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MEDICAL DEVICES: MANAGING THE MISMATCH

An outcome of the Priority Medical Devices project

Methodology briefing paper

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Contents

This methodology paper was developed under the primary authorship of Josée Hansen with editing by Rhona MacDonald. The literature review was developed under the primary authorship of Warren Kaplan, with the help of Susan Mottram and colleagues at the Health Sciences Library, Leeds University. The scoping search was carried out by Hristina Petkova. Thanks are also due to Benjamin Schanker and Dima Samaha for providing valuable contributions in editing, writing, and research.

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The named authors alone are responsible for the views expressed in this publication.

Introduction

This briefing paper summarizes the methodology used by the *Priority Medical Devices (PMD)* project team for the research and subsequent content published in the report, *Medical Devices: Managing the Mismatch.* This briefing paper outlines the main steps undertaken by the *PMD* team and points to other sources of more detailed information regarding the methodology used (see the annexes of this paper and background papers 1 and 2).

Background to PMD Project structure

The *PMD* project was established by WHO in 2007 with financial support from the Ministry of Health, Welfare and Sport of the Netherlands. The project was overseen by an Advisory Group of specialists in different areas of health care and medical devices. The writing of the report, *Medical devices: managing the mismatch* was supervised and reviewed by a Steering Group of medical devices specialists, expert clinicians, experts in regulation and renowned academics.

Aims and Objectives of the PMD Project

The *PMD* project aimed at identifying gaps in the availability of medical devices and obstacles that might be hindering the full use of medical devices as public health tools. A second objective was the development of a methodology for identifying the medical devices needed to meet global public health needs. A third objective was to propose a possible research agenda for exploring how the gaps could be resolved and the obstacles removed.

As the project progressed, however, the following findings suggested that a change in the original objective of the project was necessary: 1) there are many medical devices available but not the most appropriate ones; 2) there are few gaps in the availability of medical devices on the market. These unanticipated findings prompted a project shift in focus to 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.

Methodologies used: purpose and rationale

Annex 1 describes in detail each step taken by the PMD team. The purpose and rationale for the methodologies used are outlined below.

Taking a health needs approach to medical devices

A major objective of the *PMD* project was to develop an approach to choosing medical devices that is based, first and foremost, on the need for a positive health outcome. The *PMD* project team devised a stepwise approach to meeting public health needs. The first step in this approach identifies the most important public health problems. For the purposes of the *PMD* project, this meant mapping the high-burden diseases according to the *Global Burden of Disease (GBD) and Risk Factors*. The second step identifies how these health problems are best managed. To achieve this second step, the *PMD* project analysed relevant clinical guidelines. The third step links the results of the first two steps and produce a list of medical devices needed for the management of the identified high-burden diseases. This step involves identifying the category of medical devices and then identifying the specific models of devices required to perform the necessary procedures.

In more detail

Following the mapping exercise to identify and map the high-burden diseases according to the *Global Burden of Disease (GBD) and Risk Factors,* the *PMD* project team selected relevant evidence-based clinical guidelines, developed to describe the management of 15 high-burden diseases, in order to identify the medical devices recommended for the management of a specific disease in clinical practice. Only clinical guidelines published after 2000 were included and selected separately for all 15 high-burden diseases and disabilities where the title referred to the disease or disability. WHO guidelines were selected, if possible. At the start of the project in 2007, WHO had developed guidelines for eight of the selected 15 high-burden diseases. For the purpose of the *PMD* project, medical devices were extracted from the 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.

All medical devices (or techniques that involve medical devices) identified in the selected clinical guidelines were included in an "Availability Matrix" that formed the baseline of medical devices needed to manage the disease. Medical devices were categorized as preventive, diagnostic, therapeutic and assistive devices, according to the stages of health care. For these four subcategories, a distinction was made between medical devices for general use (e.g. stethoscope or thermometer) and disease-specific medical devices. More detailed information on the steps involved is available in Background paper 1.

The methodology used in this 3-step approach, and the subsequent findings, guided the content chosen to include in the report. However, some other methods were used by the *PMD* project team to provide a more contextual, in-depth, and qualitative analysis.

Literature reviews

The *PMD* project team performed preliminary literature reviews to determine the extent to which information and outcomes of research on medical devices were publicly available. Then, an extensive literature review was conducted within the Ovid Medline, University of Leeds, and International Network of Agencies for Health Technology Assessment (INAHTA) database systems to evaluate past systematic reviews and meta analyses of clinical trials using medical devices for three of the high-burden diseases--cardiovascular disease, tuberculosis, and diabetes. The search strategy used for this literature review is described in Annex 2.

Pilot surveys

Two pilot surveys were devised and validated, one for countries and one for specialists, to gather quantitative and qualitative information about medical device gaps. In addition, expert focus groups, round-table discussions and individual consultations helped to provide valuable qualitative information.

Country surveys

Six countries were selected according to Human Development Index level. The questionnaire was sent to in-country WHO representatives who then forwarded the survey to the respective Ministry of Health and key health care-related associations in each selected country. The survey included questions around medical devices for three representative high-burden diseases: diabetes mellitus—an example of a noncommunicable disease; tuberculosis (TB) —an example of infectious disease; and road traffic accidents—an example of a condition for which early intervention could prevent long-term disability.

Specialist surveys

This country survey was adapted to form a specialist questionnaire that contained medical device-related questions on each of 15 high-burden diseases. This questionnaire was sent directly to appropriate specialists in each of the high-burden diseases. The specialist survey was designed to help identify any clinical problems associated with the medical devices recommended for each high-burden medical condition. The selected specialists were also encouraged to suggest clinical areas that may require further medical device research.

Purpose of the literature reviews and surveys

These specifically designed and validated questionnaires, combined with a comprehensive literature search and review, were used as the basis for identifying the evidence for, and experience of, medical device innovation, choosing and using

medical devices, and identification of the problems and challenges in these key areas, as well as possible ways of overcoming these barriers. Medical device activities were categorized in this way (i.e. medical device innovation and choosing and using medical devices) because these categories cover the processes and stages involved in the agenda to improve access to appropriate medical devices, and are directly or indirectly associated with the crucial 4 components—availability, accessibility, appropriateness, and affordability.

For a more detailed description of the pilot surveys, see Background paper 1.

Areas of note

Disability

Currently, no global burden of disability has been developed. Moreover, most clinical guidelines do not mention assistive products. In fact, the clinical guideline identified very few, if any, assistive products required to help functioning for those with the 15 high-burden diseases and disabilities. Therefore, to assess the assistive product gap, a different concept had to be used. The *PMD* project attempted to develop a linking methodological process that would help to identify assistive products needed by people with disabilities resulting from the selection of high-burden diseases. This process was complex and included a five step approach: 1) identification of 15 high-burden diseases by using the GBD; 2) description of ICD-10 and ICF as complementary systems; 3) bridging the GBD and ICF through core sets and functioning profiles; 4) delineating the ISO 9999; and 5) relating the ICF to the ISO 9999.

As a result, the project was able to bridge the 15 high-burden diseases to functions through ICF core sets. For those diseases where a core set did not exist, a functioning profile was developed. For a more detailed description of the methodology used, see Background paper 2.

An exercise in reality

The *PMD* project team devised an exercise that could be used as a prompt to the areas that researchers, medical device choosers, and users should consider and apply to any of these key medical devices. However, it must be noted that this exercise is not an exact science. After having performed a needs assessment according to the stepwise approach (see above) and identifying the key medical devices involved, the following 4 questions could be applied.

1. Is this medical device currently available?
2. Is it currently accessible?
3. Is it currently appropriate to the specific context?
4. Is it affordable?

A negative answer to any of these questions requires further investigation that can be worked through to ascertain the main contributing factors to the negative answer. It is then possible to formulate a potential research framework for identifying clinical, technological, and/or process and systems knowledge-gaps to best improve access to appropriate medical devices and best address public health needs.

The answers to some of the 4 key questions may depend on local factors, but there are likely to be some common areas that can be more universally addressed, especially in low-income settings, such as the need for developing a more appropriate designs, appropriate staff training programmes, and manageable maintenance systems.

The final methodology

One of the main objectives of the *PMD* project was to identify possible future areas of research which could help to improve access to appropriate medical devices. In order to do this, *PMD* project conducted a scoping search of the literature on recent or current research in the field of medical devices. The scoping search aimed to identify studies in the "pipeline" and to discover which medical devices are currently of scientific and developmental interest. Consistent with the overall methodology of this report, the scoping search was based on terms related to high-burden diseases and some cross-cutting themes (see annex 3 for the details of the search strategy for this scoping exercise).

To verify the findings from the scoping search, the *PMD* project team asked clinical experts from each of the 15 high-burden diseases to comment on the initial analysis. The *PMD* project team then drafted some possible areas of future research in each disease option which were reviewed by a second expert. These research areas are couched in terms of medical device availability, accessibility, appropriateness, and affordability.

Methodology limitations

There are several limitations associated with the methodologies used by the *PMD* project.

- Using global burden of disease estimates as an indication of public health needs for medical devices produces research priorities pertinent more to global than to regional or national priorities.
- As ongoing research is included in the scoping exercise, there is no evidence yet that the results of this research will bring therapeutic benefits.
- Using management of specific diseases as a starting point for determining future research needs excludes research needed on medical devices for general use, such as hospital beds, sterilizers, and operating lamps.
- The proposed research areas represent the result of a highly selective process and therefore do not cover all possible relevant research areas.
- Assessing the need for research in specific areas calls for knowledge about current ongoing research. Yet, in the notoriously competitive environment of medical device development, information about their R&D is rarely publicly available.
- A constraining factor in the preparation of the suggested research agenda has been the paucity in the clinical guidelines consulted, of specific medical devices required for recommended health-care pathways.
- Research on tools for the prevention of ill-health and disability is a vital need but beyond the scope of the suggested research agenda.

Conclusions

Despite the limitations of the methodologies used by the *PMD* project (as listed above), these methods were rationally chosen, robustly conducted, extensively reviewed, and have lead to pragmatic outcomes. The resources, background papers*, and reports developed from the *PMD* project will hopefully improve the use of medical devices, by facilitating their development and promoting their targeted use to address global health needs. But the work does not end here. As the report *Medical devices: managing the mismatch* shows, there is much more to be done to progress the access to appropriate medical devices agenda.

List of background papers

Hansen J et al. *A stepwise approach to identify gaps in medical devices (Availability Matrix and survey methodology)* [Background paper 1 of the Priority Medical Devices project]. Geneva, World Health Organization 2010 (WH0/HSS/EHT/DIM/10.1). (http://whqlidoc.who.int/hq/2010/WHO_HSS_EHT_DIM_10.1_eng.pdf

Bougie T et al. *Building bridges between diseases, disabilities and assistive devices: linking the GBD, ICF and ISO 9999.* [Background paper 2 of the Priority Medical Devices project]. Geneva, World Health Organization 2010 (WH0/HSS/EHT/DIM/10.2). (http://whqlidoc.who.int/hq/2010/WHO_HSS_EHT_DIM_10.2_eng.pdf

Tice JA et al. *Clinical evidence for medical devices: regulatory processes focusing on Europe and the United States of America* [Background paper 3 of the Priority Medical Devices project]. Geneva, World Health Organization 2010 (WH0/HSS/EHT/DIM/10.3) (http://whqlidoc.who.int/hq/2010/WHO_HSS_EHT_DIM_10.3_eng.pdf

Dankelman J et al. *Increasing complexity of medical technology and consequences for training and outcome of care* [Background paper 4 of the Priority Medical Devices project]. Geneva, World Health Organization 2010 (WH0/HSS/EHT/DIM/10.4) (http://whqlidoc.who.int/hq/2010/WHO_HSS_EHT_DIM_10.4_eng.pdf

Beenkens F et al. *Context dependency of medical devices* [Background paper 5 of the Priority Medical Devices project]. Geneva, World Health Organization 2010 (WH0/HSS/EHT/DIM/10.5). (http://whqlidoc.who.int/hq/2010/WHO_HSS_EHT_DIM_10.5_eng.pdf

Petkova H et al. *Barriers to innovation in the field of medical devices.* [Background paper 6 of the Priority Medical Devices project]. Geneva, World Health Organization 2010 (WH0/HSS/EHT/DIM/10.6). (http://whqlidoc.who.int/hq/2010/WHO_HSS_EHT_DIM_10.6_eng.pdf

Carlson D et al. *Trends in medical technology and expected impact on public health.* [Background paper 7 of the Priority Medical Devices project]/ Geneva, World Health Organization 2010 (WH0/HSS/EHT/DIM/10.7). (http://whqlidoc.who.int/hq/2010/WHO_HSS_EHT_DIM_10.7_eng.pdf

Kaplan W et al. *Future public health needs: commonalities and differences between high- and low- resource settings* [Background paper 8 of the Priority Medical Devices project]. Geneva, World Health Organization 2010 (WH0/HSS/EHT/DIM/10.8). (http://whqlidoc.who.int/hq/2010/WHO_HSS_EHT_DIM_10.8_eng.pdf

Annex 1: Summary of steps taken in the Priority Medical Devices project

Process step	Justification / Goal / Procedure	Responsible Participants	Resulting Documents	Additional outcomes, remarks and conclusions
Set objectives	Develop objectives of the overall *Priority Medical Devices* project	Ministry of Health of the Netherlands WHO	Project proposal	Formulated objectives: * develop a methodology to identify gaps * identify high priority medical devices * identify cross-cutting themes * identify possible barriers to medical device innovation * propose a research agenda
Collect existing information on medical devices	Literature search to identify information on medical devices	Project team of health-care professionals, trainees, and consulted specialists	*Report assessment of available information in the public domain on medical devices.* Geneva, World Health Organization, 2007 (WHO/EHT/07.1).	No additional remarks
Identify public health priorities for the 15 high-burden diseases	In general, a similar approach as the one used for the *Priority Medicines* project was taken with the understanding that less data may be available for medical devices and that the subject matter may be more complex or broad; similar to medicines, medical devices can be prioritized according to burden of disease (diagnostic and therapeutic devices)	WHO Advisory group meeting 2-3 July 2007	Project proposal Meeting report and list of participants	No additional remarks
Identify medical devices needed in the management of high-burden diseases	Literature search on three diseases (diabetes, TB and cardiovascular disease that would need many medical devices)	Dr Warren Kaplan, Boston University Project team of health-care professionals, trainees, and consulted specialists	Annex 2	Results indicated a general paucity of randomized controlled trials (RCTs) supporting clinical effectiveness of medical devices for the investigated disease. The exception of RCTs for drug eluting stents is noted. The approach was changed from searching for clinical evidence to identifying medical devices through using the clinical guidelines.
Investigate existing clinical	A clinical perspective taken as the	Project team of health-care	Hansen J et al. A stepwise	Stepwise approach developed to