



Development of medical device policies

WHO Medical device technical series





Research and development



Regulation



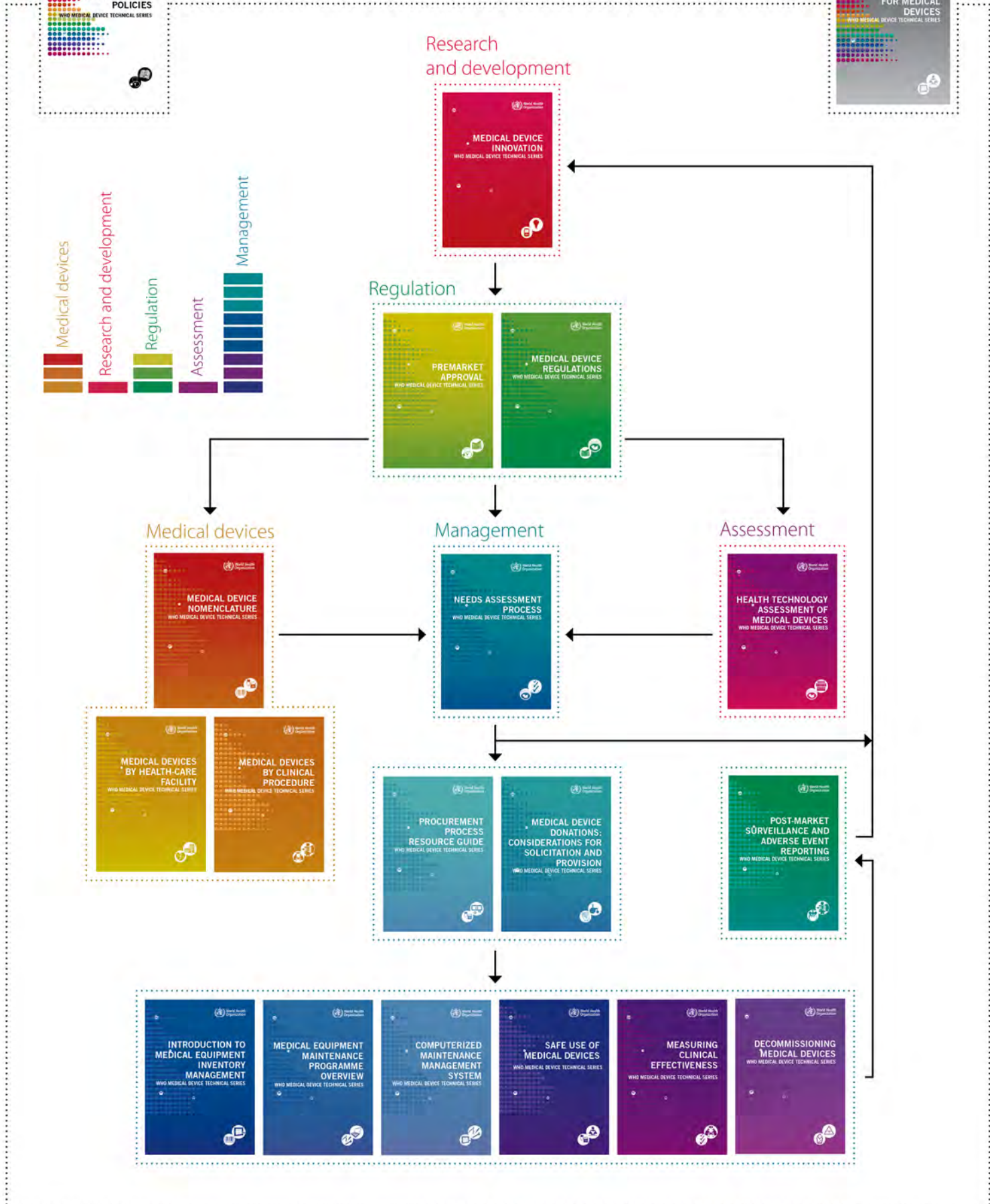
Medical devices



Management



Assessment



Development of medical device policies

WHO Medical device technical series



WHO Library Cataloguing-in-Publication Data

Development of medical device policies.

(WHO Medical device technical series)

1.Appropriate technology. 2.Equipment and supplies. 3.Health policy. I.World Health Organization.

ISBN 978 92 4 150163 7

(NLM classification: WX 147)

© World Health Organization 2011

All rights reserved. Publications of the World Health Organization are available on the WHO web site (www.who.int) or can be purchased from WHO Press, World Health Organization, 20 Avenue Appia, 1211 Geneva 27, Switzerland (tel.: +41 22 791 3264; fax: +41 22 791 4857; e-mail: bookorders@who.int).

Requests for permission to reproduce or translate WHO publications – whether for sale or for noncommercial distribution – should be addressed to WHO Press through the WHO web site (http://www.who.int/about/licensing/copyright_form/en/index.html).

The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted lines on maps represent approximate border lines for which there may not yet be full agreement.

The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by the World Health Organization in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

All reasonable precautions have been taken by the World Health Organization to verify the information contained in this publication. However, the published material is being distributed without warranty of any kind, either expressed or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall the World Health Organization be liable for damages arising from its use.

Design & layout: L'IV Com Sàrl, Le Mont-sur-Lausanne, Switzerland.

Contents

Preface	3
Methodology	4
Definitions	4
Acknowledgements	5
Declarations of interests	5
Acronyms and abbreviations	6
Executive summary	7
1 Introduction	8
2 Purpose	9
3 Policies, strategies, and action plans	10
4 Global health and medical devices	12
4.1 Global health today	12
4.1.1 Growing health inequities	12
4.1.2 Millennium Development Goals	13
4.1.3 Increasing burden of noncommunicable diseases	13
4.1.4 Medical devices in health systems	16
4.2 Global health agenda	16
4.2.1 Foundation for action: World Health Assembly resolutions	16
4.2.2 Collecting evidence on the use of medical devices	17
4.2.3 Global market for medical devices	18
5 Medical devices within the health systems of Member States	19
5.1 Prioritizing public health needs	19
5.2 National health policy and planning	21
5.2.1 Policy process	21
5.2.2 Planning	22
5.2.3 Policy management	22
6 Organizational systems for medical devices	23
6.1 General principles	23
6.2 System components	23
6.3 Organizational structures	26
6.3.1 Regulatory processes	26
6.3.2 Health technology assessment	29
6.3.3 Health technology management	29
6.3.4 Research and development (innovation)	30
7 Measuring progress: outcomes and indicators	31
7.1 Monitoring and evaluation in health systems	31
7.2 Indicators	31
7.3 Global status of medical devices: results of the baseline survey	32
8 Conclusion	37
References	38

Figures and tables

Figure 1.	National health policy framework	10
Box 1.	Elements of effective national health policies, strategies, and plans	11
Box 2.	Medical devices that address Millennium Development Goals 4, 5, and 6	14
Figure 2.	Number of deaths attributable to select noncommunicable and communicable diseases, 2004–2030	15
Figure 3.	Ten leading causes of disease burden, 2004 & 2030	15
Figure 4.	Linking the global health agenda to improve medical device access via national health plans	19
Figure 5.	Setting medical device priorities based on public health needs	20
Figure 6.	Six building blocks for health systems	21
Figure 7.	The medical device agenda within a national health policy	24
Figure 8.	The four phases of the medical device life-cycle	25
Table 1.	Characteristics of the phases within the medical device life-cycle	26
Figure 9.	Areas of implementation for health technology policies	27
Table 2.	Regulatory harmonization groups and regulatory authorities	28
Table 3.	Examples of health technology assessment agencies, networks, and international professional organizations	28
Table 4.	Examples of WHO collaborating centres on health technology management	28
Figure 10.	Monitoring and evaluation of health systems reform	31
Figure 11.	Core set of WHO indicators	32
Table 5.	WHO's strategic objective 11 and related indicators	33
Figure 12.	Distribution of countries with a national health technology policy	34
Figure 13.	Distribution of countries with a government unit responsible for the implementation of health technology policy	34
Figure 14.	Countries with a national list of approved medical devices for procurement or reimbursement by income level	35
Figure 15.	Distribution of countries with a national list of approved medical devices for procurement and reimbursement	35
Figure 16.	Distribution of countries that have a list of medical devices by health care facility or clinical procedure	

Preface

Health technologies are essential for a functioning health system. Medical devices in particular are crucial in the prevention, diagnosis, and treatment of illness and disease, as well as patient rehabilitation. Recognizing this important role of health technologies, the World Health Assembly adopted resolution WHA60.29 in May 2007. The resolution covers issues arising from the inappropriate deployment and use of health technologies, and the need to establish priorities in the selection and management of health technologies, specifically medical devices. By adopting this resolution, delegations from Member States acknowledged the importance of health technologies for achieving health-related development goals; urged expansion of expertise in the field of health technologies, in particular medical devices; and requested that the World Health Organization (WHO) take specific actions to support Member States.

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

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

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

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

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

Methodology

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

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

Definitions

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

Health technology: The application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of life.² It is used interchangeably with health-care technology.

Medical device: An article, instrument, apparatus or machine that is used in the prevention, diagnosis or treatment of illness or disease, or for detecting, measuring, restoring, correcting or modifying the structure or function of the body for some health purpose. Typically, the purpose of a medical device is not achieved by pharmacological, immunological or metabolic means.³

Medical equipment: Medical devices requiring calibration, maintenance, repair, user training, and decommissioning – activities usually managed by clinical engineers. Medical equipment is used for the specific purposes of diagnosis and treatment of disease or rehabilitation following disease or injury; it can be used either alone or in combination with any accessory, consumable, or other piece of medical equipment. Medical equipment excludes implantable, disposable or single-use medical devices.

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

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

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

Acknowledgements

Development of medical device policies was produced under the primary authorship of Adriana Velazquez-Berumen, WHO, Geneva, Switzerland with support from Yadin David, Biomedical Engineering Consultants, LLC, Houston, Texas, United States of America; Paul Rogers, WHO, Manila, Philippines; and Rhona MacDonald, Ross-Shire, United Kingdom as part of the Global Initiative on Health Technologies project funded by the Bill & Melinda Gates Foundation.

The draft was reviewed by Jennifer Barragan (WHO) and edited by Kai Lashley.

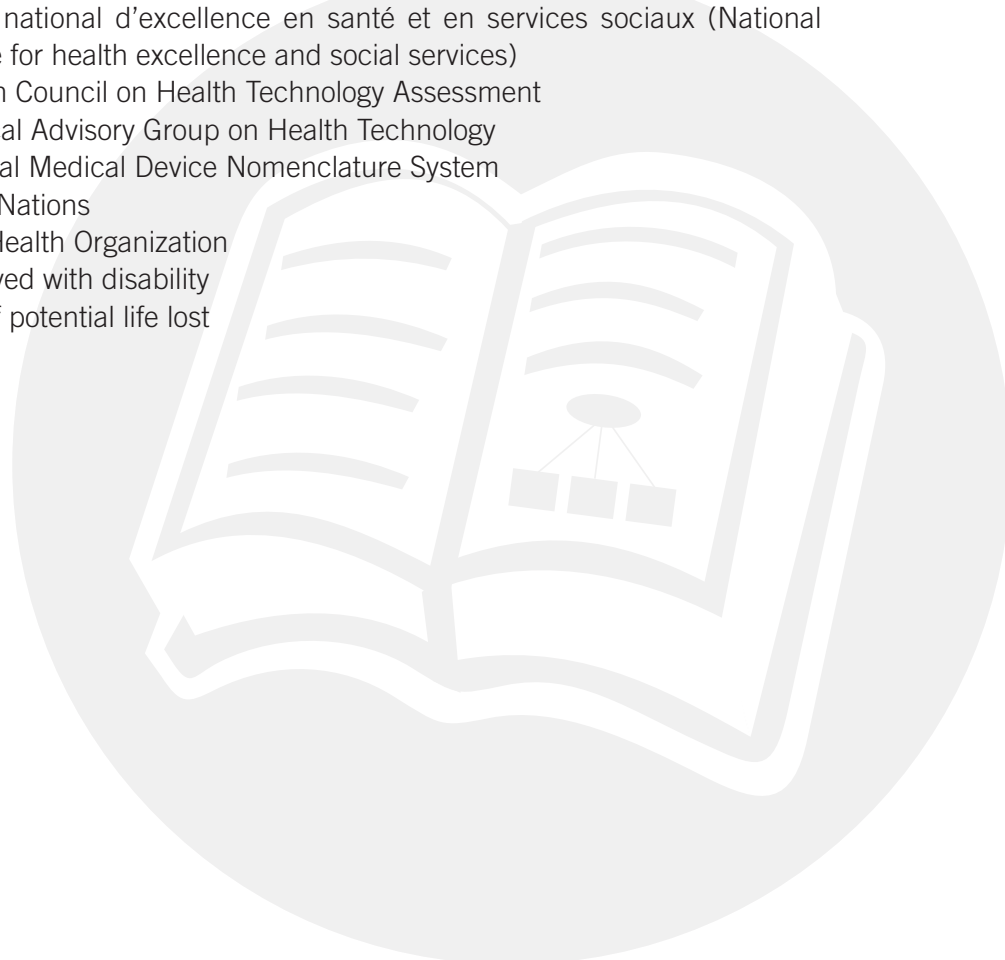
We would like to thank Karina Reyes-Moya and Gudrun Ingolfsson for administrative support throughout the development of this document.

Declarations of interests

Conflict of interest statements were collected from all contributors and reviewers to the document development. No conflicts of interest were declared.

Acronyms and abbreviations

AAMI	Association for the Advancement of Medical Instrumentation
AWHP	Asian Harmonization Working Party
CAHIAQ	Catalan Agency for Health Information, Assessment and Quality
CENETEC	Centro Nacional de Excelencia Tecnológica en Salud (National Center for Health Technology Excellence)
CMMS	computerized maintenance management system
DALY	disability-adjusted life year
EUnetHTA	European network for Health Technology Assessment
GBD	Global Burden of Disease
GHTF	Global Harmonization Task Force
GIHT	Global Initiative on Health Technologies
GMDN	Global Medical Device Nomenclature
MDG	Millennium Development Goal
NCD	noncommunicable disease
HITAP	Health Intervention and Technology Assessment Programme
HTAi	Health Technology Assessment international
HTM	health/health-care technology management
IEB	Instituto de Engenharia Biomédica, Universidade Federal de Santa Catarina (Biomedical Engineering Institute, Federal University of Santa Catarina)
INAHTA	International Network of Agencies of Health Technology Assessment
INESSS	Institut national d'excellence en santé et en services sociaux (National institute for health excellence and social services)
SBU	Swedish Council on Health Technology Assessment
TAGHT	Technical Advisory Group on Health Technology
UMDNS	Universal Medical Device Nomenclature System
UN	United Nations
WHO	World Health Organization
YLD	years lived with disability
YLL	years of potential life lost



Executive summary

When used within the context of a robust health system, medical devices improve health outcomes. Through such a system, medical devices can be effectively allocated based on the needs of a particular population. A health system, however, is only as good as the policies, strategies, and action plans that constitute it.

The World Health Organization (WHO) and its Member States recognized this in several World Health Assembly resolutions highlighting the importance of health technologies, particularly medical devices, to prevent, diagnose, treat illness, disease, and disability, and improve health and quality of life. Member States were urged to formulate appropriate national strategies and plans for assessment and management of medical devices; and WHO was requested to provide technical guidance to Member States in implementing policies on health technologies.

Policies create a framework through which to direct valuable resources. A national health policy framework includes a vision, a situation analysis, policy directions, strategies to overcome challenges, a policy implementation plan, and the leadership and governance required to achieve sustainability. When embedded within a national health policy, health technologies policies can be linked to other health systems components - financing, human resources, information, leadership and governance - that together address the needs of the target population and may result in better health outcomes.

Effective health technology policies address inequity as well as accessibility, affordability and availability of innovative and core medical devices required to target the health needs, particularly those that address the Millennium Development Goals and noncommunicable diseases. To do this the four phases of medical devices - research and innovation, regulation for device safety, assessment for better decision making, and comprehensive management - must be considered and adapted to the priority public health conditions, resources and settings.

Once the policies are compiled, organizational structures are required to implement the strategies and action plans contained therein. This includes a regulatory authority and regional and national institutions to optimally assess and manage health technology, with the support of specialized professionals in biomedical engineering and related areas. Monitoring and evaluation of the strategies, objectives or action plans and the use of indicators to trace effectiveness will increase accountability and provide feedback for improvement of the policy and its implementation process.

The number of countries with existing health technology policies and with units to implement those policies, data available from WHO's baseline country survey on medical devices, shows that there is forward movement in the development and implementation of health technology policies. However, because medical devices are complex to select, manage and use, it is important to ensure that new policies are developed appropriately and existing ones are modified as necessary to make them as effective as possible. Proper integration of health technology policies and strategies within the framework of a national health plan has the potential to harness the political support to ensure improved access, quality and use of medical devices, enhance the best use of the resources in a framework of universal coverage, respond to the needs of the population, and ultimately achieve better health outcomes.

1 Introduction

Policies, strategies, and action plans for health technologies, specifically for medical devices, are required in any national health plan. Within the context of a robust health system they ensure access to safe, effective, and high-quality medical devices that prevent, diagnose, and treat disease and injury, and assist patients in their rehabilitation.

Medical devices range from simple tongue depressors to complex radiotherapy systems; more than 10 000 types and 1.5 million pieces of medical equipment are available today. While most often used in health care settings, medical devices are being increasingly used by patients in other settings. Assistive devices like hearing aids and contact lenses are two examples.

The array of devices, their uses, the settings in which they are applied, and all of the components of the life-cycle of the device - including innovation, regulation, assessment, management, safe use, and decommissioning - require rigorous policies. These policies should be tailored to particular health sector functions in order to guarantee the best use of resources and the unique needs of the population according to the local or national priorities. The World Health Assembly, in resolution WHA60.29, acknowledged the need to have appropriate national strategies and plans and to provide technical guidance in implementing policies on health technologies. The following examples illustrate how policies on medical devices (health technologies) can fit within a national overarching health policy:

- Regulations of medical devices minimize risk to the population;
- Safe use and availability of medical devices improve health service delivery;
- Affordability of medical devices increases health service coverage
- Telemedicine enhances patient-centred care;
- Health technology assessment provides basis for priority setting and informed decision making;
- Needs assessment helps in the rational allocation of resources; and
- Research and innovations respond to the needs of a particular health system and population.

Experience has proven that policy and strategy documents on medical devices and other health technologies are most effective when embedded into national health plans, documents that guide the health sector. Developing these documents requires input from as many stakeholders as possible: academia, patients' organizations, professional organizations, politicians, and specifically from biomedical engineers.

This document, part of the technical series on medical devices, will present a picture of current global and national health trends, and the different components of the policies, strategies, action plans, and indicators that are related to every stage of medical devices – innovation, regulation, assessment, management, safe use, and decommissioning.

2 Purpose

The purpose of this document is to raise the awareness of the importance of developing and implementing health technology policies – comprised of regulatory, health technology management, and health technology assessment components – within the context of a national health plan. The focus is particularly on policies related to the safe and appropriate use of medical

devices, a subset of health technology. Policies include guidance for the rational selection of medical technology that best serves the needs of the target population and identification of financial and human resources. Furthermore, policies can promote the safe and appropriate use of devices during their life-cycle. All of this should ultimately result in a better health system.



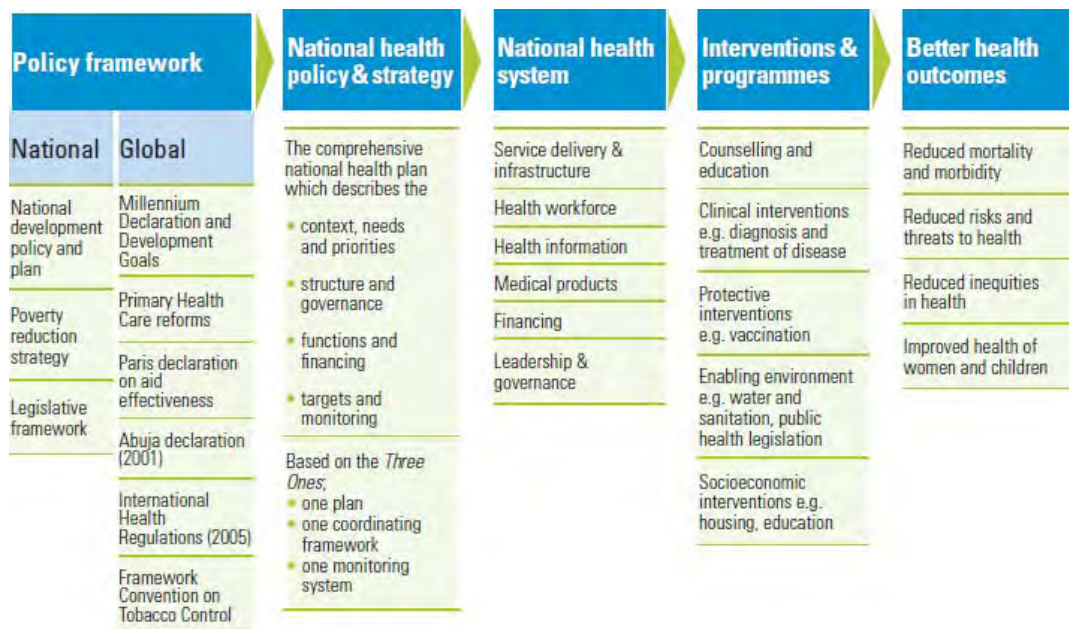
3 Policies, strategies, and action plans

Within WHO there is a renewed focus on policy dialogue around national health policies, strategies, and plans. In March 2009, a meeting of the WHO Global Policy Group took place to encourage the support of the development of national health policies, strategies, and plans. It was determined that in order to have better health outcomes, coherent policies within a comprehensive approach to address economic, social, and environmental determinants of health was needed. Figure 1 shows how a comprehensive approach can lead to better health outcomes.

Medical products, which include medical devices, pharmaceuticals, and other commodities have the very important role within the health system to deliver better health outcomes. It is, therefore, important to consider these products when designing national health plans, policies, and strategies.

There are different definitions for the term ‘policy’. However, for the purpose of this document the word ‘policy’ is defined to include a vision, strategies, action plans, indicators, and a monitoring and evaluation system to measure implementation. Box 1 lists the elements of effective health policies, strategies, and plans.

Figure 1. National health policy framework



Source: (1).

Box 1. Elements of effective national health policies, strategies, and plans

National health policies, strategies, and plans must articulate in a comprehensive, balanced, and coherent fashion:

- Vision, values, goals, targets, and intersectoral policy alignment
- A robust *situation analysis*, covering:
 - assessment of *social determinants* of health and health needs, including current and projected disease burdens and health challenges;
 - assessment of *expectations*, including current and projected demand for services as well as social expectations;
 - assessment of *health system performance* and of performance gaps in responding to needs and expectations;
 - assessment of the *capacity of the health sector* to respond to current and to anticipate future challenges;
 - assessment of *health system resources* (human, physical, financial, informational) and of resource gaps in responding to needs and expectations;
 - assessment of *stakeholder positions* (including, where appropriate, of external partners).
- The possible scenarios and *policy directions* for:
 - improving health equity;
 - making services people-centred so as to respond to priority needs and expectations;
 - protecting and promoting the health of communities and public health;
 - building the capacity to deal with crisis and future challenges.
- A comprehensive *strategy* to respond to the challenges and implement the policy directions
 - The implications of these policy directions for:
 - › service delivery (service networks as well as programs, actions aimed at individuals as well as public health actions aimed at populations);
 - › health workforce;
 - › medical products and technologies, and infrastructure;
 - › information;
 - › health financing, and
 - › governance of the health sector
 - Their implications for working with other sectors
 - Their resource implications and the associated costs
 - The investment strategy and a strategy for mobilizing the funds required
- The *leadership and governance arrangements for implementing the strategy* in terms of:
 - role of various institutions and stakeholders;
 - monitoring performance, measuring outcomes, organizing research and adapting the strategy to changing circumstances;
 - regulatory and legal frameworks to ensure sustainability;
 - working with other sectors to ensure health is taken into consideration in all policies;
 - dealing with the donor community in countries where donor funding is an important contributor to financing the health sector.

How these content components are sequenced and partitioned among policy, strategy and planning documents, and where the emphasis is put, depends to quite some extent on the specific country-context.

Source: (1).

4 Global health and medical devices

Medical devices are critical to the delivery of health care, particularly for the prevention, diagnosis, and treatment of diseases. Making appropriate medical devices available and affordable in health care settings is linked to health equity, and service delivery that is more responsive to the needs of patients.

4.1 Global health today

4.1.1 Growing health inequities

Evidence suggests that the impressive health gains achieved over recent decades are unequally distributed and have largely failed to reach the poor and other marginalized or socially excluded groups. Persistent and growing inequalities in health are increasingly evident, both between and within countries. For example, the poorest 20% of the global population are roughly 10 times more likely to die before the age of 14 than the richest 20% (2). This figure comes from data gathered about social determinants of health: the conditions in which people are born, grow, live, work, and age (including access to the health system). These circumstances are shaped by the distribution of money, power, and resources at global, national, and local levels, which are themselves influenced by policy choices. The social determinants of health are mostly responsible for health inequities – the unfair and avoidable differences in health status seen within and between countries. Evidence points to a two-way relationship between poverty or inequity and health. In the ‘vicious cycle’, poverty breeds ill-health, and ill-health causes more poverty. In the ‘virtuous cycle’, higher income is linked to good health, and good health is linked to higher income and welfare.

Responding to increasing concern about these persisting and widening inequities, WHO established the Commission on Social Determinants of Health in 2005 to provide advice on how to reduce them. The Commission’s final report in 2008 (2) contained three broad recommendations, the second of which was to tackle the inequitable distribution of power, money, and resources. This included the call for health equity to become a marker of government performance and for the United Nations (UN) to adopt health equity as a core global development goal and use a health framework outlining social determinants to monitor progress.

Equity in the accessibility of medical devices was the theme of a meeting held in July 2010.¹ Hosted by WHO, the meeting dealt with the following topics:

- Health technology is one of the weakest components of the national health system, and the absence of suitable health technology policies is at the root of the problem.
- Costs within health systems are increasing and the gap between needs and resources is widening. Access to health technologies and medical devices, therefore, requires higher public investment and priority allocation to deficit areas in order to decrease inequities.
- Factors that can promote or limit access to medical devices include: market availability, cost, the decision making process, infrastructure and environmental factors, capacity to utilize the devices, timely replacement, cost recovery or systems for reimbursement, and transparency in the medical devices market.

¹ http://whqlibdoc.who.int/hq/2010/WHO_HSS_EHT_DIM_10.15_eng.pdf

- Health systems can provide both the information necessary to measure equity in health care and the solutions for improving equity.
- Requirements for increased access to medical devices are: harmonized regulatory systems, transparent and ethical procurement processes, and appropriate health technology assessment.

4.1.2 Millennium Development Goals

Since 2000, the global health agenda has been focused on achieving the Millennium Development Goals (MDGs) with firmly defined overall roadmaps and detailed indicators. The work of achieving equitable access to, and optimal use of, medical devices is a critical component towards achieving the MDGs. Medical devices are particularly important for Goals 4, 5, and 6; they offer tangible ways to help achieve the targets (see Box 2). In order for this to be successful, however, priority actions in the area of medical devices need to be implemented.

4.1.3 Increasing burden of noncommunicable diseases

Though resources available to invest in medical devices are vastly different, the main health problems facing wealthy and developing countries are becoming remarkably similar. I am referring in particular to the rise of chronic diseases, like cardiovascular disease, stroke, cancers, and diabetes. Once associated with affluence, these diseases now impose their heaviest burden on poor and disadvantaged populations. This shift in the disease burden clearly demonstrates the need for fairness in access to medical devices, including those appropriate and affordable for long-term care (5).

—Dr Margaret Chan, WHO Director-General

The increase of noncommunicable diseases represents one of the major health challenges to global development in the coming century. It threatens economic and social development as well as the lives and health of millions of people. Based on current trends, by the year 2020 these diseases are expected to account for 73% of deaths and 60% of the disease burden (6). Low- and middle-income countries suffer the most from noncommunicable diseases. These diseases disproportionately affect poor and disadvantaged populations, contributing to widening health inequities between and within countries. Figures 2 and 3 show the increasing burden of disease due to noncommunicable diseases.

Within the framework of the First Global Ministerial Conference on Healthy Lifestyles and Noncommunicable Disease (NCD) Control held in April 2011,² a policy brief on essential medicines and technologies stated that, “equitable access can be achieved through rational selection, affordable prices, sustainable financing and reliable systems. Control of NCDs can improve through a rational selection of a limited range of essential medicines and technologies, along with independently developed evidence-based clinical guidelines, for cost-effective interventions. The lack of appropriate, available and accessible health technologies to assist in timely diagnosis ultimately leads to complicated cases that require expensive clinical interventions, or if unattended, result in increased premature mortality rates.”

Policy makers, therefore, can promote and implement effective strategies to increase the access to health technologies that will reduce the noncommunicable disease burden.

² For further reading on essential medicines and technologies for NCD care http://www.who.int/nmh/events/moscow_ncds_2011/conference_documents/moscow_ncds_roundtable_10_access_to_essential_medicines_and_technologies.pdf

Box 2. Medical devices that address Millennium Development Goals 4, 5, and 6

MDG 4: Reduce child mortality

Target: Reduce by two thirds the under-five mortality rate by 2015

Indicators: Under-five mortality rate; infant mortality rate; proportion of one-year-old children immunized against measles

The first 28 days of a baby's life carry the highest risk of mortality. More than 3.5 million deaths – close to 40% of all child deaths – occur in this period worldwide each year (3). In order to enhance the chances of neonatal survival, innovative technologies are being developed and tested for clinical effectiveness, safety, and affordability. One example is the portable infant warmer; it prevents hypothermia in premature and low-birth-weight babies by maintaining them at a constant temperature for up to four hours without the use of electricity.¹

Conventional medical devices also assist in preventing child mortality. Examples include affordable safe injection devices for vaccination, and even simple technology such as bandages, dressings, eye-droppers, scales, sphygmomanometers, stethoscopes, tongue depressors, IV lines, aspirators, gloves, and infusion pumps.

These and other devices are discussed in the *Pocket book of hospital care for children: guidelines for the management of common illnesses with limited resources*. (4). The publication presents up-to-date clinical guidelines based on a review of current published evidence, for both inpatient and outpatient care in resource limited hospitals (where basic laboratory facilities and essential drugs and inexpensive medicines are available). It focuses on the inpatient management of the major causes of childhood mortality: pneumonia, diarrhoea, severe malnutrition, malaria, meningitis, measles, HIV infection and related conditions. It also covers neonatal problems and surgical conditions of children that can be managed in small hospitals.

MDG 5: Improve maternal health

Target: Reduce by three quarters the maternal mortality ratio by 2015

Indicators: Maternal mortality ratio; proportion of births attended by skilled health personnel

Most maternal deaths during childbirth are preventable. The availability and use of specific medical devices during antenatal care, delivery, and postnatal care saves lives. Some of these devices are conventional and others are being tested for efficacy. In the former category are sphygmomanometers, pulse oximeters, oxygen, IV lines, Doppler monitors, surgical kits and equipment, laboratory equipment for biochemical and microbiological tests, and blood transfusion sets²; in the latter are anti-shock garments in case of haemorrhage and the portable ultrasound.

MDG 6: Combat HIV/AIDS, malaria, tuberculosis, and other diseases

Target: Halt and begin to reverse the spread of HIV/AIDS by 2015

Indicators: HIV prevalence among population aged 15–24 years; condom use at last instance of high-risk sex; proportion of population aged 15–24 years with comprehensive knowledge of HIV/AIDS; ratio of school attendance of orphans to school attendance of non-orphans aged 10–14 years.

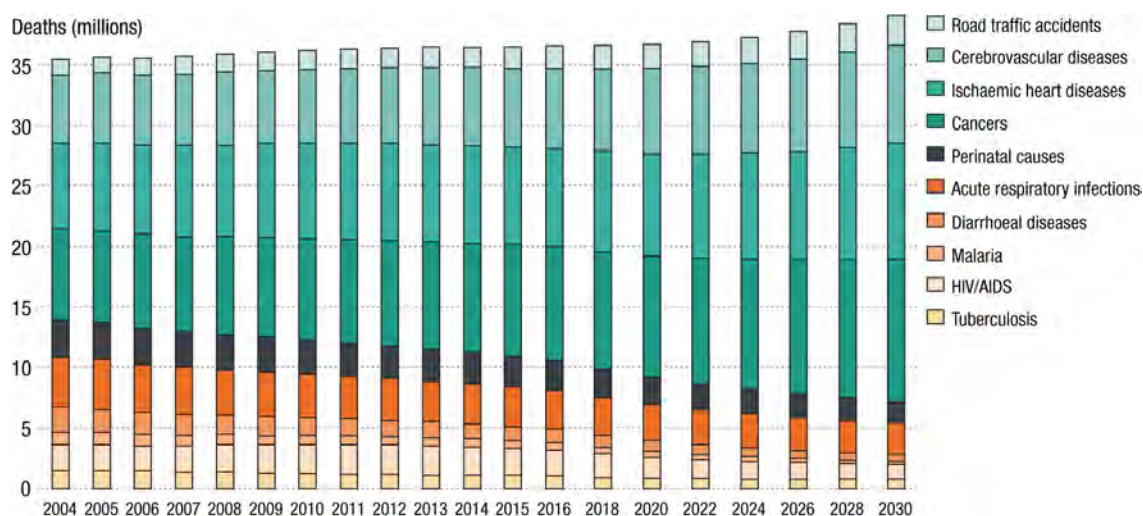
Timely diagnosis of HIV/AIDS, TB, or malaria is critical to preventing mortality. Treatment can prevent complications arising from these diseases, and saves lives. Innovations such as the portable on site cell sorter and counter for HIV and malaria diagnosis can help address this issue.³

¹ See for more information: http://www.who.int/pmnch/events/2010/08_lowcost_warmer.pdf and http://www.who.int/pmnch/events/2010/2010_pf_innovation_warmers/en/index.html

² See for more information: http://portal.pmnch.org/downloads/low/Knowledge_for_Action_Annex1_lowres.pdf

³ See for more information: http://www.who.int/medical_devices/poster_a14.pdf

Figure 2. Number of deaths attributable to select noncommunicable and communicable diseases, 2004–2030



Source: (7).

Figure 3. Ten leading causes of disease burden, 2004 & 2030

2004 Disease or injury	As % of total DALYs	Rank		Rank	As % of total DALYs	2030 Disease or injury
Lower respiratory infections	6.2	1	→	1	6.2	Unipolar depressive disorders
Diarrhoeal diseases	4.8	2	→	2	5.5	Ischaemic heart disease
Unipolar depressive disorders	4.3	3	→	3	4.9	Road traffic accidents
Ischaemic heart disease	4.1	4	→	4	4.3	Cerebrovascular disease
HIV/AIDS	3.8	5	→	5	3.8	COPD
Cerebrovascular disease	3.1	6	→	6	3.2	Lower respiratory infections
Prematurity and low birth weight	2.9	7	→	7	2.9	Hearing loss, adult onset
Birth asphyxia and birth trauma	2.7	8	→	8	2.7	Refractive errors
Road traffic accidents	2.7	9	→	9	2.5	HIV/AIDS
Neonatal infections and other*	2.7	10	→	10	2.3	Diabetes mellitus
COPD	2.0	13	→	11	1.9	Neonatal infections and other*
Refractive errors	1.8	14	→	12	1.9	Prematurity and low birth weight
Hearing loss, adult onset	1.8	15	→	15	1.9	Birth asphyxia and birth trauma
Diabetes mellitus	1.3	19	→	18	1.6	Diarrhoeal diseases

Source: (7).

4.1.4 Medical devices in health systems

Medical devices save lives, improve health and quality of life, and are indispensable for the prevention, diagnosis, treatment, and management of all medical conditions, diseases, illnesses, and disabilities. Medical devices, and in particular, assistive devices, also are important for rehabilitation and enable people with disabilities to continue to function. Without medical devices, routine medical procedures – from bandaging a sprained ankle, to diagnosing HIV/AIDS or implanting an artificial hip – would be impossible.

Although a crucial component of health care, medical devices are most effective when considered in the wider context of the complete health care package necessary to address public health needs: prevention, clinical care (investigation, diagnosis, treatment and management, follow-up, and rehabilitation), and access to and delivery of appropriate health care. For example, the wide availability of disposable syringes and needles supports universal health coverage. Their safety and ease of use puts people first – the first tenet of people-centred primary health care. Yet robust public health policies are needed to ensure the use and safe disposal of these devices and to ensure sound governance and community participation (e.g. public awareness and education campaigns about their benefits).

A medical device needs to be appropriate for the context or setting in which it is intended. Context in this sense refers to linking the correct medical device with its corresponding health need to maximize its effectiveness. Thus, when attempting to provide equitable health care, the ‘four As’ – availability, accessibility,

appropriateness, and affordability – should be considered and addressed in the relevant section of the national health technology policy.

4.2 Global health agenda

4.2.1 Foundation for action: World Health Assembly resolutions

The field of medical devices is large, diverse, competitive, and highly innovative. This is an area of great promise, sometimes spectacular promise, sometimes seductive promise. It is also an area with a number of problems and pitfalls, some familiar, others unique. As many have noted, the field of medical devices requires, and deserves, its own unique agenda. Health officials and hospital managers in all countries, at all levels of development, need guidance (5).

—Dr Margaret Chan, WHO Director-General

WHO is the directing and coordinating authority for health within the UN system. It is responsible for providing leadership on global health matters, shaping the health research agenda, setting norms and standards, articulating evidence-based policy options, providing technical support to countries, and monitoring and assessing health trends. This serves to fulfil WHO’s mission: the attainment by all peoples of the highest possible level of health.

Medical devices are indispensable to health care systems. One cannot function without the other. Recognizing this, the World Health Assembly (WHO’s highest decision-making body) resolved to strengthen both health systems – as part of WHO’s focus on primary health care – and health technologies, such as medical devices. In 2003, resolution WHA56.6 requested Member States adequately fund primary health care to reduce health

inequities. Resolution WHA62.12 in 2009³ urged continued political commitment to the values and principles of primary health care through strategies and plans in all technical areas. Resolutions on noncommunicable diseases also led to WHO action: a global strategy and action plan for the prevention and control of noncommunicable diseases.⁴

Health technologies have transformed incredibly over the past two decades and, thus, WHO has responded with a number of resolutions. A resolution on eHealth, WHA59.28, was approved in 2006. Further resolutions made by the World Health Assembly chart a course for WHO and Member States with respect to health technologies: WHA60.29 in 2007 instructs WHO “to provide technical guidance and support to Member States where necessary in implementing policies on health technologies, in particular medical devices especially for priority diseases, according to different levels of care in developing countries”⁵; the 2007 WHA60.30 resolution relates to public health, innovation, and intellectual property; resolution WHA61.21 in 2008 established a global plan to promote innovation (such as calling on industry to develop innovative health technologies⁶); and resolution WHA62.12 urges Member States to improve access to appropriate health products and technologies to support primary health care.

3 http://www.who.int/hrh/resources/A62_12_EN.pdf

4 <http://www.who.int/nmh/publications/9789241597418/en/>

5 http://www.who.int/medical_devices/resolution_wha60_29-en1.pdf

6 http://www.who.int/medical_devices/initiatives/en/

4.2.2 Collecting evidence on the use of medical devices

As part of the GIHT, a baseline survey on medical devices was completed in 2010. It was designed to determine the availability of policies, guidelines, standards and services for the assessment, management and regulation of health technology in Member States and Associate Members. It is WHO’s intention to determine the key areas for the development of health technology programmes in regions and countries which require support, as well as to share knowledge and information among the participating countries.

The preliminary results for participating low-income countries were as follows:

- 33% have a national policy for health technology;
- 55% have an authority responsible for implementing and enforcing medical device regulations; and
- 85% have a designated unit within the ministry of health at federal or national level that claims to technically manage medical devices (9).

For middle-income countries and high-income countries the results are more encouraging. However, there is clearly need for further support in development of national policies but also development and enforcement of medical device regulations. Effective and efficient technical management of medical devices remains a concern in most low-income countries and middle-income countries despite the existence of dedicated responsible units at the national level.

4.2.3 Global market for medical devices

Global expenditure on medical devices increased from US\$ 145 billion in 1998 to US\$ 220 billion in 2006, representing an annual growth rate exceeding 10%. There is however a disparity in expenditures between high-income countries and low- and middle-income countries: sales of medical technology are concentrated in high-income nations, particularly in North America, Europe and Japan. The average per capita spending on health in the Region of the Americas, for example, was

US\$ 2636, while the average in the South-East Asia Region was just US\$ 31 (10).

Further evidence of this disparity is provided by the Global Forum for Health Research, which estimated that US\$ 160.3 billion was spent globally on health research and development in 2005 with only 3% spent by low- and middle-income countries. High-income countries spent the other 97%, mostly to generate products, processes, and services for their own health care markets (10), which have little in common with the needs of low-income settings.



5 Medical devices within the health systems of Member States

WHO's mission of attaining the highest possible level of care for all can be accomplished through outlining a health systems framework, defining public policies, and implementing activities as outlined by the World Health Assembly resolutions, some of which were discussed previously. National health policies in which public health needs have been prioritized are important in not only meeting WHO's mission but also in realizing the goals of the global health agenda which includes achieving the MDGs, reducing the incidence and severity of noncommunicable diseases and neglected tropical diseases, and improving health regulations through the strengthening of health systems. Figure 4 illustrates how the global agenda and mission of WHO relate to the health system of the Member State resulting in equitable access to safe and quality medical devices and eventually to better overall quality health service delivery. This chapter will discuss how Member States can prioritize their public health needs, work through the policy-making

process and plan for health technology, and ultimately how they can manage the resulting policy in an efficient manner.

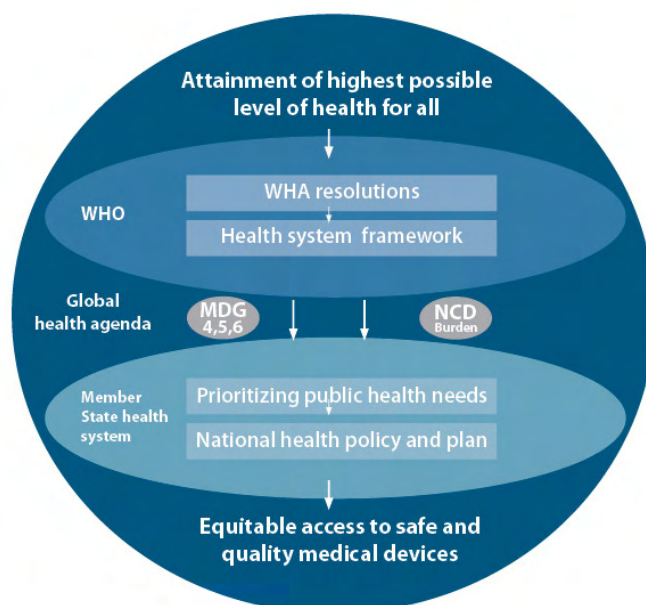
5.1 Prioritizing public health needs

A variety of data are required to prioritize the public health needs of Member States. Health systems in sub-Saharan Africa, for example, face different challenges than do those in the rest of the African Region. Therefore, an overall needs assessment should be performed to ensure that national strategies and actions plans for medical devices directly match public health priorities.

Such assessments are aided by burden of disease data; they are important when prioritizing actions on health technologies in countries. Statistics on mortality, loss of health due to diseases and injuries, and risk factors are available for most countries.¹

¹ <http://www.who.int/whosis/whostat/en/>

Figure 4. Linking the global health agenda to improve medical device access via national health plans



In the Global Burden of Disease (GBD) study, the disability-adjusted life year (DALY) is a time-based measure that combines years of life lost due to premature mortality (YLL) and years lived with a disability (YLD), and is used to assess disease burden. Though figures vary dramatically across regions, the average global burden of disease in 2004 was 237 DALYs per 1000 population, of which about 60% was due to YLL and 40% to YLD. The GBD study quantified the disease burden for individual countries as well (6). When evaluating a health system of a particular country, data from this study can highlight pressing health needs (6; see also relevant national data sources²).

The next step is to link disease burden data with specific health technologies (medical devices) that can be used for prevention (in some cases), diagnosis, treatment, and rehabilitation. WHO provides some guidance in this area (8).

While burden of disease data are vital in setting priorities for action on medical

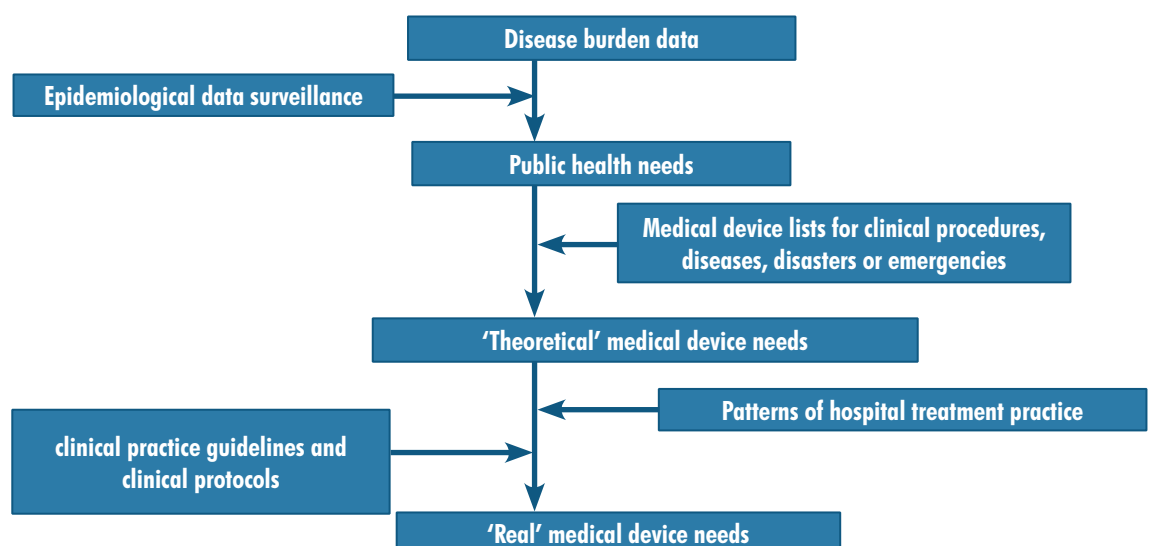
devices, they can be outdated, incomplete, or unavailable. When conducting a needs assessment, GBD data should be supplemented with data from epidemiological disease surveillance and patterns of hospital treatment practice to ensure the closest match of priority actions and public health needs. Disease surveillance data may be held nationally or regionally. WHO also publishes global disease surveillance data.³

Collecting data from actual patterns of hospital treatment can also be useful in determining the gap between practice and need, and also therefore inform prioritizing actions. Such data are usually recorded nationally or at the subnational level as part of national hospital reporting requirements. WHO has performed such a gap analysis at the international level which might provide useful insight for informing a similar but more detailed process at the national level (8). Figure 5 illustrates the sequence of steps to determine medical device needs based on priority public health needs.

² http://www.who.int/topics/global_burden_of_disease/en/.

³ See: <http://www.who.int/topics/epidemiology/en/>

Figure 5. Setting medical device priorities based on public health needs



5.2 National health policy and planning

The World health report 2008 (11) described a need for public policies to complement the drive for universal health coverage and service delivery reform. Effective public policies in the health sector are:

- health systems policies (related to financing, essential drugs, technology, human resources) on which primary care and universal coverage depends;
- public health policies that address priority health problems and include prevention and health promotion; and
- policies in other sectors, known as 'health in all policies', which call for intersectoral collaboration to achieve positive health outcomes.

Each of the health systems policies should not be considered singly but rather with other elements in the system like financing, information, service delivery, health workforce and governance, as shown in Figure 6.

5.2.1 Policy process

The nature of policy-making is that it is a process, and most often a contested one. This is also true for policy-making in the area of health technology. In recognition of the contested nature of policy-making and the valid interests of a range of stakeholders, the following principles should be applied:

- Base policy-making on the core values of primary health care.⁴
- Ensure a mechanism for endorsement of the process by senior government officials.
- Ensure the process is broadly consultative and involves participation of all major stakeholders.
- Ensure the process is transparent and decisions are reached based on evidence.

An effective national policy is achievable with action at all levels. This means considering resources and capacities as well as legal and political commitment.

⁴ More information on primary health care at: <http://www.who.int/whr/2008/en/index.html>

Figure 6. Six building blocks for health systems



Source: (11).

The major policy decisions for medical devices relate to the four major areas of activity: research and development, health technology assessment, health technology regulation, and health technology management. The integration of these four areas into national health plans, with specific policies that include strategies and indicators for follow-up is recommended.

5.2.2 Planning

Planning for health technology should be driven by the priority public health needs described above. It should also be integrated into health sector planning processes, outputs, and cycles at national, subnational, and local levels. Planning must be comprehensive (cover all areas of activity) and coherent (i.e. compatible with subplans). Once again, the plan should cover all aspects of the four major areas of activity: research and development, health technology assessment, health technology regulation, and health technology management.

5.2.3 Policy management

The existence of evidence-based policy and plans will not result in the desired improved health outcomes without a system of active management.

In addition to the existence of policies, plans, and organizational structures there is the further requirement for the development of suitable organizational structures, associated management processes, and sufficient management and technical capacity. Chapter 6.3 provides some general guidance on organizational structures.

Management processes must be developed for implementation of plans and must include appropriate oversight, reporting, and monitoring and evaluation. As plans are always imperfect, it is necessary to ensure that mechanisms are also in place to enable

appropriate adjustments according to findings as implementation proceeds, while remaining consistent with policy. Furthermore, budgets and plans should be reviewed and updated at regular intervals by a designated governance committee in order to ensure that they always address the current needs of those they are intended to serve.

Strong management capacity alone can result in improved health outcomes in the absence of policy and even plans. However, such an approach is not systematic or balanced and at higher risk of failure and is therefore not advised. Conversely, the existence of policy, plans, organizational structures, and management processes will not result in improved health outcomes in the absence of sufficient and suitable management capacity.

Sufficient and suitable management capacity requires the deployment of financial and human resources. It will be necessary for Member States to allocate sufficient regular budgets, at national and subnational levels, to establish an equipment replacement programme and hire sufficient numbers of qualified and trained staff to implement effective and efficient health technology management. Support from external financial donors may be useful in starting a programme, developing capacity, and providing occasional injections of funds for equipment purchase or further training, but unless Member States commit sufficient regular funds, sustainable improved health outcomes will not be achieved.

A final but important component of an effective management approach will be the integration of all activities into a wider quality assurance programme with a philosophy of continuous improvement and including the necessary safeguards to ensure patient safety.

6 Organizational systems for medical devices

There are many steps along the path to successfully devising an effective agenda to improve global access to appropriate, safe, and high-quality medical devices. This chapter describes the relationship between these steps and a method to ensure their successful implementation.

6.1 General principles

While health care as a human right is enshrined in the Universal Declaration of Human Rights (12), this has not led to universal access to health care. As discussed earlier, universal access and equity in health care remains elusive. *The World health report 2008* addressed this issue in the context of primary health care (11). “Primary care and social protection reforms depend on choosing health-systems policies, such as those related to essential drugs, technology, human resources and financing, which are supportive of the reforms and promote equity and people-centred care” (11).

Strong health systems are built on six ‘building blocks’ informing policy: financing, human resources, information, service delivery, governance, and medical products, vaccines, and technologies (13). The multiple relationships and interactions among these components convert these building blocks into a system (14). If any of these components are missing, the health system cannot function at the level necessary to improve the health of the population. Each building block has its own unique challenges in terms of policy and organizational systems. This chapter will discuss the final building block – health technologies (medical devices).

6.2 System components

Health systems are dependent on health technologies to deliver desired health outcomes. It is critically important to plan medical device programmes in accordance with policies and protocols that will result in equitable access to safe, appropriate, and high-quality medical devices.

Medical devices are vital to the provision of health care and improving the health of populations. From the innovation phase to the replacement phase, an agenda for medical devices consists of four critical characteristics: availability, accessibility, appropriateness, and affordability. These four components help to widen the scope of the medical device agenda so that it does not just focus on ‘upstream’ innovation efforts but also on choosing which medical devices to procure in a rational and appropriate way, and to ensure that they are used effectively and equitably.

This chapter describes how implementing the four phases of the medical device life-cycle at global, regional, country, and local levels can lead to improved access to safe, high-quality medical devices (8). Only truly integrated phases, which inform and build upon each other, can provide the needed engine to move towards sustainable national health goals. Broadly, the phases are:

1. Medical device research and development
2. Medical device regulations
3. Medical device assessment (health technology assessment)
4. Medical device management (health technology management)

These four phases will be effective only when they receive support and are overseen by trained staff. While the interdependence of these phases is important, the operation within each should also be planned and executed with protocols that match the functionality level (national, regional, local) in order to achieve the desired outcomes.

All stakeholders should know the paths between the four phases, the mechanism of inputs and outputs that build interactions between the phases and lead to the desired common goal. Indeed, “all stakeholders are accountable for the success or failure of access to appropriate medical devices – a fundamental factor in improving the health of populations” (15).

Figure 7 shows the relationship between the medical devices agenda and the interaction and dependence of successful functionality of each phase on the total expected outcomes of safety, quality, universal coverage, and equity. It further shows the system-wide need for an

overall strategy and structure to accept input from each phase and to provide outputs (deliverables) in order to create an effective plan for optimizing resources.

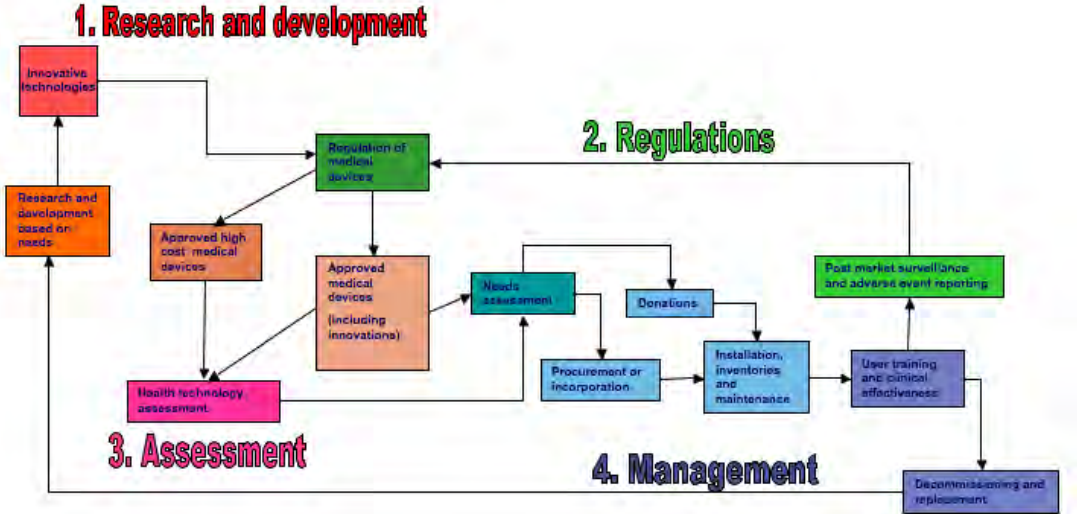
Within each phase of the medical devices agenda there is a need for resources, in particular human resources, individuals with specific skills and competencies to plan, implement, process, and support the unique functionality that the phase is responsible for delivering. Examples include skills in the field of epidemiology and health economics for the health technology assessment phase, and clinical engineering skills for the health technology management phase. Human resources training will be an integral part of the health technology life-cycle plan as well.

The commitment for, and the execution of, a continuous improvement plan within and between the four phases is critical to success. At any point in time, these phases can be evaluated in terms of functionality, and opportunities for improvement proposed. This continuous

Figure 7. The medical device agenda within a national health policy



Figure 8. The four phases of the medical device life-cycle



improvement plan crosses all phases where specific performance indicators are being monitored, reviewed, acted upon, and measured. This is shown graphically in Figure 8. The monitored parameters should be used in the continuous improvement plan, to facilitate moving the health programme towards its goals.

The life-cycle of medical devices can be ‘entered’ and reviewed at any phase. For example, starting at the research and development phase, the input parameters driving this phase are national policy on health technology research and development and identified population health needs. These parameters frame the work conducted within this phase and feed into innovation in science and engineering. Alongside population needs and linkages with industry, national policy should focus on offering incentives to industry to generate innovative health products and make them available to those that require them. Without high-level political support and additional investment, the large potential of essential medical products and technologies will remain untapped, leading to unnecessary disease, disability, death,

and economic waste (16). The strategy for this phase will result in products that will feed into the next phase in the life-cycle: the regulatory phase.

The regulatory phase protects the public through the publication of standards, testing protocols, pre-market approval, registration, post-market surveillance, and adverse event reporting. Local facilities should have training in incident investigation methodology, risk management, and reporting functions. National policy is important in this phase as well; it ensures that new devices will be safe for consumers.

The health technology management phase covers a wide range of functions that begins with input from the previous phases and ends with output that effectively and safely supports the desired clinical services. Functions that should be delivered during this phase (and outcomes monitored) include: identification of needs; specification for procurement (including donated equipment); complete inventory of assets (devices and supplies); a designated maintenance programme

Table 1. Characteristics of the phases within the medical device life-cycle

	R&D	Regulations	HTA	HTM
Perspective	Innovative knowledge, application and tools for health services	Safety & efficacy	Population served	Health services provider
Orientation	Personal health services	Population safety	Population health	Community health services
Requirement (Output)	Improved and/or new tools & services	Mandatory compliance	Recommendations on highly complex technologies	Operational rules and guidance for all medical devices
Method	Innovation and improvement	Performance testing, safety assessment & post-market reporting	Systematic analysis, critical review	Operational management of technology life-cycle
Criteria	Market adoption	Safety and quality standards	Epidemiology data, statistics, analysis of efficacy, effectiveness, and appropriateness	Needs analysis, specifications, reliable device availability for clinical use
Outcome	Enhanced health services	Risk mitigation and prevention of harm	Responsiveness and maximization of clinical outcomes and cost-effectiveness	Improved health delivery; sustainable availability of high-quality and safe devices

Source: Adapted from (17).

based on risk reduction and safe operation, matching timely availability of safe and high-quality devices with health services provided; monitoring of a device’s clinical effectiveness; upgrades; and decommissioning.

The four phases of the medical devices agenda can function at all levels – local, regional, and national. The characteristics of each of the four phases, specifically, their perspectives and impacts are described in Table 1.

Access to safe, high-quality health services is dependent on a cohesive policy. If only one of the four phases has been well planned, supported and executed with trained staff, for example, improvement of the overall system will not be achieved. Only when all of the four phases are planned, well supported, and coordinated together will the overall programme reach its desired outcome – universal coverage of safe, equitable, high-quality health services.

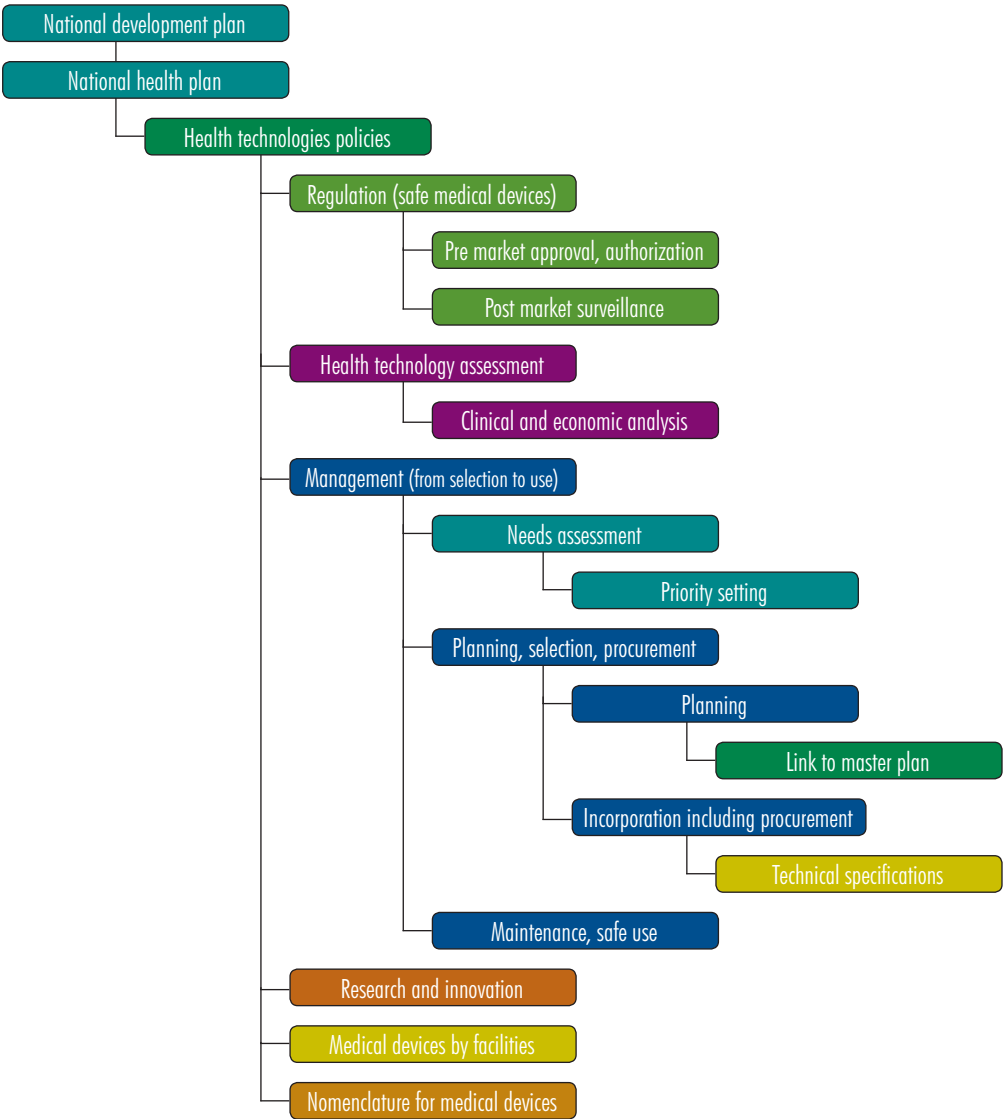
6.3 Organizational structures

In order to implement policies and strategies on health technologies, organizational structures are required at different levels within the country. Depending on governmental structures, these can be centralized or decentralized units dedicated to the four phases of health technologies. Figure 9 shows the 4 areas that will be primarily involved in the implementation of the health technology policies – regulation, health technology assessment, management or clinical engineering, and research and innovation – and the support areas of nomenclature and lists of medical devices that are used in many of these processes.

6.3.1 Regulatory processes

It is recommended that a medical devices regulatory unit be a part of the national regulatory authority, which conducts pre-market approval, registration, and post-market surveillance. The regulatory process is similar to that for medicines,

Figure 9. Areas of implementation for health technology policies



food, and other medical products but different technical capacities are required to analyse medical devices, which are classified by level of risk. It is therefore advisable that biomedical engineers trained in regulatory procedures are considered for the purpose of analysing technical dossiers, and that the regulatory authorities have harmonized processes that will enhance safety and the dissemination of innovative devices.

WHO has provided some guidance on the regulation of medical devices in its publication *Medical devices regulations,*

overview and guiding principles.¹ Due to the complex regulatory process and the advances in the innovation of devices, a new volume set, as part of this technical series will be developed in the near future.

Various countries have a national regulatory authority with an exclusive section or unit that reviews the medical device process. Table 2 contains examples of regulatory agencies, as well as two organizations that develop, compile

¹ For further reading: http://www.who.int/medical_devices/publications/en/MD_Regulations.pdf

Table 2. Regulatory harmonization groups and regulatory authorities

Harmonization groups	
Global Harmonization Task Force (GHTF)	http://www.ghtf.org/
Asian Harmonization Working Party (AHWP)	http://www.ahwp.info/
Countries	
Australia	http://www.tga.gov.au/industry/devices.htm
Brazil	http://www.anvisa.gov.br/eng/index.htm
European Commission	http://ec.europa.eu/consumers/sectors/medical-devices/documents/guidelines/index_en.htm
Saudi Arabia	http://www.sfda.gov.sa/En/MedicalEquipments
United Republic of Tanzania	http://www.tfda.or.tz/
USA	http://www.fda.gov/MedicalDevices/default.htm

Table 3. Examples of health technology assessment agencies, networks, and international professional organizations

Agencies	
Institut national d'excellence en santé et en services sociaux (INESSS) in Canada	http://www.inesss.qc.ca/
Health Intervention and Technology Assessment Programme (HITAP) in Thailand	http://www.hitap.net
WHO Collaborating Centres on HTA	
Swedish Council on Health Technology Assessment (SBU) in Sweden	http://www.sbu.se/en/
Catalan Agency for Health Information, Assessment and Quality (CAHIAQ) in Spain	http://www.gencat.cat/salut/depsan/units/aatrm/html/en/Du8/index.html
Institute of Population Health in Canada	http://www.cgh.uottawa.ca/whocc/
Networks of agencies	
International Network of Agencies of Health Technology Assessment (INAHTA)	http://www.inahta.org/ (54 member agencies internationally)
European network for Health Technology Assessment (EUnetHTA)	http://www.eunetha.net/Public/About_EUnetHTA/HTA/
The International Information Network on New and Emerging Health Technologies (EUROSCAN)	http://www.euroscan.org.uk/
Professional organizations	
Health Technology Assessment international (HTAi)	http://www.htai.org/

Table 4. Examples of WHO collaborating centres on health technology management

WHO Collaborating Centres on health technology management		
Centro Nacional de Excelencia Tecnológica en Salud (CENETEC)	Mexico	http://www.cenetec.salud.gob.mx/interior/english.html
ECRI Institute (ECRI)	USA	http://www.ecri.org
Instituto de Engenharia Biomédica, Universidad Federal de Santa Catarina	Brazil	http://www.ieb.ufsc.br

and disseminate regulatory practices, to ensure the safety, effectiveness and performance of medical devices: the Global Harmonization Task Force (GHTF), and the Asian Harmonization Working Party (AHWP).

6.3.2 Health technology assessment

The unit for health technology assessment can be governmental or private and can serve at national, regional, or local (hospital) levels. At the national level, it provides recommendations on public policies regarding medical devices as they relate to the needs of the population and the national priorities. Usually this unit is comprised of interdisciplinary professionals such as epidemiologists, librarians, health economists, biomedical engineers, medical doctors, researchers, and analysts.

In Table 3, examples of health technology assessment agencies, collaborating centers for WHO, international networks and finally a professional organization is presented.²

6.3.3 Health technology management

Governmental units for health technology management, or clinical engineering, can also be located at the national, regional or local (hospital) level. These units address topics that range from needs assessment to safe use of medical devices.

In some countries the national health technology management team is part of a centre of national excellence that issues national standards and guidelines for best practice in all areas of health technology management. Such a centre may also provide training on health technology management and provide maintenance.

Decision-makers can consult national centres for health technology for information on a host of issues including: medical equipment per facility, technical specifications, procurement best practices, maintenance procedures, content of user training courses, and steps required for certificate of need authorization. However, in some cases national centres may choose to concentrate on a particular area. For example, the Directorate of Biomedical Engineering in Jordan only manages maintenance issues related to medical equipment. Examples of collaborating centres are found in Table 4.

There are several options for developing a service for health technology management. The key for selecting the right model is to choose one that integrates health technology management into the existing health management system and health delivery system model.³

When creating a health technology management system, it is suggested to:

- Choose a team for health technology management at each facility and administrative level.
- Link health technology management teams as part of a referral network.
- Ensure there are resources in place to perform all necessary health technology management activities.
- Ensure that the health technology management team manager at each level is a member of the relevant health management team.
- At each level, establish a health technology management working group that reports to the health management team and is responsible for reviewing the status of equipment and for planning future needs.

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

³ See the 'How to manage' series of health care technology guides for more information: http://www.healthpartners-int.co.uk/our_expertise/how_to_manage_series.html

Health technology management teams will likely need to work together at national, sub-national and facility levels to ensure coordination and supervision across the entire system. Clarification of roles and responsibilities at each level will greatly facilitate coordination between the different levels and also enable a clearer estimation of human and other resources required to run the system. It is advisable to encourage information exchange with the health technology assessment agency and regulatory authorities as well.

6.3.4 Research and development (innovation)

Research and development is usually performed in high-level research institutions like national institutes of health or in the academic sector, with networks of universities. It is usually coordinated by a science or research council at the national level. In order to address national needs effectively, it is very important to link the academic and research strategies to the health priorities of the population.



7 Measuring progress: outcomes and indicators

Indicators and outcomes show stakeholders that particular policies or programmes are working – or not. With them, stakeholders can gauge effectiveness and have points of reference on which to base future actions. This chapter will review the outcomes and indicators of health technologies.

An effective national health plan will include one (or more) sections on health technologies, with governmental units enacting health technology policies on the four areas indicated in Chapter 6: research and development (innovation), regulation, assessment, and management.

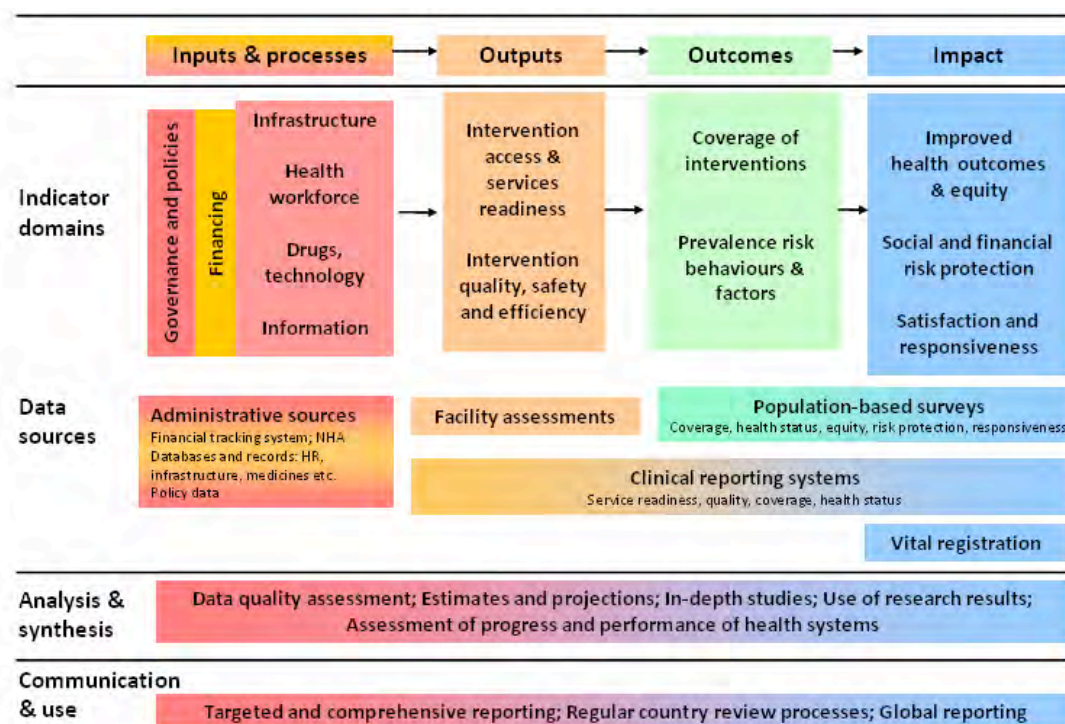
7.1 Monitoring and evaluation in health systems

Improved health outcomes are the objective of all health system interventions, but are impossible without monitoring and evaluation. A joint WHO/World Bank working group developed a broad framework for monitoring and evaluation of health systems reform, shown in Figure 10.

7.2 Indicators

An essential and accepted component of effective monitoring and evaluation is the ability to measure progress in achieving

Figure 10. Monitoring and evaluation of health systems reform



Source: (19).

desired outcomes, typically through the use of indicators.

Indicators must be defined appropriately to be useful, and their data readily and routinely collected. Indicator data can be used for determining priority areas for intervention, tracking progress, planning programmes, assessing programme effectiveness, coordinating donors and raising funds. WHO can also use the data to tailor its expertise and target programmes and resources to individual country needs (20). Figure 11 shows the core indicators used by WHO for health systems reform.

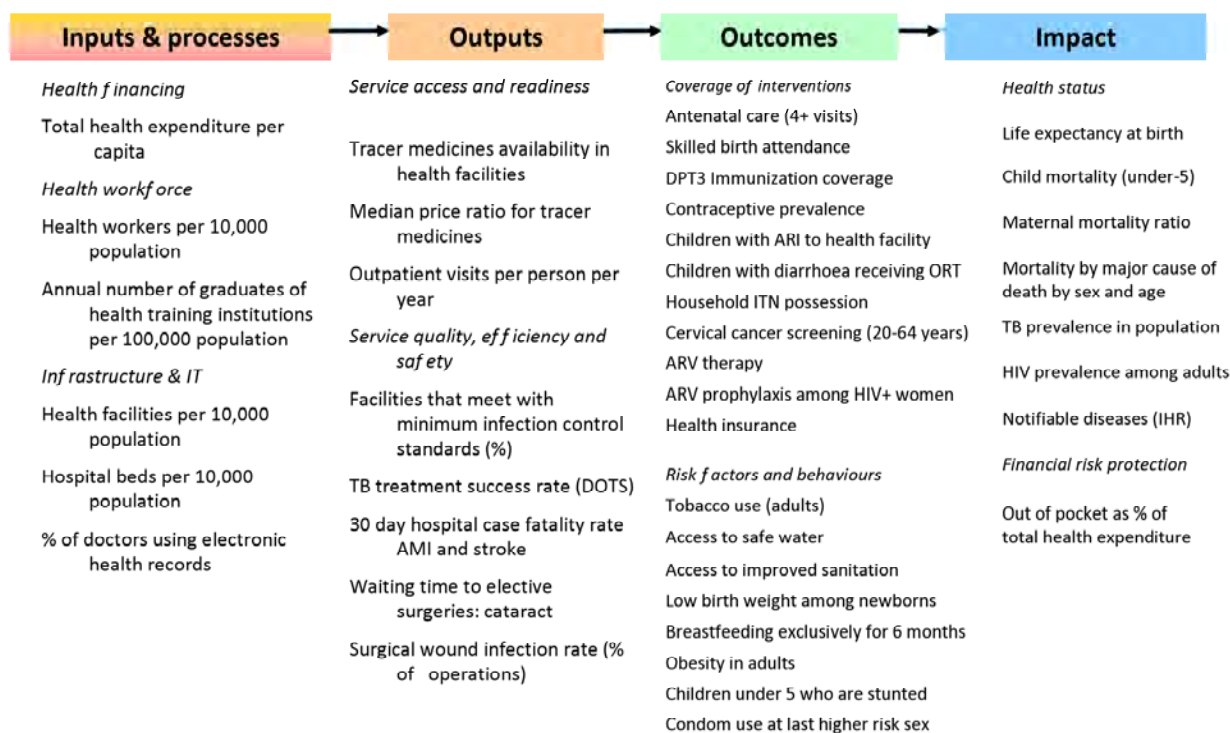
The World Health Assembly has approved 13 strategic objectives and indicators of the medium term strategic plan 2008–2013 (20). Objective 11 is to achieve

equitable access to safe, high-quality medical products and technology (which include medicines, vaccines, and medical devices). The indicators used within WHO for the 2010–2011 biennium to measure progress towards that objective are shown in Table 5.

7.3 Global status of medical devices: results of the baseline survey

By December 2010, 145 countries had responded to the baseline country survey on medical devices. Through this survey, a focal point for health technologies was nominated within each ministry of health who would be responsible for updating pertinent information and communicating with WHO.

Figure 11. Core set of WHO indicators



Source: (20).

Table 5. WHO's strategic objective 11 and related indicators

Strategic objective 11: To ensure improved access, quality, and use of medical products and technology.			
Area of work	Indicator	Baseline (2010)	Target (2011)
<i>National policies</i> (11.1: Formulation and monitoring of comprehensive national policies on access, quality, and use of essential medical products, and technologies advocated and supported)	11.1.1: Number of countries receiving support to formulate and implement official national policies on access, quality and use of health technologies	68 countries	73 countries
	Number of countries receiving support to design or strengthen comprehensive national procurement and supply systems	25 countries	30 countries
<i>Standards and guidelines</i> (11.2: International norms, standards, and guidelines for the quality, safety, efficacy, and cost-effective use of medical products and technologies developed, and their national and/or regional implementation advocated and supported)	11.2.1: Number of new global quality standards, reference preparations, guidelines, and tools for improving the provision, management, use, quality, and effective regulation of health technologies	30 per biennium	30 additional outputs
	11.2.4: Number of countries whose regulatory authorities have been assessed, supported, and accredited	30 countries	45 countries
<i>Evidence-based use</i> (11.3: Evidence-based policy guidance on promoting scientifically sound and cost-effective use of medical products and technologies by health workers and consumers, developed and supported within the Secretariat and regional and national programmes)	11.3.1: Number of national or regional programmes receiving support for promoting sound and cost-effective use of health technologies	10 programmes	15 programmes
	11.3.2: Number of countries using up-to-date national equipment lists (updated within the past five years) of essential medical devices for public procurement/reimbursement	80 countries	95 countries

Of the 62 Member States that have health technology policies, 49 indicated that they have incorporated them into their national health plan. Figures 12 and 13 show the distribution of those countries with policies and with units to implement those policies respectively.

Concerning indicator 11.3.2 from the WHO strategic objectives, results from the survey showed that 58% of the countries that responded do not have a list of approved medical devices for procurement or reimbursement. Figures 14 and 15 show this graphically.

Another survey question asked Member States about the existence and use of lists of medical devices by health care

facility and or by clinical procedure. Several countries answered affirmatively (Figure 16). However, many countries still lack this information and WHO is currently developing these lists to assist all Member States.

All the information retrieved through the survey (e.g. policies on health technologies from different countries, including indicators, lists of approved medical devices, and lists by health care facilities and procedures) will be available on the WHO web site for further review and reference.¹

¹ See http://www.who.int/medical_devices/en/ and http://www.who.int/gho/health_technologies/medical_devices/en/

Figure 12. Distribution of countries with a national health technology policy

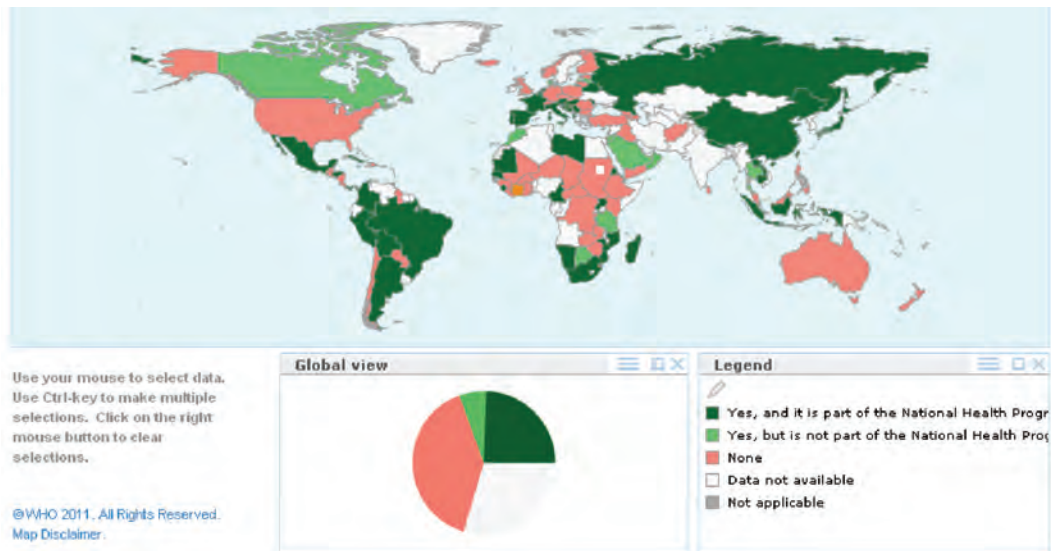
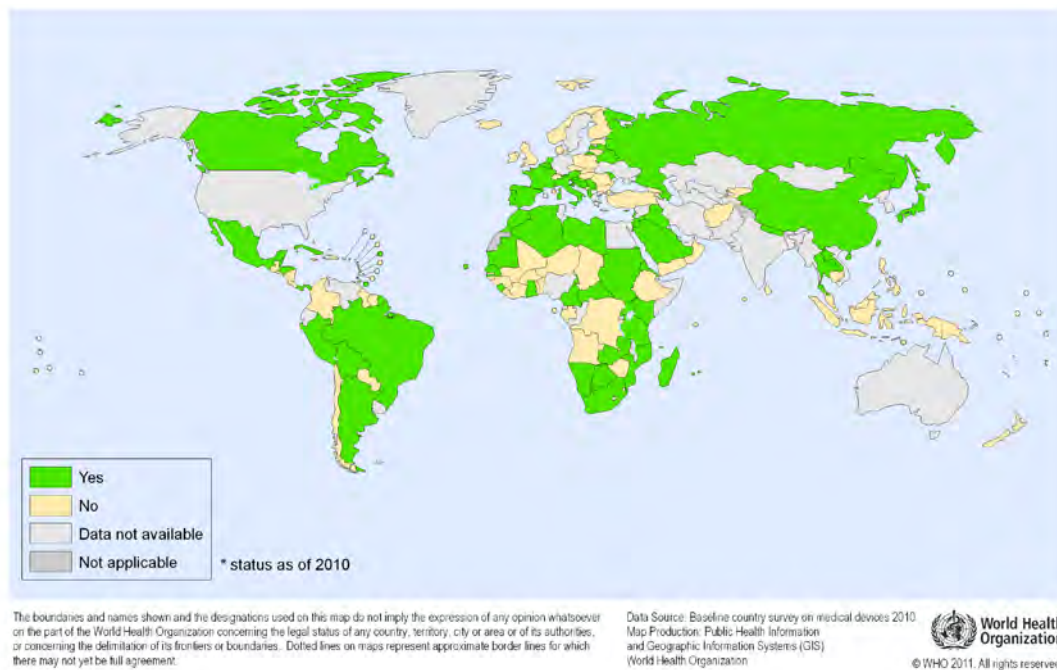
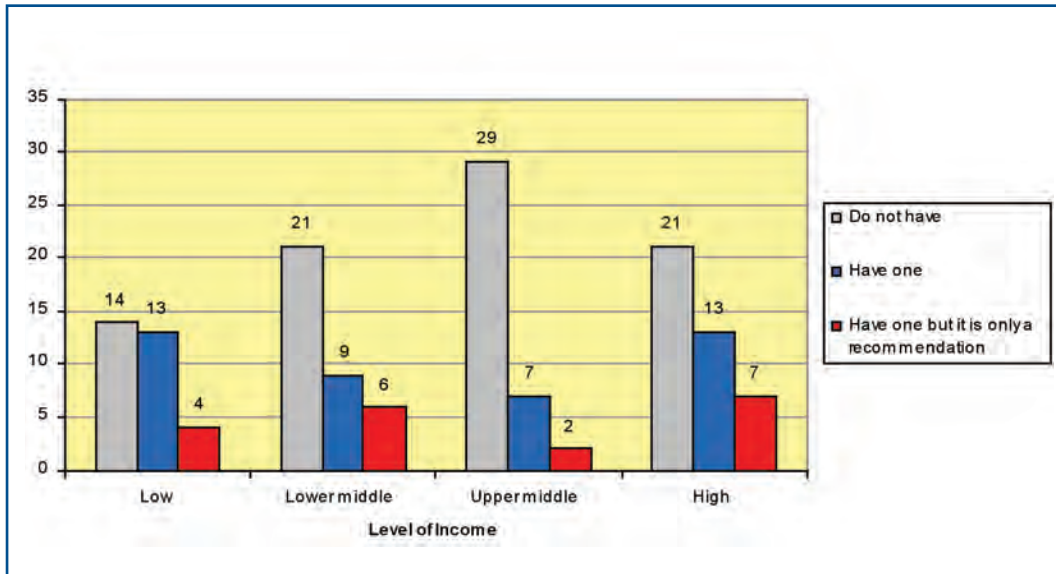


Figure 13. Distribution of countries with a government unit responsible for the implementation of health technology policy*



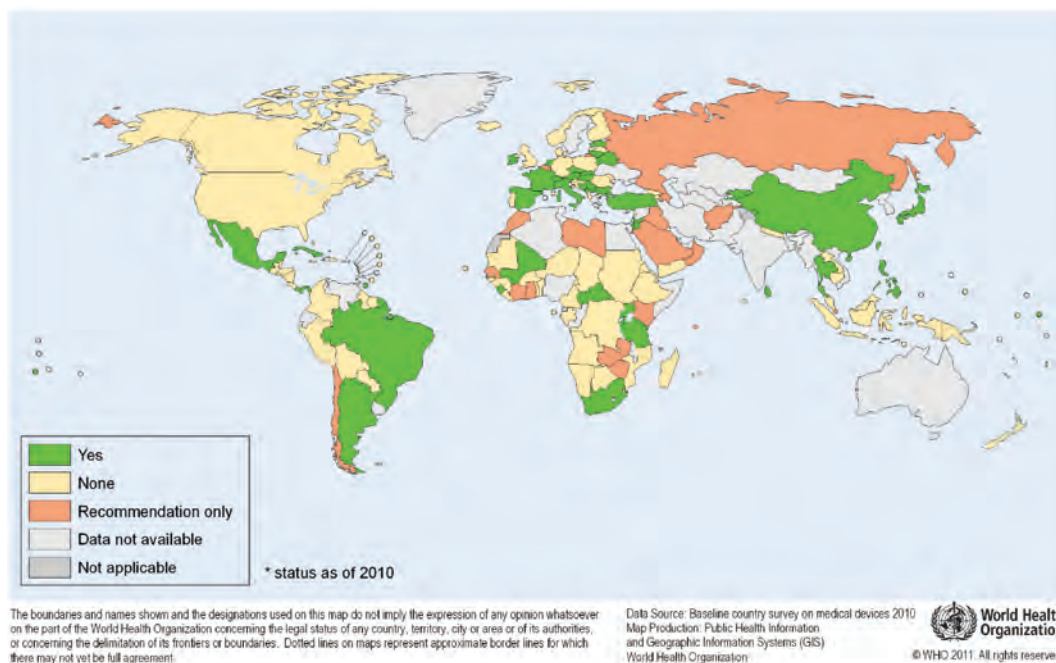
Source: (9).

Figure 14. Countries with a national list of approved medical devices for procurement or reimbursement by income level



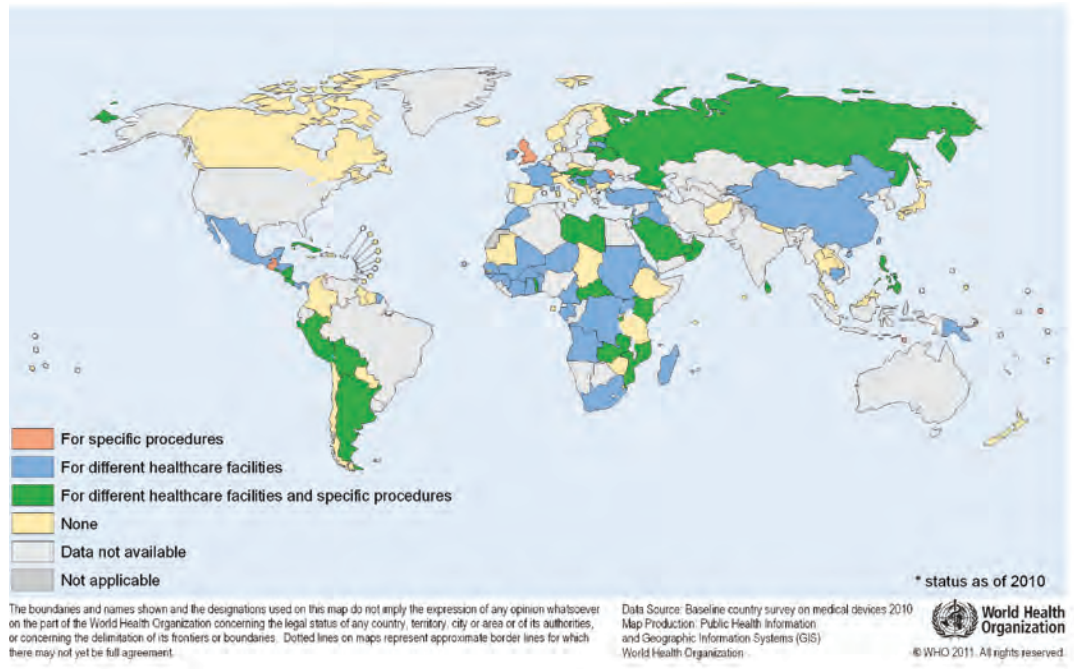
Source: (9).

Figure 15. Distribution of countries with a national list of approved medical devices for procurement and reimbursement*



Source: (9).

Figure 16. Distribution of countries that have a list of medical devices by health care facility or clinical procedure*



Source: (9).

8 Conclusion

Data show that policies, strategies, and action plans for medical devices are being developed in Member States. It is promising that this has been done in many countries within national health plans, such that specific public health needs are being considered. Of course, more work needs to be done to ensure wider implementation, particularly to link health systems components cohesively and to more fully engage all stakeholders. These stakeholders – governments authorizing budgets, professional organizations, the private sector, nongovernmental organizations, funding agencies, and the medical technology industry – play a critical role in implementing country or regional policies on medical devices.

As stated in WHO's strategic objectives and in resolution WHA60.29 on health technologies, WHO will continue to work in support of the formulation and monitoring of comprehensive national policies, norms and standards, and evidence-based policy guidance, to ensure improved access to high-quality medical devices.

Over the past 20 years, WHO and professional organizations have developed important documents as well as country and regional workshops on health technologies. In the past three years, the GIHT, with the support of the Bill & Melinda Gates Foundation, has given health technologies greater exposure through guidelines, tools, and regional- and country-specific action plans. More recently the baseline country survey on medical devices has provided valuable data on the state of medical device policies, forming the basis for future action. Recommendations from the First Global Forum on Medical Devices in 2010 will continue to raise the awareness of the crucial role that medical devices play in the prevention, diagnosis, and treatment of disease and rehabilitation. The hope is that the higher profile of medical devices will translate into better health care for the global population, allowing them to enjoy a better quality of life.

References

1. *Provisional agenda item 10 for the sixty-third Session of the Regional Committee, Bangkok, Thailand, 7–10 September 2010*. Geneva, World Health Organization, 2010 (SEA/RC63/9; http://www.searo.who.int/LinkFiles/RC_63_a-10-SEA-RC63-9.pdf, accessed 1 May 2011).
2. *Social determinants of health*. Geneva, World Health Organization, 2008 (http://www.who.int/social_determinants/en/, accessed 29 April 2011).
3. *Child and adolescent health and development: progress report 2009*. Geneva, World Health Organization, 2010 (http://whqlibdoc.who.int/publications/2010/9789241599368_eng.pdf, accessed 4 May 2011).
4. *Pocket book of hospital care for children: guidelines for the management of common illnesses with limited resources*. Geneva, World Health Organization, 2005 (http://www.who.int/child_adolescent_health/documents/9241546700/en/index.html, accessed 4 May 2011).
5. Opening address at the WHO First Global Forum on Medical Devices. Bangkok, Thailand, 9–11 September 2010 (http://www.who.int/dg/speeches/2010/med_device_20100909/en/index.html, accessed 4 May 2011).
6. *Global burden of disease and risk factors*. Geneva, World Health Organization, 2006.
7. *Global burden of disease: 2004 update*. Geneva, World Health Organization, 2008.
8. *Medical devices: managing the mismatch*. Geneva, World Health Organization, 2010 (http://whqlibdoc.who.int/publications/2010/9789241564045_eng.pdf, accessed 25 May 2011).
9. *Preliminary results of the baseline survey on medical devices*. World Health Organization, 2010.
10. *Landscape analysis*. Geneva, World Health Organization, 2010 (http://whqlibdoc.who.int/hq/2010/WHO_HSS_EHT_DIM_10.13_eng.pdf, accessed 4 May 2011).
11. *World health report 2008: primary health care—now more than ever*. Geneva, World Health Organization, 2008.
12. *Universal declaration of human rights*. Geneva, United Nations, 1948 (<http://www.un.org/en/documents/udhr/index.shtml>, accessed 27 April 2011).

13. *Everybody's business: strengthening health systems to improve health outcomes: WHO's framework for action*. Geneva, World Health Organization, 2007.
14. Alliance for Health Policy and Systems Research. *Systems thinking for health systems strengthening*. Geneva, World Health Organization, 2009.
15. *First WHO Global Forum on Medical Devices: context, outcomes, and future actions*. Report on the meeting from 9–11 September 2010, Bangkok, Thailand. Geneva, World Health Organization 2011 (http://www.who.int/medical_devices/gfmd_report_final.pdf, accessed 4 May 2011).
16. *Medium-Term Strategic Plan 2008-2013* (Amended draft). Geneva, World Health Organization, 2007 (http://apps.who.int/gb/ebwha/pdf_files/MTSP2009/MTSP4-en.pdf, accessed 27 April 2010).
17. *Health technology assessment of medical devices*. Geneva, World Health Organization, 2011.
18. Temple-Bird C et al. 'How to Manage' series of health care technology guides. St Alban's, Ziken International (Health Partners International), 2005 (http://www.healthpartners-int.co.uk/our_expertise/how_to_manage_series.html, accessed 4 May 2011).
19. *Monitoring and evaluation of health systems strengthening: An operational framework*. Geneva, World Health Organization, 2010 (http://www.who.int/healthinfo/HSS_MandE_framework_Oct_2010.pdf, accessed 27 April 2010).
20. *WHO 2008–2013 action plan for the Global Strategy for the Prevention and Control of Non-Communicable Diseases*. Geneva, World Health Organization, 2007.



Department of Essential Health Technologies

World Health Organization

20 Avenue Appia

CH-1211 Geneva 27

Switzerland

Tel: +41 22 791 21 11

E-mail: medicaldevices@who.int

http://www.who.int/medical_devices/en/

ISBN 978 92 4 150163 7

