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World Health Organization

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

August 2010

Contents

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[j,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