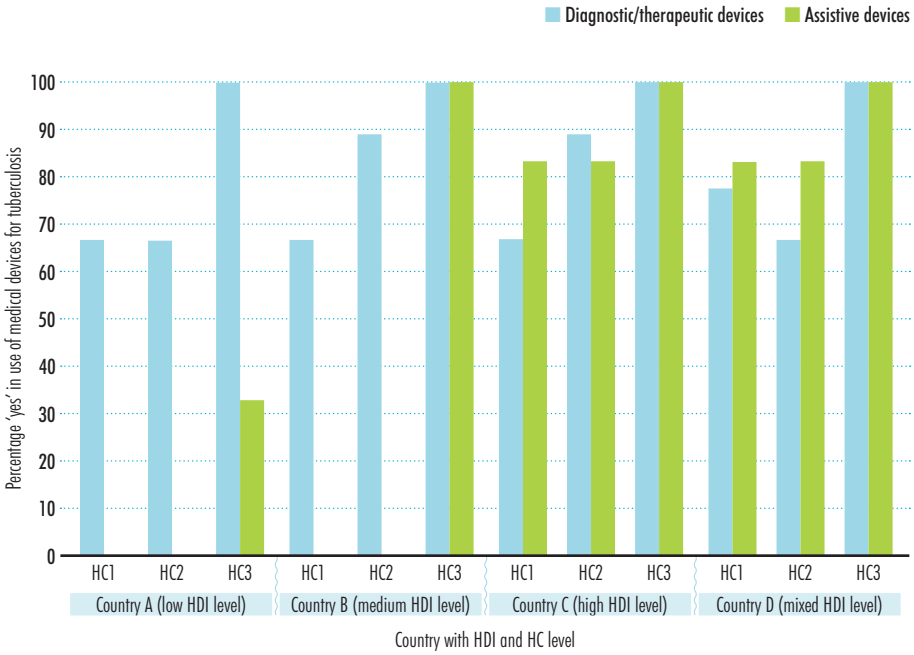
[a] HC = health-care; HC 1 = primary health-care level; HC 2 = secondary health-care level; HC 3 = tertiary health-care level).

Figure 2a. Diabetes: Percentage 'yes' answers on the use of diagnostic, therapeutic and assistive medical devices by country and by healthcare level[a]



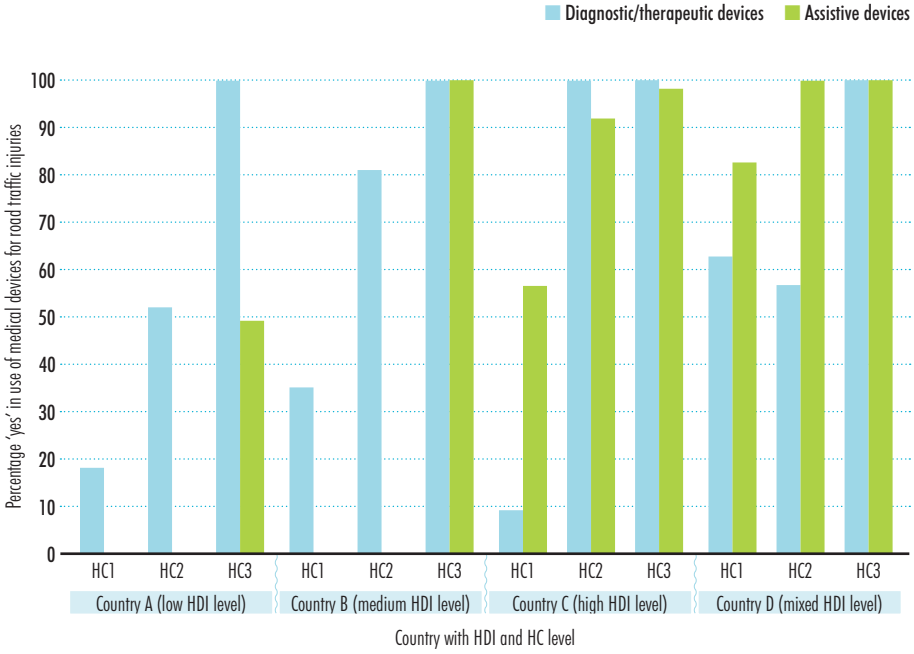
[a] HDI, Health Development Index; HC 1, primary health-care level; HC 2, secondary health-care level; HC 3, tertiary health-care level.

Figure 2b. Tuberculosis: Percentage 'yes' answers on the use of diagnostic, therapeutic and assistive medical devices by country and by healthcare level[a]



[a] HDI, Health Development Index; HC 1, primary health-care level; HC 2, secondary health-care level; HC 3, tertiary health-care level.

Figure 2c. Road traffic injuries: Percentage 'yes' answers on the use of diagnostic, therapeutic and assistive medical devices by country and by healthcare level[a]



[a] HDI, Health Development Index; HC 1, primary health-care level; HC 2, secondary health-care level; HC 3, tertiary health-care level.

Accessibility of technical information

Country D and Country B do not indicate any difficulty with regards to access to technical information. Country A reports difficulties accessing technical information on procurement, maintenance and use of medical devices in relation to the three conditions. Country C reports the lack of access to technical information on maintenance/repair and daily use of medical devices for diabetes.

For medical device use in general, the gaps are smaller: Country A reports that accessibility of technical information associated with maintenance and repair of devices is lacking for diabetes and traffic injuries.

Future needs

Respondents were asked to identify, in descending order of urgency, the three most pressing diseases or conditions (and the associated medical devices needed in their management) emerging over the next five years. Table 1 shows their responses.

The majority of the diseases indicated are noncommunicable diseases. Medical devices indicated by the respondents are mainly diagnostics and therapeutic devices. Assistive devices are not mentioned.

Discussion of the country survey

The questionnaire is aimed at getting information on three high-burden diseases. The lists of procedures and diagnostic and therapeutic devices were adapted for the three individual diseases/conditions chosen: diabetes, TB and road traffic accidents.

The results of the survey did not meet data collection expectations: an insufficient number of stakeholders responded. However limited the data were, they did show that the use of medical devices and the accessibility of technical information is clearly associated with health-care level and HDI index level.

Health-care level is clearly an important factor in relation to medical devices in all diseases in all countries. At the tertiary health-care level, many or all devices are reported to be in use in all four countries.

Table 1. Emerging priority diseases according to respondents

Disease[a]	Country A	Country B	Country C	Country D
Disease 1	**Airway disease (Asthma)**	**Diabetes**	**Acute heart failure**	**Diabetes**
Medical devices associated	X-ray machines, pulse oximeters, nebulizers, inhalers	Blood pressure machine; glucometers, stethoscopes, diagnostic sets	(Promotion and prevention, medical assistance)[b]	Insulin pump
Disease 2	**Ischaemic heart disease**	**TB**	**Cancer**	**Cancer**
Medical devices associated	electrocardiogram (ECG) machines, lab equipment for angiography/ angioplasty	X-ray, laboratory microscope, laboratory incubator, water bath, centrifuge, X-ray film-processor	(Promotion and prevention, medical assistance)[b]	Diagnostic equipment
Disease 3	**Road traffic accidents**	**Injuries**	**Cardiovascular disease**	**Cardiovascular disease**
Medical devices associated	X-ray imaging devices, orthopaedic equipment, medical supplies for resuscitation	C-arm X-ray machine, diathermy machine, suction machines, orthopaedic instruments, orthopaedic operating table, anaesthetic machines, theatre operating lamp, patient ventilators, ECG monitors, infusion pumps	Promotion and prevention, medical assistance[b]	Pacemaker, defibrillator

a Disease 1 indicates highest priority; Disease 2, second-highest priority; Disease 3, third-highest priority.
b These activities are not medical devices.

However, it is not the case at the primary and secondary health-care levels, where diagnostic and therapeutic devices for diabetes and road traffic accidents are only reported to be used in Country C and Country D.

In general, assistive devices are being used less often than diagnostic and therapeutic devices. Country A, which reported the lowest use of clinical procedures and medical devices, is the country with lowest HDI according to the Human Development Report *(2)*.

The difference in availability of medical devices according to health-care levels is consistent across the selected countries. As expected, the gaps in availability follow HDI levels (i.e. the lower the HDI level, the larger the gap in availability).

Overall it was concluded that the questionnaire might serve as a tool to identify gaps and to uncover differences related to HDI level in the availability of medical devices within and between countries.

However, given the low response rate and the limited number of stakeholders from each country that were involved, more data was needed. Therefore, a separate survey was developed inquiring specialists in a specific disease on the use of medical devices. Results of this survey are discussed in the following section.

The specialist survey: a methodology to identify the gaps in the availability of medical devices in the management of high-burden diseases

The specialist survey is the second survey conducted by the *PMD* project. It s aims to provide another angle from which to assess the gaps in the availability of medical devices in relation to 15 high-burden diseases.

Methodology

Development of the specialist survey started with the country survey. It was adapted to contain questions on 15 high-burden diseases/conditions. Questions about the health-care system were replaced by a single question on the context to which the specialist would be referring: low-, medium- or high-resource setting. The medical devices needed in the management of each disease were listed in the questionnaire. Questionnaires for each disease/condition consisted of 12 questions.

Specialists were selected through WHO or international or national umbrella organizations. For each disease/condition, 10–15 experts were selected in order to allow for a clearer picture of where the gaps exist in access and availability of medical devices. Selection was limited to specialists who had a minimum of five years experience working in a specific area over the past eight years.

The survey was also conducted using a web-based questionnaire, hosted by QuestionPro™. Specialists linked to the survey through the Internet. A response monitoring system was set up to enable WHO to send reminders and provide assistance if needed.

Gap scores were defined as the difference between the medical devices needed according to the clinical guidelines and the medical device(s) available. A relative gap score was computed based on the number of medical devices per disease. The gaps in the availability of assistive devices were evaluated through a set of six sub-questions for each disease, each of them covering a certain category of assistive medical devices (Annex 2). Questions on general issues like technical information and accessibility were scored in a similar way. However, since these questions reflect an opinion about availability rather than a verified fact about availability, these responses were analysed separately. In most opinion-related questions, the respondents are requested to illustrate their opinions by giving some qualitative examples.

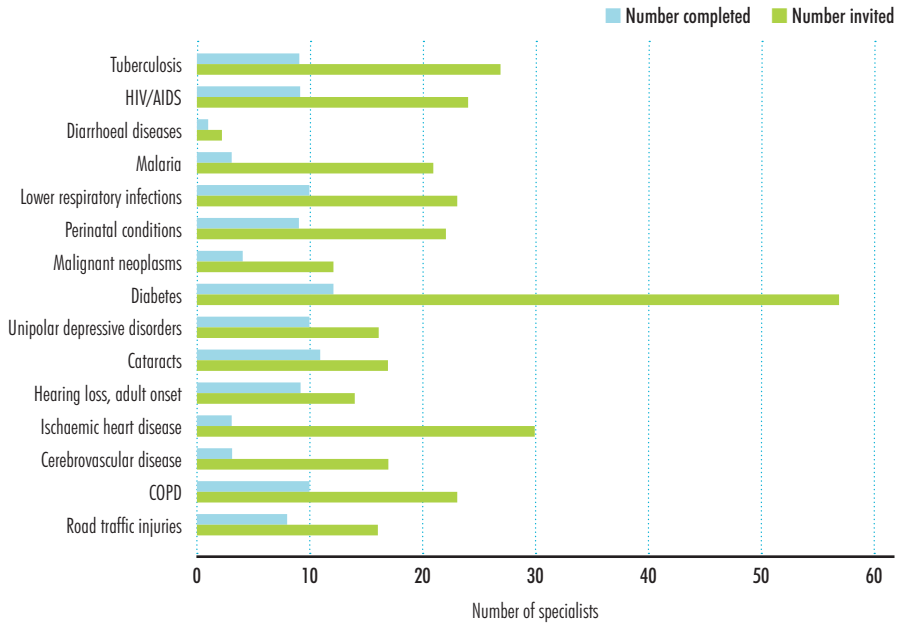
Results

A total of 321 questionnaires were sent to specialists and 122 were returned (most were completed online, though a few responded with hard copy). Nine surveys were excluded as they were incomplete. This is equivalent to a net response rate of 35% (111/321) (Figure 3), a value that is comparable to the response rates found in other web-based surveys *(3)*. For diabetes, the International Diabetes Federation (IDF) was willing to send the questionnaire through their network, resulting in 57 of the 321 questionnaires sent to diabetes specialists.

Initially, only five diseases received the required number of 10 responses. In order to be able to make a broader analysis, it was decided to accept diseases receiving nine responses, which meant that nine diseases were included for analysis (representing 89 responses): TB, HIV/AIDS, lower respiratory infections, perinatal conditions, diabetes, unipolar depressive disorder, cataracts, hearing loss (adult onset) and chronic obstructive pulmonary disease (COPD). The other six diseases were excluded because too few responses were received.

Responses were also analysed with respect to HDI levels. Table 2 shows the distribution of HDI levels for the 111 responses accepted and 89 surveys analysed, both of which were used to determine gap scores. The distribution of HDI level is similar in both groups: the 111 surveys accepted for general analysis

Figure 3. Number of specialists invited (n=321) in each area of expertise (disease) and the number of specialists having completed the survey (n=111; 35%)



46% refer to a context with a low HDI, compared to 48% among those 89 that are disease specific; further, 30% and 31% of the surveys, respectively, refer to a context with a middle HDI score and 24% and 21% to one with a high HDI score.

Not applicable (NA) scores

An 'NA' (not applicable) answer can be given for several reasons. A respondent might have limited or no experience to respond to a particular question, be uncertain of the answer, not having understood the question, or may think the question is inappropriate.

A high percentage of NA answers might indicate a lack of validity of one or more questions in the survey. If this would be the case, the methodology of surveying to identify the gaps in the use of medical devices would need to be reconsidered.

The percentage of questions answered in any individual specialist response as 'NA' are generally low – maximum 10%, except for diarrhoeal diseases (but this result comes from only one valid survey returned) and for unipolar depressive disorders. The findings support the validity of the questions in the survey, with the possible exception of those for unipolar depressive disorders.

Gap scores

Fact-based GAP scores are based on the answers in relation to clinical procedures, the actual use of medical devices, whether medical devices in use were included in the table of medical devices, and the availability of assistive devices.

GAP scores for questions in which the opinion of the respondent is asked for (GAP opinions) are scored separately; for example, questions that query the accessibility of various kinds of technical information for diagnostic and therapeutic medical devices for disease-specific as well as general use, and the availability of training opportunities for medical devices. Figure 5 shows the GAP scores for the nine diseases.

The scores based on facts do not vary widely between diseases (<0.20), with

Table 2. Summary of responses to the specialist survey

	Low HDI level	Medium HDI level	High HDI level	Total
Total responses	58	35	29	122
Number of surveys accepted for analysis	51	33	27	111
Number of surveys on disease specific analyses (nine or more responses per disease)	43	28	18	89

Figure 4. Disease-specific results by HDI level

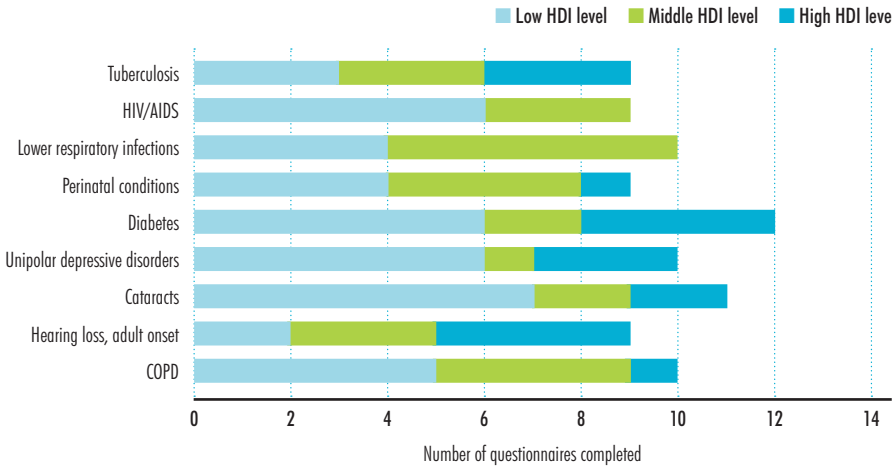
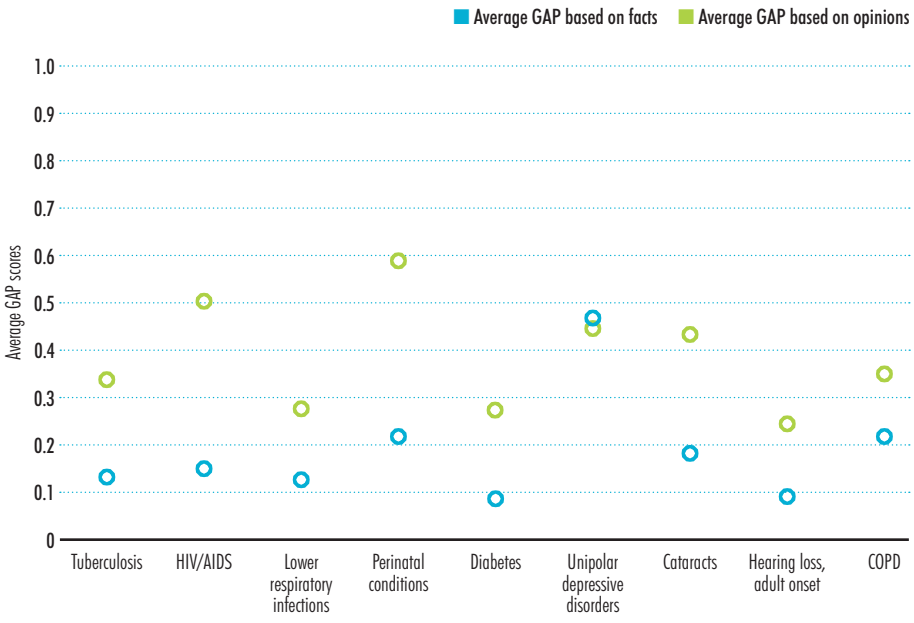
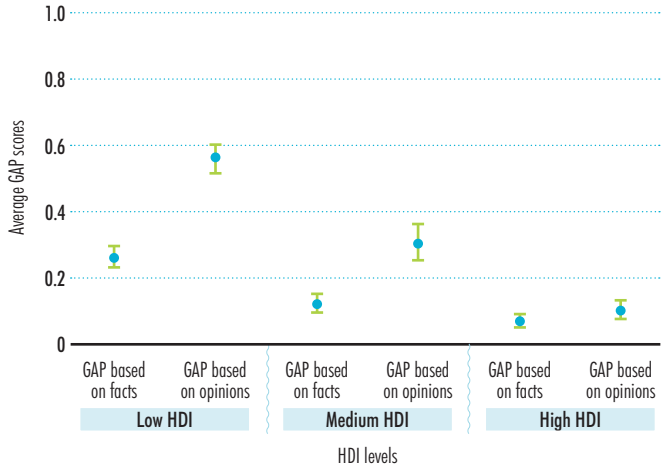


Figure 5. Average GAP scores for fact- and opinion-based responses, by disease[a]



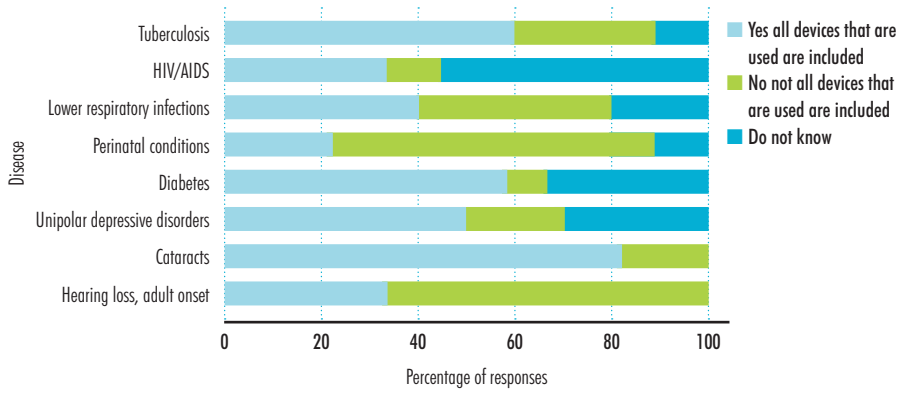
[a] Based on 89 responses.

Figure 6. Average GAP scores based on facts and opinions, by HDI level[a]



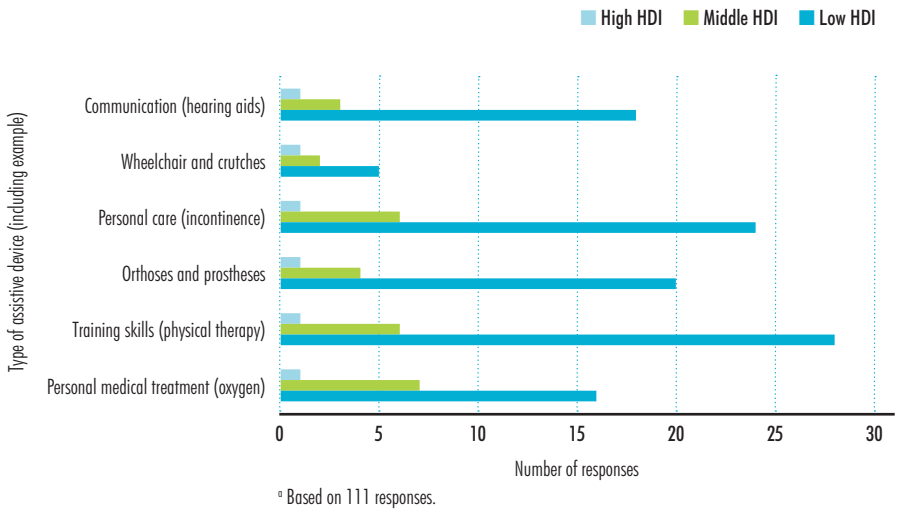
[a] Based on 111 responses.

Figure 7. Use of medical devices that are not listed in the clinical guidelines, by disease[a]



[a] Based on 89 responses.

Figure 8. Lack of availability of assistive devices by HDI level[a]



[a] Based on 111 responses.

the exception of unipolar depressive disorders (0.50). The GAP scores based on opinions are generally somewhat higher (differences varying from approximately 0.10 to approximately 0.40) than those based on facts, unipolar depressive disorders being an exception.

GAP scores show a clear and statistically significant relation to HDI. The correlation between HDI and fact-based GAP scores is 0.40 and between HDI and opinion-based GAP scores 0.56 (Kendall's tau, df=109; both $p < .01$). The differences in GAP scores across the three HDI levels are slightly greater for the opinion-based scores than the fact-based scores. The average GAP scores (both those based on facts and opinion) are plotted in Figure 6.

Medical devices in the management of disease

The survey responses showed a wide variety of medical devices suggested by the guidelines are not being used. The evaluation of the results was therefore limited to those devices mentioned by at least half of the respondents for a specific disease. More than half of the specialists report one (for cataracts) or two devices (for unipolar depressive disorders and COPD) not in use.

Figure 7 depicts the quantitative results of the following question: What medical devices are actually used but not listed in the clinical guidelines?

Assistive devices

The survey contains questions that addressed the availability of assistive devices. Figure 8 shows the results of these questions according to HDI. Except for wheelchairs and crutches, these devices are generally unavailable in contexts with a low HDI. Gaps in availability are largest in devices related to training skills and personal care.

Relation between availability of disease-specific devices and assistive devices

The correlations between the GAP score for disease-specific devices and the GAP score for assistive devices (matched to their specific disease) were analysed.

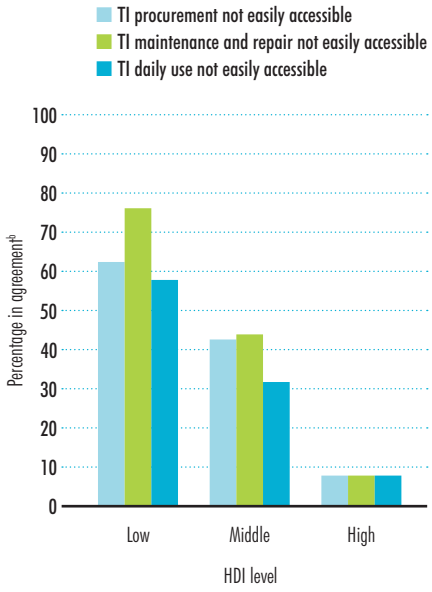
Statistically significant correlations (Kendall's tau; p<.05; df=7) were found for five diseases: lower respiratory disease (0.86), perinatal conditions (0.72), diabetes (0.70), COPD (0.68) and unipolar depressive disorders (0.68). No significant correlation was found in tuberculosis, hearing loss, cataracts and HIV/AIDS.

Accessibility of technical information

The survey contained a question on technical information for medical devices for each specific disease (Figure 9) and a question on technical information for medical devices in general use (e.g. ventilators, sterilizers, etc.).

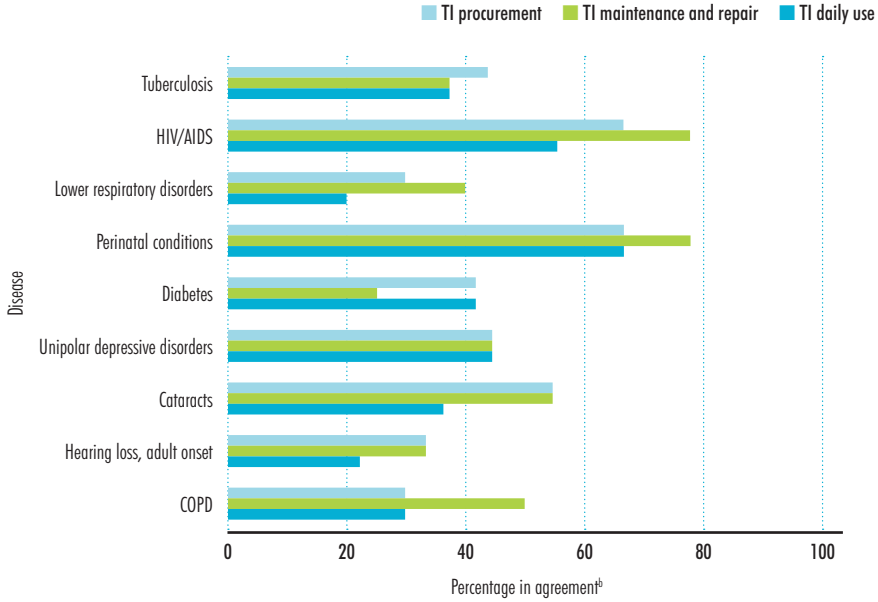
Accessibility is clearly related to HDI: lack of access to devices is mentioned more frequently when the specialist is referring to a context within a low HDI. When looking at various kinds of technical information, the biggest gaps appear in the information regarding maintenance and repair. Though the problems in devices for specific use seem to be somewhat greater than those for devices in general use, the overall pattern of results is similar.

Figure 9. Lack of availability of technical information for disease-specific medical devices, by HDI level[a]



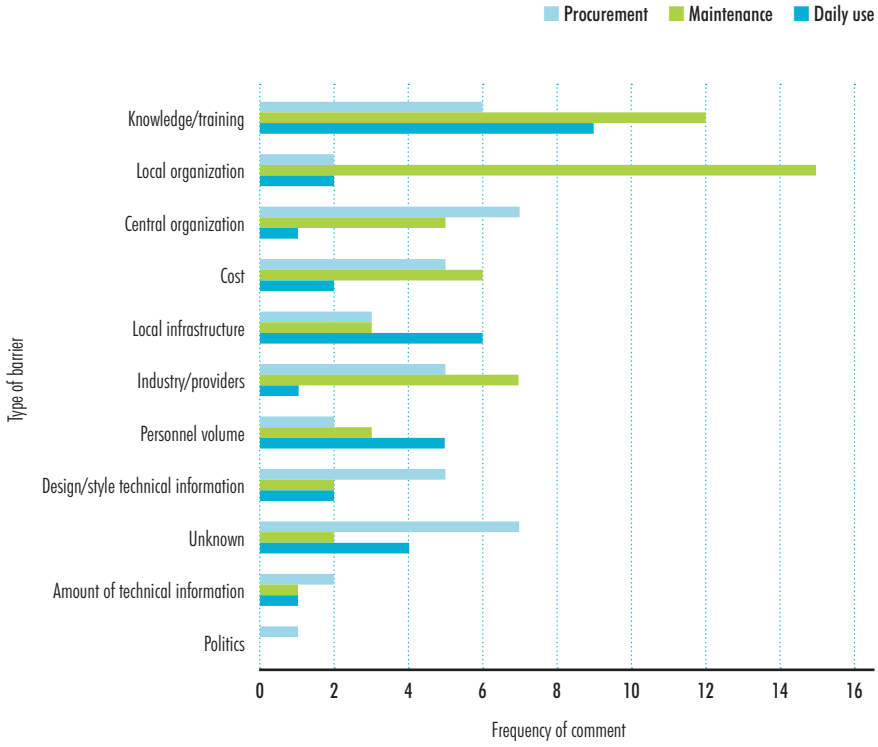
[a] Based on 111 responses.
[b] Not applicable (NA) responses excluded.
TI, technical information.

Figures 10. Lack of availability of technical information for disease-specific medical devices[a]



[a] Based on 89 responses.
[b] Not applicable (NA) responses excluded.
TI, technical information.

Figures 11. Barriers mentioned in the explanations of why certain type of technical information were not easily accessible[a]



[a] Based on 111 responses.
TI, technical information.

Accessibility to technical information for devices related to perinatal conditions and HIV/AIDS is less than for devices of other diseases (Figure 10). For devices related to diabetes, the accessibility to technical information for their maintenance and repair is somewhat better than is the case for devices in use for other diseases (Figure 10).

Examples of where gaps exist

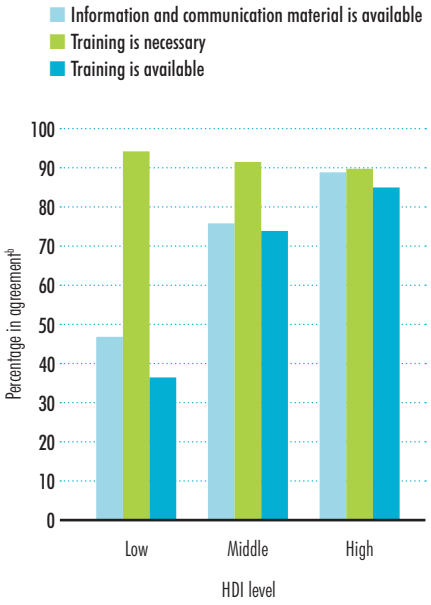
The specialists were asked to give examples of medical devices for use with specific diseases where technical information is needed but not easily accessible. Sixty-three specialists listed a total of 121 medical devices. Of these respondents 40 were referring to contexts with a low HDI, 17 were referring to those of a middle HDI , and six respondents to contexts with a high HDI . Spirometers (5x) and electroconvulsive therapy (ECT) machines (3x) were reported as most frequently being unavailable. (All responses to the question regarding a dearth of technical information are listed, by disease and according HDI, in Annex 3, Table A.)

Regarding medical devices in general use, specialists were also asked to explain why technical information is not easily accessible. All responses have been inspected and coded a posteriori, starting with the various categories of identified barriers *(4)*. Some of these categories have been combined and their number reduced to 10, plus a further category titled 'Unknown'. The results are depicted in Figure 11.

Technical information for maintenance and repair of devices was most frequently indicated as lacking. The barriers most frequently cited were 'local organization' and 'knowledge/training' (Figure 12). Additional responses show that 'local infrastructure' and 'lack of knowledge/ training' are most frequently mentioned barriers regarding technical information for daily use.

Barriers in accessing information on device procurement are indicated to be due to lack of a proper central organization structure and lack of knowledge/training.

Figure 12. Lack of availability of communication and information materials and the need and availability of training, by HDI level[a]



[a] Based on 111 responses.
[b] Not applicable (NA) responses excluded.

Accessibility of communication and information material, and need for training

When asked if training for a specific medical device is needed but not available, 68 respondents confirmed this need for a total of 130 medical devices. Forty-one respondents spoke of a context with a low HDI score, 20 to a context with a middle HDI and seven to a context with a high HDI score. The devices most frequently cited as unavailable but needed are: phacoemulsification (9x), ventilators (8x), ECT devices (5x) and spirometry (5x). (All responses to this question are listed, by disease and according HDI, in Annex 3, Table B.)

Figure 12 shows the lack of information materials according to HDI and the need for training in the use of medical devices.

Future expectations

Ninety-four of the 111 respondents provided 260 suggestions for the future expectations category of the survey. Most answers related to a medical device; some indicated the need for a better technical and digital infrastructure, for better information.

Most frequently mentioned medical devices desired are:

- Oxygen supplies (9x, for various diseases and various HDIs);
- Non-invasive ventilators (8x: 4x in both lower respiratory infections and COPD; 6x when referring to medium HDI and twice to low HDI); also mentioned are (invasive) ventilators (4x; twice in perinatal conditions, once in COPD and once in road traffic accidents), 3x when referring to low HDI and once when referring to medium HDI;
- Spirometry (8x; 3x in lower respiratory disease and 5x in COPD, mostly in contexts with low HDI scores);
- Phacoemulsification (7x; all in cataracts, various HDI); and
- Cochlear implants (4x; all in hearing loss; mostly in medium and high HDI).

There are no significant differences between HDI levels regarding the responses about future expectations. (All responses to this question are listed, by disease and according HDI level, in Annex 3, Table C.)

Discussion of the specialist survey

To arrive at a foundation of evidence, the specialist survey methodology (i.e. the questionnaire) has to be sensitive to differences in availability of medical devices. The data garnered from the preliminary survey support this assumption.

The lack of availability and accessibility of technical information, especially on maintenance and repair of medical devices, appear to be largest in contexts that have a low HDI score. In addition, the questionnaire detected differences in gap scores between HDI levels.

The use of relative and standardized GAP scores (Annex 2) enabled the comparison of diseases. Gaps in availability of medical devices are small with a limited variation between diseases. The distinction between gaps based on fact and opinion revealed a difference in scores; the gaps based on opinion were somewhat larger. This result cannot easily be explained, but one

possible explanation is that questions asking for opinions elicited responses on the discrepancy between the current situation and wishes and ambitions regarding the availability or accessibility of technical information. The difference between the opinion-based gaps and fact-based gaps is more pronounced when respondents referred to contexts with a low HDI score. To narrow the difference between opinion-based responses and fact-based responses, future survey questions need to be reworded to factual questions (stating instead of agreeing).

A substantial variation between diseases was observed in the availability of assistive devices. Significant correlations were established between GAP scores for diagnostic and therapeutic devices, and for assistive devices in some diseases. Since these correlations were not apparent in all diseases, a separate further analysis of gaps in diagnostic and therapeutic devices on the one hand, and assistive medical devices on the other seems necessary to get a fuller picture of the gaps in availability of the two types of devices in the treatment of a given disease.

The number of 'not applicable' responses in the survey was generally low, which indicates the questions were appropriately suited to the specialists answering them. The comments received were generally positive; only a few respondents submitted negative comments on format or contents of the survey.

The consistency in the types of barriers in connection with the lack of accessibility of the three types of technical information (procurement, maintenance and repair, and daily use) supports the validity of the questionnaire. Further, the result of the specialist survey justifies considering the survey as a useful methodology to identify the gaps in medical devices across health-care levels and HDI levels.

It must be stressed, finally, that the survey was an investigation aimed at testing a methodology rather than garnering representative results on gaps worldwide. The limitations to the survey methodology are discussed in turn.

Limitations

The wording of questions and the use of general and clearly-stated concepts and definitions are crucial to obtain accurate responses. The fact that medical devices in clinical guidelines are described in generic terms (and unsystematically) needs to be addressed in future surveys. Further, terms like 'availability' and 'accessibility' may have introduced some bias in the responses. Finally, a relatively small sample size in the country survey (n=4) suggests that results should be viewed with caution, and larger sample sizes would be beneficial in future studies.

Despite the limitations, the following conclusions on problems in low HDI contexts can be made:

- medical devices are needed in the management of a specific disease according to the clinical guideline, but may not be in use;
- assistive medical devices are generally unavailable;
- in many settings, technical information is not easily accessible for disease-specific medical devices, as well as for devices in general use (especially technical information related to maintenance and repair); and
- training opportunities are lacking in many areas.

Overall conclusions drawn from the surveys

The research question employed for the *PMD* project was: is a survey methodology useful to obtain valid information on availability and use of medical devices and related materials?

The resulting conclusions from the overall survey methodology (Annex 1) are:

- A questionnaire was found to be an appropriate tool with which to gather data. However, questions must be carefully worded and standardized terminology employed.
- A web-based survey was found to be an appropriate tool to conduct the survey. The lack of reliable Internet access in some countries was a barrier to using the web-based survey.
- Survey response improved when respondents were contacted directly (i.e. in the specialist survey) compared to indirect contact (i.e. the country survey).
- The concept of a relative gap (GAP score) is useful when comparing the use of medical devices across diseases, especially considering that clinical guidelines for different diseases often contain a highly variable number of medical devices.
- The survey proved to be sensitive to detect variations in HDI and health-care level, as expected.
- The results of both questionnaires show internal consistency: that is, between the type of technical information not easily available and/or missing, and the possible causes reported (barriers).
- The gaps in availability of devices and related technical information and training opportunities are larger in contexts with a low HDI rating.
- Gaps in availability of assistive devices and gaps in availability of diagnostic and therapeutic devices are not always correlated. Separate assessments are needed.

It would be valuable for future surveys to include questions that are limited to a few variables, such as lack of availability of diagnostic and therapeutic medical devices; lack of availability of assistive medical devices; and lack of availability of technical information and other conditions related to infrastructure (e.g. buildings, power supply, and running water). Further, a standardized nomenclature of medical devices according to the respective intended purpose would support the common understanding of terms and facilitate international work.

It would be valuable for future surveys to consider the following points and objectives to enhance the data gathered.

- Use standardized wording and terms for medical devices.
- Identify three gap scores: on therapeutic and diagnostic medical devices; on technical information and training related to diagnostic and therapeutic medical devices; and on assistive medical devices.
- Use both the Internet and hard copy resources to obtain responses.
- Develop a set of criteria for selection of respondents to obtain representative results.
- Adapt the selection of respondents according to variations within a country or a region.
- Have specialists indicate the health-care level and (if applicable) the HDI status of the region on which they are reporting.
- Validate the survey in a selected number of contexts (countries/region).

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Annex 1: Steps to identify the gaps in the availability and accessibility of medical devices for 15 high-burden diseases through surveying selected countries and selected specialists

Annex 1

Steps	Actions
COUNTRIES SURVEY	
Select three diseases: diabetes (noncommunicable), TB (communicable), road traffic accidents (other) in selected countries	
Develop a web-based survey according to the medical devices mentioned in the clinical guidelines	List the medical devices. Add general questions on level of care, opinion on general issues regarding medical devices and future expectations
Validation of the list	Ask specialists and members of the Advisory Group to the PMD project for comments on the web-based survey
Perform web-based survey on a country level in selected countries (offering hard copy surveys for those countries that request it)	Send the survey to the WHO country office asking them to contact stakeholders to complete the survey[a]
Result The use of medical devices according to the clinical guideline(s), and the accessibility of technical information are clearly associated with health-care levels in the selected countries. Responses did not meet study expectations in terms of reflecting the opinions of the various stakeholders, or receiving timely response	
SPECIALISTS SURVEY	
Adapt survey to 15 high-burden diseases. General questions limited to level of HDI	Create questions and sub-questions for each of the 15 diseases
Select 10–15 specialists from low-, medium- and high-resource settings for each of the 15 diseases	Selection process: 1. Contact WHO focal points and network of experts 2. Approach international umbrella associations for specific diseases 3. Approach country umbrella associations for specific diseases 4. Ask Advisory Group to the PMD project
Perform web-based survey	1. Send survey invitations to specialists for each of the 15 selected diseases (expected response rate 50%) 2. From July 28, 2008, updates and reminders every fortnight 3. Further follow-up 4. Collect results and score the survey responses
Result Internal consistency of the responses leads to the conclusion that the format and content of the specialist survey is suitable to identify gaps in the availability of medical devices and related information. The use of relative gaps – the methodology to correct for differences in number of devices for different diseases – has proven useful to compare gaps between diseases. Results show that gaps are widest in low-income countries, specifically assistive devices. Technical and educational information is lacking generally, but especially in low-income countries	
COUNTRIES SURVEY	
Discuss and match the results of the survey with expert opinions during an informal consultation (20–21 November 2008)	
Result The results of the specialist survey are consistent with the results of country survey	

a Problem: very difficult to contact stakeholders and obtain their responses. Time frame for survey responses was not met.

Annex 2: Quantifying the lack of availability and accessibility in the use of medical devices: GAP scores

The concept of a gap indicates deficiencies in availability or accessibility of medical devices. A gap is defined as the discrepancy between medical devices needed (according to clinical guidelines) in the management of a disease and the medical devices actually available and in use within a given context.

The gaps in the availability of assistive devices are evaluated by reviewing responses to a set of six sub-questions, each of them discussing a type of assistive medical device. Gaps are calculated by applying scoring rules to all sub-questions requiring a non-text answer. A score of zero reflects the absence of a gap, otherwise the score of a sub-question will be: -1, reflecting the maximum gap. A positive score indicates that the number of medical devices used in practice exceeds the number of devices outlined in the guideline, with an assigned score up to a maximum of +1. Only valid responses are used in the calculation of these gap scores (i.e. NA responses are excluded).

Fact- and opinion-based GAP scores

The questionnaire consisted of two types of questions: those about factual use of medical devices and those on opinions regarding the availability and accessibility of information materials, one leading to a fact-based score and the other to an opinion-based score, respectively.

GAP scores based on facts were derived from questions on *list of procedures, list of diagnostic and therapeutic medical devices, actual use of unlisted (i.e. outside the clinical guidelines) medical devices and list of assistive medical devices.* GAP scores based on opinions were derived from *statements about accessibility of technical information for disease-specific diagnostic and therapeutic medical devices, statements about the accessibility of technical information for medical devices in daily use and question statements about information and training for disease-specific diagnostic and therapeutic medical devices.*

The value of the GAP score obtained in questions on factual use is a relative measure indicating the degree to which the medical devices needed in the clinical management of a disease are *in fact* not used (according to specialists having recent experience in the management of this disease).

The value of the GAP score obtained in questions on opinions about availability or accessibility is a relative measure indicating whether the specialists *agree* with certain statements about the (lack of) accessibility of technical information materials related to the medical devices and the availability of training opportunities. In most opinion-related questions respondents were requested to illustrate their opinions by giving some qualitative examples.

Comparability across diseases: relative gaps

The number of sub-questions depends on the number of medical devices listed for a specific disease; some diseases require more devices than others. To compensate for these differences a relative gap score was developed.

The general shape of both relative measures is: (sum of valid responses to a gap) / (maximally attainable sum of responses on the gaps).

The numerator may vary between zero and a negative value (number of valid answers to sub-questions, indicating a gap), and the denominator is the number of valid responses in this group of sub-questions multiplied by -1. This number will be negative. Consequently, the value of the relative gap may vary between 0 (no gap) and 1 (largest possible gap). If no valid responses are obtained, no relative gap can be established.

Relative GAP scores may be used in several ways: as a general gap-indicator concerning a number of different questions, but also as a more specific gap-indicator, based on just one topic (e.g. assistive devices).

Annex 3 Tables with explanations on some qualitative questions posed in the specialist survey[1]

1 Comments in the tables were imported verbatim from the survey. Efforts have been made to clarify responses but be aware that in some cases, clarification of terms or ideas was not possible.

Table A. Comments on question 205 – *Please give examples of medical devices where technical information is needed and is not available* – by disease and HDI[a]

#	Disease	HDI level	Comments by respondents
1	Tuberculosis	Low	Fluorescent microscopes are poorly maintained, Staff are unfamiliar with the maintenance of new LEF-Fluorescent microscopes
2	Tuberculosis	Low	Specifications for quality equipment Maintenance of bio safety equipment
3	Tuberculosis	Low	Drug susceptibility testing (DST) laboratory equipment
4	Tuberculosis	Middle	There is no information on medical devices for TB
5	Tuberculosis	Middle	There are no such devices
6	Tuberculosis	Middle	No translation to the national language, no enough staff
7	HIV/AIDS	Low	Flow cytometers Clinical chemistry analysers Haematology analyser
8	HIV/AIDS	Low	Gen sequencing machine as this is new equipment we got under Global Fund Round 5
9	HIV/AIDS	Low	Automates d'hématologie; Automates de biochimie
10	HIV/AIDS	Middle	CD4 count and viral load testing device
11	HIV/AIDS	Middle	The information is needed, e.g. QA/QC, medical devices type, testing results reports.
12	Diarrhoeal	Low	Description of cholera cot and measurements for their local production; Source for high grade plastics for cholera beds; Methods for establishing intraosseous infusion; New WHO growth Chart
13	Malaria	Low	Programmes will sometimes have limited access to information on maintenance of microscopes, partly due to inability for find existing information in their language. Same issues may pertain for procurement
14	Malaria	Low	PCR technology for parasite identification. Measurement of plasma drug levels
15	Malaria	Low	Malaria Rapid Diagnostic Tests (performance and operation characteristics); Microscopy (Maintenance and repairs) and (Quality assurance); QBC; QA for daily use with all devices (no system in place)
16	Lower respiratory infections	Low	Spirometers
17	Lower respiratory infections	Low	Equipment for sputum culture
18	Lower respiratory infections	Low	Spirometer Diagnostic kit for Legionella, Mycoplasma, Chlamydia, viruses. Pneumococcal antigen detection
19	Lower respiratory infections	Low	X-ray
20	Lower respiratory infections	Middle	Spirometry
21	Lower respiratory infections	Middle	Urinary test for pneumococcus quantitative techniques for sputum cultivation BAL methodology
22	Perinatal conditions	Low	Incubator, infant warmer, oximetery, phototherapy lights, Self inflating resuscitation bags and laboratory equipment, CPAP, Ventilation
23	Perinatal conditions	Low	Very poor maintenance and repair facility and poor use of daily protocol and use instructions
24	Perinatal conditions	Low	Incubator, phototherapy unit
25	Perinatal conditions	Low	Ultrasonography of anterior fontanel Maintenance and use of closed incubators
26	Perinatal conditions	Middle	Ventilators, Blood gas Machines
27	Malignant neoplasms	Low	Flexible upper GI endoscope Electrocautery
28	Malignant neoplasms	High	With the devices I am familiar with the information is available that however does not mean that it is available in such matter that it understandable and or can easily be used
29	Diabetes	Low	Maintenance of DCA-2000 machine used for HbA1c testing (but the bigger problem is the cost – see below)

#	Disease	HDI level	Comments by respondents
30	Diabetes	Low	Laser photocoagulation machines Dialysis machines Biochemistry equipment A1C kits
31	Diabetes	Low	Biochemistry analysers
32	Diabetes	Middle	Home blood glucose measurement device
33	Diabetes	High	All information is easily available. I do not understand why the system is asking for comments
34	Diabetes	High	Technical information is held in different places; therefore one has to be familiar with a range of access points. Technical information about National Health Service procured equipment is more difficult to find than information for patients generally.
35	Unipolar depressive disorders	Low	ECG, ECT machine
36	Unipolar depressive disorders	Low	Basic information on illness, management, family attitudes etc.
37	Unipolar depressive disorders	Low	ECT machines Equipment for blood tests, e.g. thyroid function
38	Unipolar depressive disorders	Low	To me, unipolar depression is foremost a clinical diagnosis based on a good interview
39	Unipolar depressive disorders	Low	Computerized CBT and ECT
40	Unipolar depressive disorders	Low	ECT machines
41	Unipolar depressive disorders	Middle	ECG
42	Unipolar depressive disorders	High	Technical information is available
43	Cataracts	Low	Spare bulbs, probes and some accessories are often not easy to procure
44	Cataracts	Low	Surgical microscope
45	Cataracts	Low	Phacoemulsification YAG laser
46	Cataracts	Low	Information for procurement and maintenance of Keratometer, A scan, Surgical equipments are not readily available
47	Cataracts	Low	We are using phacoemulsification machine, If some defect comes, we are unable to repair, and we have problem for services similarly, for operating microscope, if some defect comes, we are unable to repair as well as we have problem for services
48	Hearing loss, adult onset	Low	Tympanometer, Acoustic reflex, Auditory Brainstem Evoked Response, OAE, Operating Microscope, Micro Surgery equipment
49	Hearing loss, adult onset	Low	Audiometers, Tympanometers, ABR, AOE
50	Hearing loss, adult onset	Middle	Audiometer & Tympanometer maintenance and calibration, Hearing aids repair, ear protector procurement
51	Hearing loss, adult onset	Middle	Auditory Brainstem Response (ABR) machines
52	Hearing loss, adult onset	High	Hearing aids
53	Hearing loss, adult onset	High	Hearing aids
54	IHD	Low	Stem Cell Therapy Intravascular ultrasound imaging (IVUS)
55	IHD	Middle	Image Software, new lab. biomarkers and devices. Robotic Devices
56	CVD	High	Standards for quality control and maintenance of large capital equipment and machines, such as MRI, CT and Angiography, are not widely recognized
57	COPD	Low	Mechanical ventilators
58	COPD	Low	ABG
59	COPD	Low	Use & Interpretation of Spirometry, Mechanical ventilation
60	COPD	Low	Spirometers, Oxygen concentrators, Pulse Oximeter, In-check-dial, CPAP etc.
61	COPD	Middle	Non invasive ventilation bilevel positive airway pressure(BiPAP for home care)
62	COPD	Middle	Antitrypsin deficiency screening test, carbon monoxide transfer test
63	COPD	Middle	Non invasive ventilation Lung transplantation
64	COPD	High	Technical information is available in most of medical devices.
65	Road traffic accidents	Low	Ventilators
66	Road traffic accidents	Low	Anaesthetic equipment. Ventilators.
67	Road traffic accidents	Middle	Electroshock device
68	Road traffic accidents	Middle	Anaesthesia equipment
69	Road traffic accidents	High	Prosthesis

a Comments in the tables were imported verbatim from the survey. Efforts have been made to clarify responses but be aware that in some cases, clarification of terms or ideas was not possible.

Table B. Comments on question 207 – *Please give examples of medical devices used in the management of disease where training is needed for proper use and is not available* – by disease and HDI

#	Disease	HDI level	Comments by respondents
1	Tuberculosis	Low	LED Fluorescent microscopes are more sensitive, but staff requires training to maintain the specificity of Ziehl Nielsen (ZN) microscopy
2	Tuberculosis	Low	Modern TB diagnosis
3	Tuberculosis	Middle	Bactec system
4	Tuberculosis	Middle	Training for all medical devices is available
5	Tuberculosis	Middle	Drug susceptibility test
6	Tuberculosis	High	To my knowledge, there are no device or equipment for which the information, education and training is not available in Switzerland
7	HIV/AIDS	Low	Flow cytometers Clinical chemistry analysers Haematology analyser
8	HIV/AIDS	Low	Gene sequencing and viral load testing
9	HIV/AIDS	Low	Automates de numération de CD4
10	HIV/AIDS	Middle	CD4 count and viral load testing device
11	HIV/AIDS	Middle	It is critical needed for Lab training for QA/QC and right operation, but a few training are conducting in country D
12	Diarrhoeal	Low	Bedside measurement of serum/plasma electrolytes; CPR equipment and techniques; Intra osseous infusion (needle and methods); Gluco check machine
13	Malaria	Low	May not be available in language necessary (e.g. for rapid diagnostic tests (RDTs), microscopy)
14	Malaria	Low	1: Polymerase chain reaction (PCR) technology for identification of malaria parasites 2: Measurement of anti malarial drugs in blood
15	Malaria	Low	Malaria Microscopy; Malaria Rapid diagnostic tests (Training on basic principles and Quality Assurance)
16	Lower respiratory infections	Low	Equipment for sputum culture
17	Lower respiratory infections	Low	Spirometer Diagnosis of atypical pneumonia
18	Lower respiratory infections	Low	Laboratory of sputum culture analysis
19	Lower respiratory infections	Middle	Spirometry
20	Perinatal conditions	Low	Incubator, Infant warmer, Resuscitation bags, oximetry, phototherapy, CPAP and ventilation
21	Perinatal conditions	Low	Bilirubin and other lab equipments and incubator use and maintenance
22	Perinatal conditions	Low	Incubator, pulse oximeter, infusion pump
23	Perinatal conditions	Low	Nasal CPAP training Parenteral Nutrition Open and closed incubator care Anterior fontanel ultrasonography Resuscitation training (availability is still scratchy)
24	Perinatal conditions	Middle	At tertiary centres training is available but not at other facilities. From my position I cannot be more specific
25	Perinatal conditions	Middle	Ventilators, blood gas machines
26	Perinatal conditions	Middle	Ventilators, blood gas machines
27	Malignant neoplasms	Low	Lobectomy, pneumonectomy, extended resection equipment, upper GI endoscopy
28	Malignant neoplasms	High	The interpretation and or guidelines for diagnostic devices is lacking
29	Diabetes	Low	It's more that the equipment is not available because of the cost. If the equipment was available, then the training may be there in-country as well. I don't see training or communication materials as the main problem. For instance n Papua New Guinea and a number of other countries where we assist, blood glucose testing using meters and strips is prohibitively expensive for patients and often unavailable even in health centres. This is because of cost. Yes, teaching does need to be given where the machines are available, but that can usually be done OK. For HbA1c testing, it is the cost of the tests which is the problem - machines lie idle as the hospital can't afford the cartridges. Yes maintenance can be a problem with these as well, but we do have access to international advice with this. For dialysis, it's too expensive, so there is no training by definition
30	Diabetes	Low	A1C meters Photocoagulation machines, Dialysis machines, cardiovascular/radiological assessment machines (echography, MRI, CT Scans
31	Diabetes	Low	Glycosylated haemoglobin
32	Diabetes	Middle	HbA1c device
33	Diabetes	High	Many people with diabetes are just provided with blood glucose meters but are not trained in how to use them properly. Training for very technical diagnostic and assessment equipment will be required by health-care professionals using it. Such training opportunities vary across the United Kingdom
34	Unipolar depressive disorders	Low	ECG
35	Unipolar depressive disorders	Low	Counselling and cognitive behavioural therapy
36	Unipolar depressive disorders	Low	ECT

#	Disease	HDI level	Comments by respondents
37	Unipolar depressive disorders	Low	Good clinical flowcharts for diagnosis and management to be used by primary care physicians in low-income countries
38	Unipolar depressive disorders	Low	ECT machine
39	Unipolar depressive disorders	Low	ECT and computerized CBT
40	Unipolar depressive disorders	Middle	ECG
41	Unipolar depressive disorders	High	ECT, TMS, DBS
42	Cataracts	Low	Phacoemulsification machines, Laser machines and Fundus assessment equipments
43	Cataracts	Low	Phacoemulsification
44	Cataracts	Low	Phacoemulsification machine surgical instrument
45	Cataracts	Low	Phacoemulsification YAG laser
46	Cataracts	Low	Phacoemulsification machine, Keratometry and A scan. Equipments are not available in the public sector
47	Cataracts	Low	Yes, in phacoemulsification surgery. Maintenance of operating microscope, Slit Lamps, ophthalmoscopes (both type). Vitrectomy Machine for Management of complication
48	Cataracts	Middle	In use of phacoemulsification device, biometry equipment
49	Cataracts	Middle	Training in phacoemulsification is not readily available and limited
50	Cataracts	High	Phako training is available in limited time and in special locations.
51	Hearing loss, adult onset	Low	Audiometer, Tympanometer, Auditory Brainstem Evoked Response, OAE, Operating Microscope, Micro Surgery equipment, Gromet insertion tube
52	Hearing loss, adult onset	Low	ABR, otoaucoustic emissions (OAE)
53	Hearing loss, adult onset	Middle	Hearing aid fitting, only performed by manufacturers and sales technicians Tympanometer proper use Cochlear implant training only in private sectors and abroad
54	Hearing loss, adult onset	Middle	Hearing aid fitting and adjustment
55	Hearing loss, adult onset	High	Hearing aids
56	Hearing loss, adult onset	High	Cochlear Implants
57	IHD	Low	IVUS
58	IHD	Middle	Cardiac assist devices. Robotic Devices. new image software
59	CVD	High	There are inconsistent performance standards, in general, where interventional stroke treatment with catheters, balloons, clot retrieving devices and thrombolytics are concerned
60	COPD	Low	Advanced mechanical ventilators
61	COPD	Low	Arterial blood gas (ABG)
62	COPD	Low	Spirometry Mechanical ventilation Lung volume reduction surgery (LVRS surgery)
63	COPD	Low	Spirometry is the best example for the same
64	COPD	Middle	Non invasive ventilation
65	COPD	Middle	The technique of inhaler and soaker use. How to perform reliable spirometry tracing and interpret
66	COPD	Middle	Blood gas analysing, Spirometer, Non-invasive ventilator
67	COPD	Middle	1) Non invasive ventilation!
68	Road traffic accidents	Low	Ventilators, ultrasound machine, central lines, R heart catheterization
69	Road traffic accidents	Low	Training is not entirely lacking, but it is inadequate. Also, some training needs to be in form of support supervision and apprenticeship, not people going off to a course, and chalking it up as done. This is true of all equipment which gets updated, or new versions come, but the people trained on the use the old types have to learn on the job. This may be true for a whole range of equipment, from anaesthesia, to Ultrasound, to endoscopes, etc.
70	Road traffic accidents	Middle	Electroshock device
71	Road traffic accidents	Middle	Refer WHO Generic Emergency Essential Equipment in the WHO IMEESC toolkit

Table C. Comments on question 501 – *Medical devices which could have high impact in five years' time in countries whose income level you have chosen as a reference* – by disease and HDI level

#	Disease	HDI level	Comments by respondents
1	Tuberculosis	Low	Point of care TB diagnostics, with ability to diagnose HIV-associated and drug-resistant TB in addition to drug-susceptible TB disease
2	Tuberculosis	Middle	Laboratory TB diagnostics (ELISA, PCR etc.) Communication devices HCW-patient Air-flow devices
3	Tuberculosis	Middle	Laboratory equipment
4	Tuberculosis	High	surgical units for operation of severe forms of TB, like MDR-TB Oxygen for patients with respiratory failure due to TB
5	Tuberculosis	High	Interferon Gamma Release Assay (IGRA)
6	HIV/AIDS	Low	HIV test kits Medical devices for diagnosing all forms of TB (latent, active, MDR and XDR TB) CD4, PCR, Viral load machines. Haematology analysers including, Full blood count, Liver function, Renal function. Safe injection and infection control
7	HIV/AIDS	Low	CD4 machines Viral load machines HIV resistance monitoring Chemistry analysers
8	HIV/AIDS	Low	Automates de comptage des CD4 pour le niveau intermédiaire; Automates d'hématologie pour le niveau intermédiaire; Automates de biochimie pour le niveau intermédiaire
9	HIV/AIDS	Low	Sequencer for HIV resistance testing
10	HIV/AIDS	Middle	drug resistance testing device
11	HIV/AIDS	Middle	HIV drug resistant testing, TB liquid rapid culture, HCV/HBV viral load testing.
12	Diarrhoeal	Low	In the reference, lox-income country, the following devices are needed: 1. Cholera cot 2. High-grade plastic sheet for cholera cot 3. Weighing scale 4. Graduated stool collection buckets 5. Bowls for collection of vomit 6. Paediatric u
13	Malaria	Low	RDTs Microscopy Bedside DNA detection PCR
14	Malaria	Low	Malaria diagnostic services will have a greater impact in directing treatment policies and eventually in disease elimination.
15	Malaria	Low	Malaria Rapid Diagnostic Tests (pLDH & HRP2). This is very important due to the electricity challenge and inadequate capacity to undertake microscopy tests; Equipment for measuring blood/plasma levels of anti malarial medicines (in secondary and tertiary he
16	Lower respiratory infections	Low	1. RAPID DIAGNOSTICS to reliably identify sensitivity of the infectious agent 2. RAPID DIAGNOSTICS with high specificity and sensitivity to diagnose and confirm Lower Respiratory Tract Infections
17	Lower respiratory infections	Low	Microscope Equipment for sputum culture
18	Lower respiratory infections	Low	Spirometry Diagnosis of pneumonia
19	Lower respiratory infections	Low	The lab. equipment for research of sputum culture Oxygen concentrator Non-invasive ventilation Spirometry
20	Lower respiratory infections	Middle	CT scan X-ray Bronchoscopy c-reactive protein (CRP) Procalcitonin
21	Lower respiratory infections	Middle	Equipment for mechanical ventilation in city hospitals; Spirometer Pulse oximeter
22	Lower respiratory infections	Middle	Oxygen supply Non invasive mechanical ventilation
23	Lower respiratory infections	Middle	Non invasive ventilator support and perfect monitoring bedside bronchoscopes
24	Lower respiratory infections	Middle	Non-invasive ventilator (in some cases)
25	Perinatal conditions	Low	Resuscitation Bags, Infant Warmers, Oximetry, Incubators, Phototherapy, CPAP and Ventilation
26	Perinatal conditions	Low	All the devices mentioned are low cost but effective equipments which could have high impact to reduce the current level of high neonatal deaths
27	Perinatal conditions	Low	Pulse oximeter

#	Disease	HDI level	Comments by respondents
28	Perinatal conditions	Middle	Since the list is a mixture of instruments, supplies to equipment such as oxygen delivery I will not attempt to make a guess. However, the major difference can be achieved if more babies are born healthier, e.g. maternal complications treated earlier and better.
29	Perinatal conditions	Middle	Continuous positive airway pressure (cpap) Long lines
30	Perinatal conditions	Middle	Incubators, CPAP machines, Syringe pumps, Infusion pumps, Ventilators, Double phototherapy units/fiber optic (Bili) Blankets, Bilirubinometers, Blood gas machines
31	Perinatal conditions	Middle	Pulse oximeter, hearing screen equipment, cooling for asphyxia
32	Perinatal conditions	High	Self-inflation resuscitation bag Resuscitation face-mask Oxygen supply device and oximeter Suction apparatus Radiant warmer IV line and infusion set Phototherapy lamps and eye patches Gastric tube
33	Malignant neoplasms	Low	Traditional radiology (needs to be improved) + fine needle aspiraton (FNA) biopsy CT scan Flexible upper endoscope
34	Malignant neoplasms	Middle	Pet Scan
35	Malignant neoplasms	High	Increasing number of therapies are becoming available; many are however only effective in a subset of patients making devices that predict the most effective treatment /combination of treatments highly desirable
36	Malignant neoplasms	High	PET Endoscopic mucosal resection (EMR)
37	Diabetes	Low	1. Insulin pump 2. Inhaled insulin device 3. continuous glucose monitoring (cgms)
38	Diabetes	Low	Inexpensive blood glucose test strips (currently test strips are $0.50-$1 each in the 17+ countries that the International Diabetes Federation Program operates in. This is prohibitive for almost all patients and even for many health centres.
39	Diabetes	Low	Simply blood glucose monitoring machines More automated blood chemistry machines
40	Diabetes	Low	Glucometers and Insulin pens
41	Diabetes	Low	Glycosylated haemoglobin Laser Fundal photography Foot examination instruments Cardiovascular risk assessments
42	Diabetes	Middle	Simple tests for carotid intima-media thickness
43	Diabetes	Middle	Insulin pumps
44	Diabetes	High	Devices for telemedicine assistance Wearable artificial pancreas Islet transplantation Robotics for amputated legs Devices for early screening of complications
45	Diabetes	High	24-hour blood pressure and blood glucose self-monitoring. Insulin pump devices and linked blood glucose monitoring
46	Diabetes	High	Long term continuous glucose monitoring Closed loop insulin infusion pumps
47	Unipolar depressive disorders	Low	ECG, Assistive products for training basic skills such as physical, speech, and other therapies, ECT machine
48	Unipolar depressive disorders	Low	Only more information
49	Unipolar depressive disorders	Low	ECT machine Main impact on these disorders will be in service and personnel development
50	Unipolar depressive disorders	Low	No specific devices apart from diagnostic flowcharts. In general it will help if basic devices such as stethoscopes will be available because they will help to improve diagnosis in general
51	Unipolar depressive disorders	Low	Palmtop and web-based technology to facilitate integrated diagnoses of depression along with other chronic diseases; promote use of evidence-based guidelines for self-management and physician interventions; and support of continuing care and adherence
52	Unipolar depressive disorders	Low	Tele-Psychiatry ECT machines Computerized cognitive behavioural therapy (CBT), Diagnostic instruments Management protocols
53	Unipolar depressive disorders	Middle	I do not anticipate anything different compared to now.
54	Unipolar depressive disorders	High	Clinician guided Computerized Cognitive behaviour therapy via the web is very effective (ES~1.0, www.climateclinic.tv) but no mechanism is yet in place to pay from health insurance. We need a paradigm shift
55	Unipolar depressive disorders	High	Trans cranial magnetic stimulation (TMS)

#	Disease	HDI level	Comments by respondents
56	Cataracts	Low	Cataract surgical sets Crescent Knives and angle bevel angled knives for Small incision Cataract Surgery Phacoemulsification Machines Yag Lasers, Diode Lasers Autorefractor Keratometers A/B Scans Funduscopy equipments Chart Projectors Operating microscope
57	Cataracts	Low	Phacoemucification Various types of intraocular lenses (iols) Vitrectomy machines
58	Cataracts	Low	Phacoemulsification machine Surgical microscope
59	Cataracts	Low	Intraocular lens
60	Cataracts	Low	Vitrectomy machine, modern operating microscopes, A scan, Keratometer, Slit lamp, Phacoemulsification machine, Equipment for paediatric anaesthesia
61	Cataracts	Low	1. Operating microscope 2. Slit lamp 3. Intraocular lens 4. Medicines 5. Glasses 6. Low vision devices 7.Biometry machine 8. USG machine
62	Cataracts	Middle	Phacoemulsification machines New design intraocular lenses
63	Cataracts	Middle	Equipment to perform phacoemulsification Biometry Intraocular lenses (foldable with injectors)
64	Cataracts	High	Microscopes Phacoemulsification machines Surgical equipment
65	Cataracts	High	Phako technique with very small incision and multi focal intraocular lenses
66	Hearing loss, adult onset	Low	Tympanometer Screening and Clinical Audiometer Oto Acoustic Emission (OAE) Hearing aid
67	Hearing loss, adult onset	Low	Auditory Stady State response (ASSR)
68	Hearing loss, adult onset	Middle	High quality low-cost behind-the-ear hearing aids with AGC or PC for cochlear deafness in genetic deafness adult onset, as well as presbycusis (ageing). Affordable FM hearing aids for students Cochlear implants made available for public setting
69	Hearing loss, adult onset	Middle	Hearing aids Cochlear implant devices intelligent hearing protector
70	Hearing loss, adult onset	High	Behind the ear (BTE) hearing aids Cochlear implant
71	Hearing loss, adult onset	High	Easy-to-use software in upgrading the fitting of hearing aids small cheaper computers to make clinics more mobile
72	Hearing loss, adult onset	High	New Hearing aids
73	Hearing loss, adult onset	High	For example, digital hearing aids, cochlear implants
74	IHD	Low	IVUS Electrophysiology Laboratory
75	IHD	Middle	New image devices. Cardiac assist devices. Lab equipment for new cardiac biomarkers. robotic devices
76	IHD	Middle	Echo cardiography 3D & 4D; Equipment for CT angiography (128 slices & beyond); New types of stents; Stem Cell therapy; Percutaneous valve replacement
77	CVD	High	Handheld device for determining haemorrhage from ischaemic stroke
78	CVD	High	Effective intravascular clot extractors Drug eluting stents High-density aneurysm treating stents
79	COPD	Low	Spirometer Blood gas analyser Non invasive ventilator Oxygen concentrator
80	COPD	Low	Spirometry, ABG
81	COPD	Low	Spirometer Nebulisers Arterial blood gas analyser Ventilator
82	COPD	Low	Spirometers, blood gas analysers, MRI
83	COPD	Middle	Non invasive ventilation for home care Liquid oxygen for home
84	COPD	Middle	Oxygen extractors for home treatment with oxygen. Liquid oxygen for portable devices for exercise. Non invasive ventilation devices

#	Disease	HDI level	Comments by respondents
85	COPD	Middle	1) Non-invasive ventilators 2) Lung transplantation 3) Portable oxygen equipment for long-term oxygen supply
86	COPD	High	Spirometers which are easy to use at desk-side by GP and para medics and less expensive for wider use in daily practice. Spirometry is critical to find out early phase COPD.
87	Road traffic accidents	Low	Airway equipment, ventilators, central lines, ultrasound, blood products
88	Road traffic accidents	Middle	Mechanical ventilators, dialysis units
89	Road traffic accidents	High	Interventional radiology to diagnose and treat bleeding sources by endovascular procedures MRI scan near or in the emergency department
90	Road traffic accidents	High	All medical devices mentioned in your initial questions are important and it is difficult to be put in order of urgency
91	Road traffic accidents	High	Telemetry More EMS ambulances Preventive devices for road traffic accidents (radars, signs) Equipment for data-banking and analysis
92	Road traffic accidents	High	I believe they are available. It is strongly related to the special interest of a hospital. There is a tendency to special trauma units (which idea I support)
93	Tuberculosis	Middle	X-ray (mobile)
94	Tuberculosis	Low	Point of care (POC) diagnostics that are cheap, sensitive and specific, POC diagnostics of markers of treatment response; POC diagnostics of drug resistance
95	Road traffic accidents	Middle	Oxygen, Anaesthesia machine, Diathermy, Suction apparatus

Table D1. Comments on question 502 – *If you have any specific comments, remarks or answers on any questions, will you please indicate them in the box provided, and please include the question number(s)* – by disease and HDI level

#	Disease	HDI	Comments by respondents on the survey methodology
1	Tuberculosis	Low	Prequalification system for TB diagnostics urgently needed
2	Tuberculosis	High	Currently, the needs are covered in Switzerland and are expected to decrease, as the total number of TB is on the decline. Late sequelae are extremely rare and should remain a rarity
3	HIV/AIDS	Low	Some of the equipment discussed is not specific to the laboratory and therefore I tried best to respond e.g. CT or MRI
4	HIV/AIDS	Low	Le renforcement des systèmes de santé des pays en développement est primordial pour le succès de la lutte contre le SIDA. Cela passé par l'élaboration de plan de développement sanitaire répondant aux priorités nationales, la formation des personnels, le renforcement des infrastructures, le renforcement des équipements, la motivation des personnels
5	HIV/AIDS	Low	Some of the medical devices are found only in reference centres; There is a need for more biomedical engineers to cope with the demand for this services
6	HIV/AIDS	Middle	The information of HIV/AIDS treatment and care model is very important
7	Malaria	Low	In low-income countries, there are wealthy, well-equipped hospitals (e.g. private). Therefore, difficult to answer some questions. e.g. PCR is available, but only for a small minority of patients. Same applies to many of the questions
8	Malaria	Low	Question 201. The devices available for the management of malaria depend on the health facility. Most primary health facilities, which form an important level in the health system, do not have the essential devices. What obtains from one facility to another depends on the operational policy within the context of the local political/administrative set-up. At the secondary and tertiary level, however, these materials should be available but in most of the cases are not. Again, the availability of these devices for the management of malaria in the secondary and tertiary level depends on the management system in place and cannot be generalized. Question 501: Information required for the procurement of malaria rapid diagnostic tests are required urgently as well as their suitability in the management of malaria in the local systems. These devices are very useful in low-income countries and how a policy change to the use of these devices are an important factor to be considered. This will be followed with the development of quality assurance to maintain the confidence of its use in the system
9	Lower respiratory infections	Middle	Increasing role of physiotherapy
10	Perinatal conditions	Low	Level of care must be determined efforts should be started to maintain those levels in the various health facility
11	Perinatal conditions	Low	The most important need is birth spacing, good quality obstetric care, human resources with quality, motivated staff and enough budget
12	Perinatal conditions	Middle	Lot of equipment is donated and we would like to have principles for donations - similar to donations of medicines
13	Perinatal conditions	Middle	Maintenance of available devices must improve
14	Perinatal conditions	Middle	Maintenance of the equipment in our units is always a problem. Most of the technicians employed by the agents during their guarantee period have a very superficial knowledge. Some of them learn about the machines after getting them in-country. Equipment sits in the departmental stores for months and at times we receive it when it is out of warranty. After maintenance, it is handed over to the health ministry. Due to lack of funds and experienced personnel repairs are delayed for long periods. Getting consumables for blood gas machines, etc. is another problem that we have to face
15	Perinatal conditions	Middle	We do have equipment for proper care but number and distribution is not very good. Need for newborn resuscitation training still needed urgently
16	Diabetes	Low	See previous comments
17	Diabetes	Low	There should have been an additional choice of national availability because availability depends on where you work and I work in a Teaching Hospital. Most rural and semi urban and distant urban (from capital city) local health institutions in the country do not have all the equipment on your lists
18	Diabetes	Low	Make the devices accessible, affordable and serviceable
19	Diabetes	High	Although the tools are available, there is variation in how and who can access them according to where they live and funding levels. Therefore being available does not mean that everyone has equal access to them
20	Unipolar depressive disorder	Low	In Ethiopia, management of unipolar depression is mainly provided in a tertiary care level however few primary and secondary care institutions manage depression
21	Cataracts	Low	Low uptake of cataract surgery is related to Ignorance, poverty, poor accessibility, and skewed manpower distribution or low manpower. How can the awareness be increased and more of the underprivileged helped?
22	Cataracts	Low	The Vitrectomy machine if available in Nigerian hospitals would revolutionize the outcome of cataract surgery in children. Without it the outcome would remain below acceptable standards
23	Cataracts	Low	1. Phacoemulsification machine 2. Operating Lens 3. Slit Lamp 4. Ophthalmoscope 5. Biometry 6. USG Machine
24	Cataracts	Middle	Good insurance system to finance cataract surgery is necessary to motivate hospitals and surgeons for good training and high volume surgery
25	Hearing loss, adult onset	Low	WHO should develop General technical information needed for procurement/maintenance/daily use Guideline for each device based on countries experience (Technical Consultation Meeting?)
26	Hearing loss, adult onset	Middle	It's not just the availability of devices but training in its proper use and patient education is important.
27	Hearing loss, adult onset	High	We need to know the size of the problem first
28	IHD	Low	We should have the IVUS & Electrophysiology Laboratory
29	COPD	Low	We need Global Alliance against Chronic R espiratory Diseases GARD programme to be expanded in whole country for exact data collection and medical staff training process regarding COPD
30	COPD	Middle	Quality control of spacers manufactured locally need to be considered. And rehabilitation is not of use
31	Road traffic accidents	High	Even though the survey was on devices/equipment, it would be encouraging to explore and look into human resources, capacity building, and knowledge sharing and transfer

Table D2. Comments on Q502 – *If you have any specific comments, remarks or answers on any questions, will you please indicate them in the box provided, and please include the question number(s)* – by disease and HDI level

#	Disease	HDI	Comments by respondents on the contents of the survey
1	Diarrhoeal	Low	The questionnaire relates to the public sector, and the availability of medical devices vary widely by their types. The responses have been constructed excluding those available at large academic hospitals.
2	Lower respiratory infections	Low	Question 203 is MISSING from your questionnaire. My comment is "Nitric Oxide Measurement"
3	Perinatal conditions	Low	The survey form has been filled keeping in view, where majority of deliveries take place
4	Perinatal conditions	Low	There are some questions which has got responses other than 'yes', 'no' and 'NA'
5	Perinatal conditions	High	Re. question 501:
6	Diabetes	Low	implementation of breastfeeding, rooming-in and hand washing
7	Diabetes	High	In question 501, we have mentioned the existing devices which will have wider impact in 5 years' time
8	Unipolar depressive disorders	Low	Some of the questions seems obvious for a high-income country and might not give the real picture of what is still needed also in these countries in terms of organisation of care. The reaction of this system to the answers to the question 204 and 206 seems to go the other way around it should go
9	Unipolar depressive disorders	Middle	This is not the right kind of survey for depressive disorders
10	Hearing loss, adult onset	Middle	Treatment of depression does not require specific medical devices
11	COPD	Low	208-2: although available, very minimal and only in larger cities
12	COPD	Low	Is there a mistake in the question 206? COPD instead of DIABETES?
13	COPD	High	Question 201_18: Do you mean Surgical equipment to perform lung transplantation? Question 206: Do you mean ----medical devices to manage Diseases/COPD and that-----?
14	Tuberculosis	Low	201-9: can add serum albumin or total protein, since nutritional state is important to keep ventilation well
15	Road traffic accidents	Middle	Some questions are difficult to follow, I hope I understood the meaning of the questions