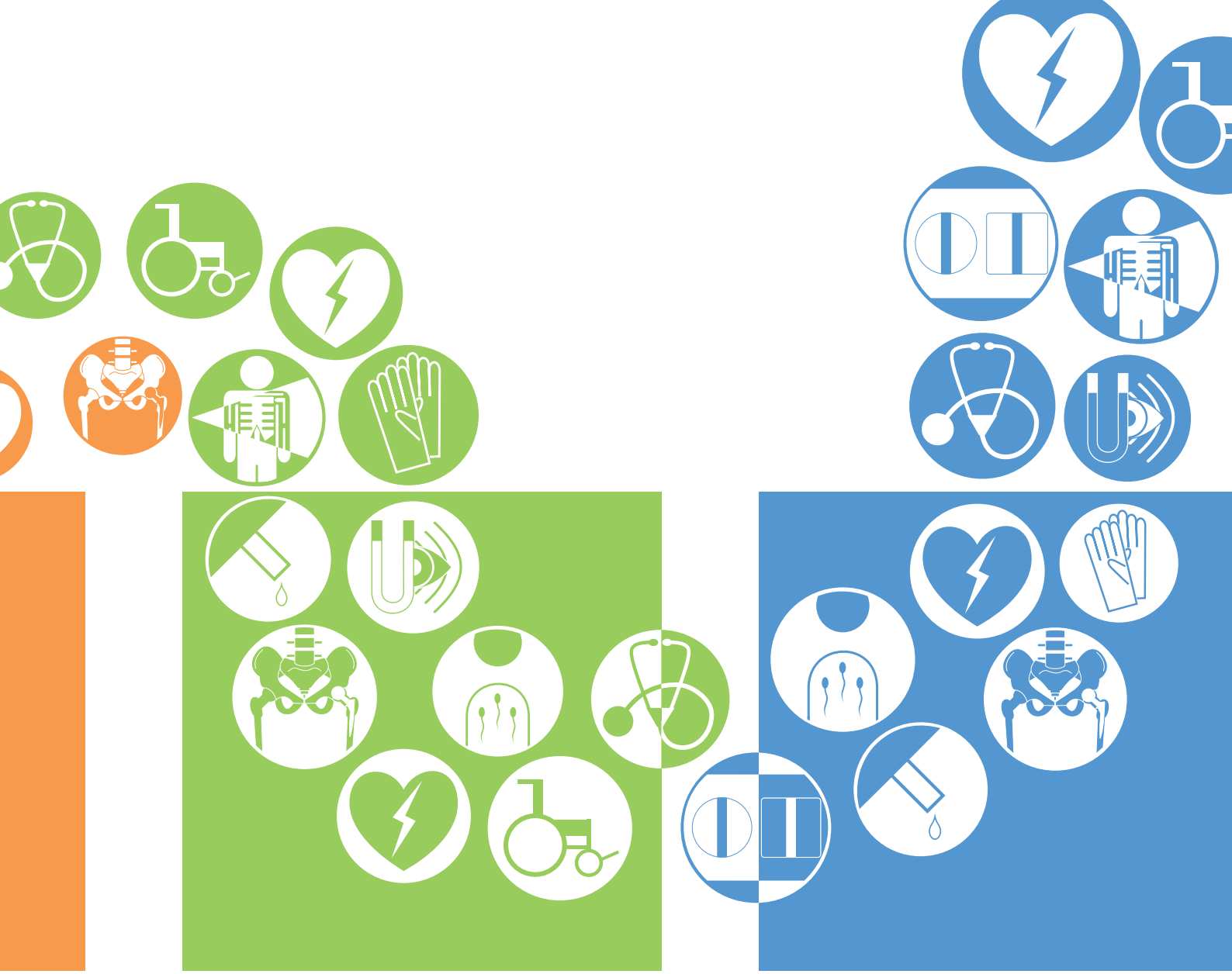

First WHO Global Forum on Medical Devices: context, outcomes, and future actions

World Health Organization

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First WHO Global Forum on Medical Devices: context, outcomes and future actions

9 –11 September 2010
Bangkok, Thailand

Acronyms and abbreviations

AGIT	Advisory Group on Innovative Technology
AIDS	acquired immune deficiency syndrome
CD-ROM	compact disc read-only memory
CPG	clinical practice guideline
DALY	disability-adjusted life year
DVD	digital video disc
GBD	global burden of disease
GHTF	Global Harmonization Task Force
HIV	human immunodeficiency virus
HTA	health technology assessment
HTAi	Health Technology Assessment International
HTM	health technology management
ICF	International Classification of Functioning, Disability and Health
IFMBE	International Federation for Medical and Biological Engineering
INAHTA	International Network of Agencies for Health Technology Assessment
ISO	International Organization for Standardization
LED	light-emitting diode
MDG	Millennium Development Goal
NGO	nongovernmental organization
SMS	short message service
TAGHT	Technical Advisory Group on Health Technologies
UN	United Nations
WHA	World Health Assembly

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Executive Summary

Medical devices – health technologies that are not medicines, vaccines or clinical procedures – save lives, improve health and are indispensable for the prevention, diagnosis, treatment and management of all medical conditions, diseases, illnesses and disabilities. But medical devices need to be accessible, appropriate for different health-care settings and affordable to populations in need. Since the adoption of resolution WHA60.29 on health technologies *(1)* by the Sixtieth World Health Assembly in May 2007, WHO has been working with partners towards devising an agenda, action plan, tools and reference documents to increase access to appropriate health technologies, particularly medical devices, to achieve one of WHO's strategic objectives of improving access, quality and use of medical products and health technologies.

Convened in Bangkok, Thailand, from 9-11 September 2010, the First WHO Global Forum on Medical Devices *(2)* built on previous work, knowledge and experience in this area, and was a pivotal point in advancing collaborative efforts to improve access to appropriate medical devices globally. Participants included high-level policy-makers from Member States, representatives from patients' organizations, nongovernmental organizations, health professionals, researchers, academic institutions, professional organizations, biomedical engineering institutions, umbrella organizations in the medical devices industry, and UN organizations. Participants from 106 countries attended the three-day Global Forum to discuss and explore existing and potential challenges and opportunities for promoting access to innovative, appropriate, affordable and high quality medical devices. A crucial outcome of the Global Forum was a consensus on the priorities for future action, resulting in agreed recommendations.

This report, the *First WHO Global Forum on Medical Devices: context, outcomes and future actions,* briefly describes the intense activity in the medical device arena leading up to the Global Forum. It outlines and discusses the main outcomes of the Global Forum, and then consolidates the information to focus on future actions for achieving global access to appropriate medical devices, through better regulation, assessment and management processes.

It is proposed that the stakeholders implement all of the priority actions outlined in this report, ideally, before the Second WHO Global Forum on Medical Devices in 2012. The WHO commitment to health technologies, particularly medical devices, is permanent and steadfast and more priority actions will be identified and implemented along the way, as necessary.

In order to increase health coverage, have better health services, and best assist populations in need, it is necessary to make all stakeholders aware of the importance of decisions relating to the design, choice and use of appropriate, safe and effective medical devices, and to act accordingly. All stakeholders, whoever and wherever they are, are accountable for the success or failure of access to appropriate medical devices – a fundamental factor in improving the health of populations.

Introduction

In September 2010, over 300 participants from around the world gathered in Bangkok, Thailand, for the first ever WHO Global Forum on Medical Devices *(2)*. The Global Forum built on three years of intense activity that followed the adoption of the first resolution on health technologies by the World Health Assembly (WHA) in May 2007 (WHA60.29). These activities included: regional meetings on health technology; a baseline country survey on medical devices; development of reference documents and tools on medical device regulations, assessment and management; and a search for innovative technologies for global health concerns. The Global Forum provided a platform for raising awareness of the importance of medical devices, identifying and planning for future, country-driven priorities, and galvanising global support for this crucial health systems component.

High-level policy-makers from 106 Member States (including representatives from United Nations (UN) and nongovernmental organizations (NGO), diverse health professionals from research and academia, as well as umbrella organizations in the medical devices industry), met for three days to learn, share and discuss a previously neglected area of huge importance to global health that requires increasing recognition in the future: access to appropriate, affordable, innovative, and high quality medical devices.

At the Global Forum's inaugural address the Prime Minister of Thailand, Mr Abhisit Vejjajiva, called on delegates, scholars, industry members, representatives from international organizations and donors to jointly commit themselves to "building fairness and reducing inequity to ensure access to affordable, safe and effective medical devices, and to quality health care for all" *(3, Appendix A)*. And in her opening speech the Director-General of WHO, Dr Margaret Chan, challenged participants to maintain the momentum emerging on medical devices following the adoption of the health technology resolution three years earlier: "We are here to help set the agenda for a more rational approach to the acquisition and use of medical devices in their full range of applications," she said. "I believe you will agree: too many people are being excluded from the benefits of medical devices, and this is a challenge we need to address" *(4, Appendix B)*.

The following section outlines the importance of medical devices and sets the scene for the remainder of this report.

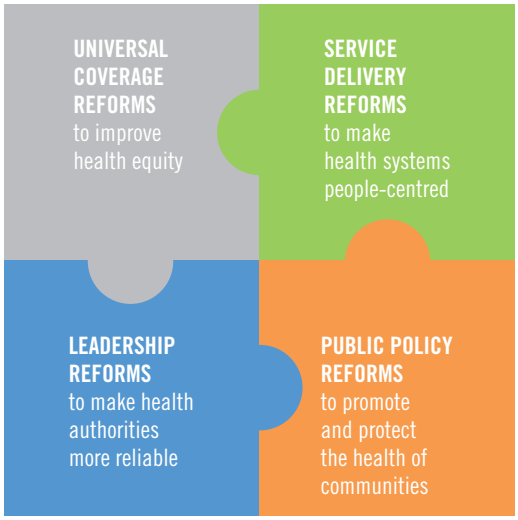
Background

Health technologies are one of the six building blocks identified by WHO as essential for all health systems (along with financing, health workforce, information, service delivery and leadership/governance) (Figure 1). If one (or more) of these six components is missing or inadequate, health systems cannot function at the level necessary to improve the health of individuals and populations in a sustainable way.

Figure 1. Six building blocks of health systems *(5)*

Furthermore, health technologies have key implications for universal health coverage, for the way in which health care is provided based on individual and population needs, on sound governance and community participation, and on public health policies (Figure 2).

Figure 2. The four interconnected factors necessary to improve population health *(6)*



The overall purpose of medical devices – health technologies that are not medicines, vaccines or clinical procedures – is to save lives and improve health and the quality of life. Medical devices also have a crucial role in the prevention, diagnosis, treatment and management of all medical conditions, diseases, illnesses and disabilities. Assistive devices, in particular, are indispensable for rehabilitation and to enhance the functionality of people with disabilities.

The few years preceding the 2007 World Health Assembly were crucial for Member States to comment on the draft health technology resolution, initially presented by Mexico to the WHO Executive Board. During

this period the WHO Secretariat prepared a grant proposal for a global initiative on health technologies that was then submitted to the Bill and Melinda Gates Foundation and signed in May 2008. Furthermore, the time was also used to reach an agreement with the Government of the Netherlands on the need for a study that focused on defining the Priority Medical Devices project and its research agenda.

These activities resulted in three outcomes that together enabled medical devices advocacy to reach a tipping point: 1) support for the Priority Medical Devices project *(7)* by the Government of the Netherlands; 2) support by the Bill and Melinda Gates Foundation for three years of intense global work on health technology policies and innovation; and, 3) acceptance by 194 Member States of the World Health Assembly health technology resolution *(1)*, which commits Member States and the WHO Secretariat to specific actions on medical devices. Each of these activities also contributes to fulfilment of a specific WHO strategic objective, namely to improve access, quality and use of medical products and health technologies.

First WHO Global Forum on Medical Devices: the context

WHO has several initiatives related to health technologies. They are detailed separately below, but should be viewed together as an integrated response to the 2007 World Health Assembly health technology resolution, which addresses the urgent need to make health technologies, in particular medical devices, globally available, accessible, appropriate and affordable, in line with WHO strategic objective of improving access, quality and use of medical products.

World Health Assembly resolution WHA60.29

In May 2007, the Sixtieth World Health Assembly expressed concern about the waste of resources resulting from inappropriate investments in health technologies. In particular, many medical devices do not meet high-priority needs, are incompatible with existing infrastructures, are irrationally or incorrectly used, or do not function efficiently. In adopting resolution WHA60.29 on health technologies the World Health Assembly acknowledged the need: "to contain burgeoning costs by establishing priorities in the selection and acquisition of health technologies … on the basis of their impact on the burden of disease, and to ensure the effective use of resources through proper planning, assessment, acquisition and management" (*1*).

Box 1 lists resolution WHA60.29 action points for Member States and the WHO Secretariat.

Box 1
Resolution WHA 60.29
URGES Member States:

(1) to collect, verify, update and exchange information on health technologies in particular medical devices as an aid to their prioritization of needs and allocation of resources;
(2) to formulate as appropriate national strategies and plans for the establishment of systems for the assessment, planning, procurement and management of health technologies in particular medical devices, in collaboration with personnel involved in health-technology assessment and biomedical engineering;
(3) to draw up national or regional guidelines for good manufacturing and regulatory practices, to establish surveillance systems and other measures to ensure the quality, safety and efficacy of medical devices and where appropriate participate in international harmonization;
(4) to establish where necessary regional and national institutions of health technology, and to collaborate and build partnerships with health-care providers, industry, patients' associations and professional, scientific and technical organizations;
(5) to collect information that interrelates medical devices, which deal with priority public health conditions at different levels of care and in various settings and environments, with the required infrastructure, procedures and reference tools;

REQUESTS the Director-General:

(1) to work with interested Member States and WHO collaborating centres on the development in a transparent and evidence-based way of guidelines and tools, including norms, standards and a standardized glossary of definitions relating to health technologies in particular medical devices;

(2) to provide support to Member States where necessary in establishing mechanisms to assess national needs for health technologies in particular medical devices and to assure their availability and use;
(3) to develop methodological tools to support Member States in analysing their health technologies in particular medical devices needs and health-system prerequisites;
(4) 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) to work jointly with other organizations of the United Nations system, international organizations, academic institutions and professional bodies in order to provide support to Member States in the prioritization, selection and use of health technologies in particular medical devices;
(6) to establish and update regularly an evidence and web-based health technologies database to serve as a clearing house which will provide guidance on appropriate medical devices according to levels of care, setting, environment, and intended health intervention, tailored to the specific needs of country or region;
(7) to provide support to Member States with vulnerable health-care systems so as to identify and put in place appropriate health technologies in particular medical devices that facilitate access to quality services in primary health care;
(8) to report on implementation of this resolution to the Executive Board and the Sixty-second World Health Assembly through the Executive Board.

Other World Health Assembly resolutions of relevance to health technologies include:

1) ***Resolution WHA58.28*** *(8)*. Adopted by the World Health Assembly in May 2005, this resolution on eHealth acknowledged: "eHealth is the cost-effective and secure use of information and communications technologies in support of health and health-related fields, including health-care services, health surveillance, health literature, and health education, knowledge and research," and urged Member States to develop and implement eHealth technologies.

2) ***Resolutions WHA60.30*** *(9)* ***and WHA61.21*** *(10)*. Adopted by the World Health Assembly in May 2007, WHA60.30 requests the WHO Secretariat to prepare background documents and support the Intergovernmental Working Group on Public Health, Innovation, and Intellectual Property for the purpose of elaborating a plan of action. Resolution WHA61.21 (adopted in May 2008), establishes a global strategy and plan of action that consists of eight elements designed to promote innovation, build capacity, improve access and mobilize resources.

3) ***Resolution WHA62.12*** *(11)*. Adopted by the World Health Assembly in May 2009, this resolution on primary health care, including health systems strengthening, urges Member States: "to improve access to appropriate medicines, health products and technologies, all of which are required to support primary health care."

Priority Medical Devices project

In 2007, with support from the Ministry of Health, Welfare and Sport of the Government of the Netherlands, WHO established the Priority Medical Devices project *(7)* to determine whether medical devices on the global market adequately meet the needs of health-care providers and patients throughout the world and, if not, to propose remedial action based on robust research. The project identified gaps in the availability of medical devices and highlighted obstacles that hinder the full use of medical devices as public health tools. A second objective was the development of a methodology for identifying the medical devices required to meet global public health needs. A third objective was to propose a possible research agenda for exploring how the gaps and obstacles that were identified could be addressed.

The Priority Medical Devices project developed a public health-based approach to medical devices. The first step in this approach identified the most important health problems: on a global level this meant using the WHO global burden of disease framework *(12)* and disease risk factor estimates. The second step referred to clinical guidelines to identify how health problems are best managed. And the third and final step linked the results of the first two steps to produce a list of key medical devices (an availability matrix) needed for the management of the identified high-burden conditions, at a given health-care level and in a given context. Further literature searches and qualitative research helped to identify challenges and possible solutions regarding selection and use of medical devices, as well as medical device innovation.

The findings of the Priority Medical Devices project are reported and discussed in the report *Medical devices: managing the mismatch (13)*, which was launched at the Global Forum in September 2010.[1]

Global Initiative on Health Technologies

Established in March 2008 by the WHO Department of Essential Health Technologies with support from the Bill and Melinda Gates Foundation, the aim of the Global Initiative on Health Technologies is to help make the benefits of core health technologies available at an affordable price, particularly to communities in resource-limited settings, in order to effectively control important health problems.

The initiative arose from the recommendations of two global consultations on health technologies hosted by WHO in February and March 2007, and from World Health Assembly resolution WHA60.29 approved in May 2007. The meetings were attended by external experts, representatives of governments, NGOs, patient associations, manufacturer umbrella associations, external stakeholders, and representatives of WHO Regional Offices and clusters.

The initiative has two main objectives:

1) To challenge the international community to establish a framework for the development of National Health Technology Programmes that will impact the burden of disease and ensure effective use of resources; and
2) To challenge the business and scientific communities to identify and adapt “innovative technologies” that can have a significant impact on public health.

1 Full report and background papers are available at http://www.who.int/medical_devices/access/en/index.html

To date, through the Global Initiative on Health Technologies, WHO and partners, (representatives of Member States, NGOs, advisers and other stakeholders) have worked to:

- Implement a Baseline Country Survey on Medical Devices, to determine the needs;
- Update and develop guidelines and tools required for the procurement, regulation, assessment, management, maintenance, donation and use of medical devices for different health care facilities and clinical procedures;
- Launch a search for innovative technologies that address global health concerns (as described below) and select some particular technologies;
- Compile and publish an e-documentation centre on health technology[2]. To date there are more than 300 published documents available in their original language.

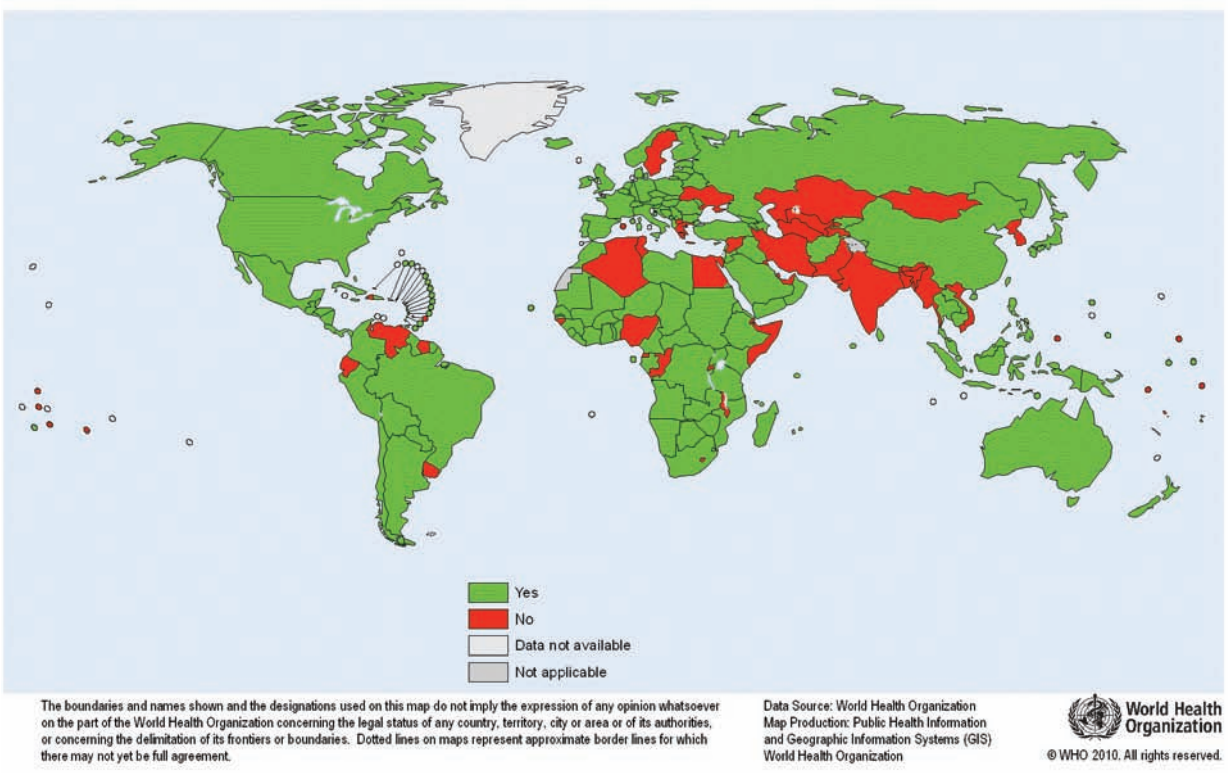
Baseline country survey

In December 2008, the need to have evidence based data and information regarding health technology at the country level led to the launch of the baseline country survey on medical devices *(14)*. Consultations were made with Member States and regional advisers before delivery to the Ministries of Health of all Member States and Associate Members in February 2010.

The baseline country survey on medical devices 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 use this data 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.

As of November 2010, 144 (out of 196) countries had supplied information in response to the 22 survey questions. See Figure 3 for the geographical distribution of country responses.

Figure 3 Baseline Country Survey on Medical Devices survey submissions



2 The e-documentation center is available at http://www.who.int/medical_devices

The results of the survey have provided useful information and a summary of the key results to date are shown in Box 2[3].

Box 2

Summary of the Baseline Country Survey on Medical Devices

Participation was distributed throughout the different regions with 39 responses from the WHO African Region, 29 from the WHO Region of the Americas, 10 from the WHO Eastern Mediterranean Region, 44 from the WHO European Region, 6 from the WHO South-East Asia Region, and 16 from the WHO Western Pacific Region. See Appendix C for a detailed list.

ALL 144 COUNTRIES

- National policy on health technology
  - 34% have a national policy as part of the national health programme or plan;
  - 9% have a separate policy for health technologies;
  - 74% of countries have a unit (at least of one individual) within the Ministry of Health that manages medical devices;
  - 66% of countries have an authority responsible for implementing and enforcing medical device specific product regulations;
  - 58% of countries carry out the procurement of their medical devices at national level.

- Donations
  - 15% of countries use WHO guidelines on health-care equipment donations;
  - 26% have developed national guidelines;
  - 58% do not have any guidelines.

- Technical specifications
  - 41% of countries have recommended technical specifications of medical devices to support procurement or donations.

- National list of approved medical devices
  - 29% of countries have a national list of approved medical devices for procurement or reimbursement. An additional 12% have one as a recommendation.

- Medical equipment management units
  - 76% of countries have a medical equipment management unit with professionally trained biomedical/clinical engineers or technicians at one or more levels (national, regional or hospital level).

- Availability of high cost medical devices
  - At least seven countries do not have any mammogram equipment;
  - 25 countries lack any type of radiation therapy.

3 Complete results are available at http://www.who.int/medical_devices/survey_preliminary_results/en/index.html

LOW-INCOME COUNTRIES[4]

Of the 49 low-income countries, 33 have participated in the survey.

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

Guidelines and tools[5]

To help define needs and develop necessary tools, a series of international meetings took place in 2009 and 2010. The participants included country representatives, regional advisers, experts, NGOs, international professional organizations and representatives of the medical device industry.

The Technical Advisory Group on Health Technologies (TAGHT) met three times (Geneva, April 2009; Rio de Janeiro, November 2009; and Cairo, June 2010) to further the activities of objective 1 of the Global Initiative on Health Technology. The summary of each meeting is outlined in Boxes 3, 4, and 5 while full reports are available on the WHO website[6].

Box 3

First TAGHT meeting: April 2009, Geneva

The purpose of this meeting was to review and analyse country experiences in order to better support Member States in developing, improving or enhancing effective national health technology policies, programmes and systems, particularly through the revision and update of existing tools or the development of new ones to address identified gaps. The recommendations of the meeting were followed up by a smaller group of selected experts who worked on the revision and update of existing tools and development of new ones, as required.

The meeting convened participants and observers from 10 countries (see Appendix C), the 25 members of the TAGHT, and staff from WHO headquarters and four of the six WHO Regional Offices.

4 Low-income countries as considered in the World Bank list of economies (July 2008) (http://siteresources.worldbank.org/DATASTATISTICS/Resources/CLASS.XLS).
5 Documents and tools will be posted on http://www.who.int/medical_devices/en/ when available
6 Full reports are available at http://www.who.int/medical_devices/events/en/index.html

Box 4

Second TAGHT meeting: November 2009, Rio de Janeiro

The specific meeting objectives were to update participants on the health technology management tools under development since April 2009; review the current challenges and strategies facing the pilot countries; and hold an interactive session for the group to present proposals for new tools based on information gathered from the earlier presentations and discussions. Progress reports on tools development were presented and discussed by working groups. Additionally, further gaps in required guidelines and tools were identified and new working groups were formed to create the additional guidelines and tools.

The meeting convened participants and observers from 22 countries (see Appendix C), 23 members of the TAGHT, four representatives from the medical device industry, and staff from WHO headquarters and five of the six WHO Regional Offices.

Box 5

Third TAGHT meeting: June 2010, Cairo

The main objectives of this meeting were to identify the key components of an action plan for the implementation of national essential health technology programmes and to measure the progress of the programme adoption; identify resources currently available, including tools developed by experts from the 1st and 2nd meetings but also additional resources that might support effective implementation; and develop a prototype tool to assist in identifying gaps in needs. The meeting resulted in the participating countries developing and presenting their action plans.

The meeting convened participants and observers from nine countries (see Appendix C), eight members of TAGHT, staff from WHO headquarters and four of the WHO Regional Offices.

WHO call for innovative technologies

The Advisory Group on Innovative Technology (AGIT) met twice (Singapore, June 2009 and Copenhagen, April 2010) to further the activities related to objective 2 of the Global Initiative on Health Technology. The summary of each meeting is outlined in Boxes 6 and 7 while full reports are available on the WHO website[7].

By the January 2010 deadline for the call for innovative technologies, 84 submissions from 29 countries were received in two categories: 1) those that described potentially commercial products; and 2) those which were not yet in the commercialized stage. Of the final 15 technologies selected, eight were in the first category and seven in the second[8]. Several of these innovative technologies were also featured in poster presentations at the Global Forum.

7 Full reports are available at http://www.who.int/medical_devices/events/en/index.html

8 Detailed information regarding the WHO call for innovative technologies is available at http://www.who.int/medical_devices/call/en/index.html

Box 6
First AGIT meeting: June 2009, Singapore

The first AGIT meeting reviewed and prioritized key health problems to be addressed in the WHO call for innovative technologies that address global health concerns. Presentations by the WHO Collaborating Centres were reviewed to identify key global health concerns that could be addressed by a call for innovative technologies, and to develop criteria for the selection of the innovative technologies.

The meeting convened 23 AGIT members, representatives from seven WHO Collaborating Centres, eight members of staff from WHO Regional Offices and headquarters, and eight observers from the medical device industry and other organizations.

Box 7
Second AGIT meeting: April 2010, Copenhagen

Participants of the second AGIT meeting assisted in the final selection of applications to the call for innovative technologies, to advise on dissemination strategies for the technologies selected and to provide recommendations regarding future calls.

The meeting participants split into groups to review a set of pre-selected applications and their potential publication on the WHO website. Consideration was also given to how the selection process would be communicated to applicants and the public. The meeting participants included 17 technical advisors, two representatives of WHO Collaborating Centres, six staff from WHO Regional Offices and four from WHO headquarters.

All of the initiatives and activities outlined above informed and influenced the agenda for the participatory discussions at the First WHO Global Forum on Medical Devices, an interactive event in which all delegates collectively identified priority actions to advance access to appropriate medical devices.

First WHO Global Forum on Medical Devices: outcomes

Convened in Bangkok, Thailand at the Plaza Athenee Hotel, from 9-11 September 2010, the goal of the First WHO Global Forum on Medical Devices was to mobilize stakeholders into action. The Global Forum provided the opportunity to share evidence, knowledge and experience to inform discussions on best practices and tools available for medical device evaluation, prioritization, regulation, assessment, management and research.

Building on all previous work, knowledge and experience in this area, the Global Forum was a pivotal point in furthering collaborative efforts to help improve:

- Incorporation and implementation of health technology policies into countries' national health plans to increase access to, encourage more rational use, and select better quality, effective medical devices, including those related to high-burden diseases and public health priorities;
- Health technology assessment to make informed decisions on the priorities of medical devices for adequate and appropriate health care coverage;
- Regulation to guarantee safe and effective medical devices;
- Management of health technologies and more efficient use of resources.
- Staff training in assessment, regulation, management (including staff retention) and operation of medical devices;
- Awareness of the need for medical device innovation and the need to identify safe, effective and appropriate solutions that help to achieve the MDGs, reduce the global burden of disease, and improve the performance of health systems.

Box 8 shows the objectives and expected outcomes of the First WHO Global Forum on Medical Devices.

Box 8

Objectives of the First WHO Global Forum on Medical Devices

- Demonstrate evidence on the need for appropriate evaluation, prioritization, regulation, assessment, management and research strategies on medical devices;
- Share knowledge on available resources: guidelines, tools, strategies, policies and best practices at national and regional levels and determine related needs;
- Bring together policy makers, professional organizations, funding agencies and key stakeholders to foster interdisciplinary partnerships and cultivate the aim of reaching a common goal;
- Encourage research, development and demonstration of appropriate and affordable quality medical devices.

Expected outcomes

- Identification of actions that can be taken for the improvement in availability, accessibility, appropriate selection, assessment, regulation, management, safety and use of medical devices;
- Compilation of best practices, available resources, tools and guidelines on medical devices for integration into national health plans;
- Establishment of a network of interdisciplinary professionals who will continue to support the role of medical devices in health systems.

The steering committee of the Global Forum comprised representatives from WHO; the Ministry of Health, Welfare and Sport, the Netherlands; the Ministry of Public Health, Thailand; Health Technology Assessment International (HTAi); the International Federation for Medical and Biological Engineering (IFMBE) and the International Network of Agencies for Health Technology Assessment (INAHTA). In addition, the international organizing committee comprised almost 50 members, including consultants, representatives from WHO Collaborating Centres, UN agencies, international professional organizations, NGOs, and WHO staff from headquarters and Regional Offices. For more details on the members of committees, see Appendix D.

The details

Programme

Given the high expectations, range and number of topics, and anticipated outcomes of the Global Forum, the programme *(15, Appendix E)* was designed to facilitate as many topics and as much discussion as possible.

Sessions were categorized into five main areas: role of medical devices to improve health service delivery; safe, accessible and affordable medical devices; health technology assessment; health technology management; and medical device regulation, and included eight plenary sessions, 18 parallel sessions, two poster sessions, and four workshops. All sessions incorporated time for in-depth discussion and participants could immediately interact (e.g. ask questions, send comments, vote) using personal electronic conferencing devices provided to them.

Speakers' and poster presentations, a webcast of the Global Forum, including plenary and parallel sessions, and the short film that opened the conference: *The power and potential of medical devices* is available on the WHO website.[1] [2]

Statistics

In response to 500 invitations, 310 participants (103 female, 207 male) from 106 countries (see Appendix C) attended the three days of the Global Forum, along with 50 speakers (19 female, 31 male), and 20 chairs (5 female, 15 male). Speakers and chairs came from low, middle and high-resource setting representing a total of 33 different countries while the 41 posters were presented by representatives from 24 countries. Box 9 lists the countries represented. Keynote speeches were made by the Prime Minister of Thailand and the WHO Director-General. Furthermore, the conference was attended by eight Ministers of Health (the Comoros, Iraq, Madagascar, the Republic of Moldova, Samoa, the Sudan, Tajikistan and Thailand), and seven vice-Ministers of Health (Angola, Japan, Mexico, the Federated States of Micronesia, Paraguay, Poland and the Syrian Arab Republic). Representatives from the International Atomic Energy Agency, the United Nations Children's Fund, the United Nations Office for Project Services (UNOPS) and the World Bank participated in the conference, along with the Assistant Director-General of Health Systems and Services, the Regional Director of the WHO South-East Asia Region, the Director of Essential Health Technologies, Regional Advisors for Health Technologies and Technical Officers from WHO. See Appendix F for a complete list of participants.

1 Detailed programme information is available at http://www.who.int/medical_devices/gfmd/en/index.html
2 The short film is additionally available at http://www.youtube.com/watch?v=92wBe8eTKBY

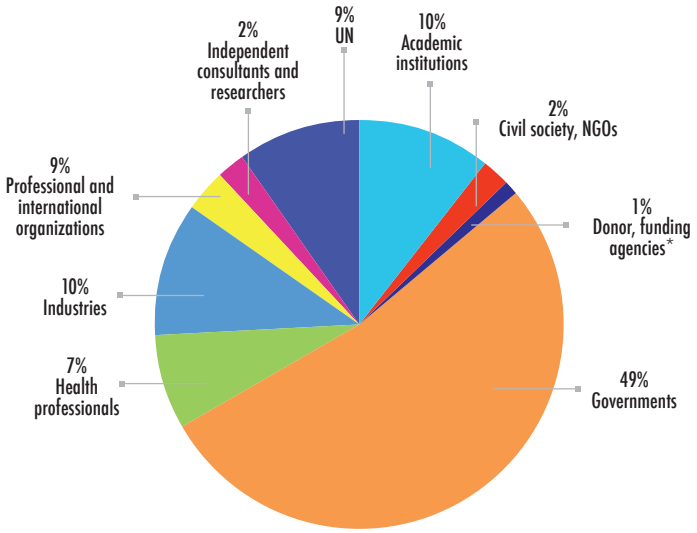
Box 9
Speaker, chair, and poster presenter country representation

Speakers and chairs
Australia
Belgium
Brazil
Canada
China
Denmark
Dominica
Egypt
Germany
Ghana
India
Italy
Japan
Jordan
Lithuania
Mexico
Netherlands
Nigeria
Norway
Pakistan
Philippines
Poland
Singapore
South Africa
Spain
Sudan
Sweden
United Republic of Tanzania
Thailand
Tunisia
Uganda
United Kingdom
United States

Poster Presenters
Albania
Argentina
Brazil
Canada
China
Colombia
Cuba
Ethiopia
Gambia
Germany
India
Italy
Japan
Jordan
New Zealand
Nigeria
Norway
Peru
Philippines
South Africa
Switzerland
United Republic of Tanzania
United Kingdom
United States

Figure 4 depicts participant breakdown by organizational category. Please see Appendix G for results from the participant feedback survey, reflecting their opinions in regards to the overall structure of the Global Forum (content of interest, presenters knowledge, and interactivity).

Figure 4. Participants of the Global Forum by organizational category



Recommendation process

One of the key outcomes of the Global Forum was to give a consensus view on priority actions. In order to enable participant agreement, the organizers of the Global Forum implemented a rigorous process, as described below.

Each parallel session was opened by the session chair and a co-chair gave a brief presentation of the work done by WHO in the topic area. Speakers (one to three per parallel session) then gave their presentations followed by questions, comments, and recommendations from participants.

The co-chair noted all of the recommendations made by participants in each session (listed by theme in Table 1). A grand total of 122 recommendations for all of the sessions was generated. At the end of each session, the recommendations were presented on screen. In a first round of voting, session participants were asked to select those recommendations they thought were the most important. The three recommendations with the highest votes for each session were selected resulting in a total of 42 key recommendations (three were omitted due to duplication or conflict of interest). All meeting participants had a subsequent opportunity to take part in a second round of voting on the 42 key recommendations. The key recommendations with the most votes were selected for a final list of 15 priority recommendations.

Table 1. Sessions by theme

Theme	Session
The role of medical devices to improve health service delivery	MDGs 4, 5 and 6 Meeting the needs The convergence of eHealth and medical devices: implications for the future
Safe, accessible and affordable medical devices	Towards safe and appropriate radiation treatment Safe medical devices for the patient, the health worker and the environment WHO call for innovative technologies that address global health concerns
Health technology assessment	Assessment for innovative and emerging technologies Health technology assessment (HTA) of medical devices: national prioritization processes The need for continuous HTA in developing countries and the role of international organizations
Health technology management	Equipment incorporation: selection, procurement and donations Health-care technology operation: training, safe use and maintenance Needs assessment: epidemiological needs, inventories and medical device lists
Health technology regulation	The need for adverse event reporting and post-market surveillance Pre-market approval including preclinical and clinical evaluation Harmonization of regulation - challenges and benefits

Table 2 presents the 42 key recommendations and the overlap between the general voting and the in-session voting. The top three recommendations within each theme were chosen as the final 15 priority recommendations. Appendix H charts the results of the round 2 voting on the 42 recommendations and Appendix I lists all 122 recommendations suggested by the forum participants.

In the closing session of the Forum, Dr Carissa Etienne, WHO Assistant Director-General emphasized that the organization intends to take forward the priority recommendations, and to seriously consider all of the remainder recommendations – work that will be prioritized and presented at the Second WHO Global Forum on Medical Devices in 2012.

The priority recommendations are considered and discussed in the final section of this report.

Table 2. The 42 proposed recommendations from the First WHO Global Forum on Medical Devices

Overall Ranking	Top recommend. in-session	
The role of medical devices to improve health service delivery		
1	X	**Promote culture of safety in developing countries by adverse event reporting and integrate patient safety concepts into the curriculum of medical professionals.**
2	X	**Highlight and share examples of appropriate technologies (locally produced, low prices, easy to use, durable and reliable) that succeeded in different national health care settings.**
3		**Use the infrastructure of teaching units and the guidelines already present for training of trainers and technicians on medical technologies.**
4		Enhance knowledge base of disease epidemiology, solutions and cost-effectiveness.
5	X	Survey countries for successful/unsuccessful e-health/telemedicine projects.
6		Conduct cost-benefit studies.
7		Strengthen patient/community involvement in all medical devices processes (design, research, provision, etc.) to improve health outcomes and ensure that needs are met.
8		Establish links between government and NGO projects and programmes.
Safe, accessible and affordable medical devices		
1	**X**	**Ensure that properly trained personnel are in place at the time of installation of radiation medicine technology.**
2		**Plan carefully at the government level for any new installation including consideration of proper infrastructure for effective use of the technology and investment in staff training.**
3	**X**	**Look at international recommendations to establish proper sharp waste management.**
4	**X**	Facilitate the emergence of clear context-specific regulatory guidelines.
5		WHO: Continue producing technical specifications of medical devices and guidance on cost assessment.
6		WHO: Foster cooperation between academia and industry.
7		Member States: Find an appropriate way of phasing out the use of mercury.
8		Conduct evidence-based comparison between mercury and digital equipment.
Health technology assessment		
1		**WHO: Support developing countries to develop capacity, learning from countries with developed health technology assessment systems and considering different models.**
2	**X**	**WHO: Promote health technology assessment as an integral part of health system research and strengthening and assist developing countries in conducting health technology assessment.**
3	**X**	**WHO: Help Member States to identify tools for prioritizing devices by using the health technology assessment process.**
4		Identify and adapt tool kits needed for health technology assessment and prioritize according to type, need and stage of development.
5		WHO and other international organizations: Use experience of developed countries to build local capacity focusing on transparency for assessing and purchasing.
6		Member States: Integrate continuous health technology assessment into the existing health system environment and health care system reforms.
7		Urge health technology assessment agencies to collaborate with developing countries.
8	**X**	WHO: Promote the value of continuous health technology assessment regarding medical devices in decisions to stakeholders in developing countries, policy-makers and industry representatives.

Health technology management		
1	X	**WHO: Support free access to nomenclature systems.**
2	X	**WHO: Urge industry to tag medical devices with a nomenclature reference.**
3		**WHO: Develop tools for needs assessment incorporating multiple dimensions (e.g. human resources, epidemiology, etc).**
4		WHO: Provide up-to-date medical device lists to be functional/procedure and facility level-based.
5		Develop toolkit for life cycle cost of equipment and standardization of equipment.
6		Provide case studies to show evidence of effectiveness of health technology management.
7	X	WHO: Develop decision-making guideline and tools to determine requirements for needs-driven procurement of technologies.
8		Develop and/or enhance training facilities for health technology managers.
9		WHO: Support and enhance the profile of health technology management and structures within ministries of health.
Health technology regulation		
1	X	**WHO: Facilitate opportunities for capacity building based on cooperation between regulatory authorities.**
2		**WHO: Facilitate capacity building for post-market surveillance and adverse event reporting in low-income countries.**
3		**Promote an exchange system for information on regulatory action.**
4		WHO and Global Harmonization Task Force (GHTF): Support governments to have harmonized standards in different countries.
5		Facilitate experience sharing and a meeting for device regulators every two years.
6	X	WHO: Encourage international databank for adverse events in addition to national databases and exchange of information.
7	X	WHO and GHTF: Take lead in the use of medical device regulation for pre-market and post-market guidance.
8		GHTF: Promote more support to assist countries to develop harmonized mechanisms.
9		WHO: Develop a programme for adverse event reporting on medical devices.

First WHO Global Forum on Medical Devices: future actions

Under the auspices of WHO, there have been three years of intense work on medical devices conducted by various groups, committees and individuals, culminating in the First WHO Global Forum on Medical Devices. The final section of this report highlights the need for an integrated action plan that takes into account all of the WHO collaborative work in health technology.

Outcomes of the First WHO Global Forum on Medical Devices

First outcome: Recommended priority actions

In response to each of the 15 priority recommendations agreed by Global Forum participants, short- and long-term actions were developed (see Table 3) through discussion with the six WHO Regional Advisers on health technology.

Table 3. Short- and long-term actions planned for the 15 priority recommendations

No.	Recommendation	Proposed Short-Term Action (2011)	Proposed Long-Term Action (after June 2011)
The role of medical devices to improve health service delivery			
1	Promote culture of safety in developing countries by adverse event reporting and integrate patient safety concepts into the curriculum of medical professionals.	- WHO medical devices unit to link with patient safety related units within WHO. - WHO to disseminate WHO Patient Safety Curriculum Guide for Medical Schools.	- WHO to work with internal and external partners to improve post-market surveillance, adverse event reporting and technology-related patient safety issues.
2	Highlight and share examples of appropriate technologies (locally produced, low prices, easy to use, durable and reliable) that succeeded in different national health care settings.	- WHO to make available on website a list of examples of appropriate/innovative technologies along with links to other relevant organizations.	- WHO to map the WHO list of innovative technologies to the research agenda of the Priority Medical Devices project. - Collaborating centers to test the ""appropriateness"" of innovative technologies by region and create a database of the results.
3	Use the infrastructure of teaching units and the guidelines already present for training of trainers and technicians on medical technologies.	- WHO to post a database of biomedical engineering related university programs and professional societies on WHO website.	- WHO to send information, recommendations and guidelines to all universities included in the database.
Safe, accessible and affordable medical devices			
4	Ensure that properly trained personnel are in place at the time of installation of radiation medicine technology.	- WHO medical devices unit to work with the radiation safety unit at WHO, International Atomic Energy Agency (IAEA) and professional organizations, such as the International Organization for Medical Physics (IOMP) to disseminate radiation guidelines.	- WHO to work with IAEA and other organizations on medical imaging and radiation capacity building, including the safe use and installation of medical radiation technologies.
5	Plan carefully at the government level for any new installation including consideration of proper infrastructure for effective use of the technology and investment in staff training.	- WHO to develop a needs assessment tool.	- WHO to facilitate the implementation of the needs assessment process (thereby enabling better planning) at the country level.
6	Look at international recommendations to establish proper sharp waste management.	- WHO to disseminate tools and guidelines on sharps waste management via health technology focal points in member states, industry, patient organizations and academia.	- WHO to assist countries in developing and implementing strategies on sound health-care waste management.

Health technology assessment (HTA)			
7	WHO: Support developing countries to develop capacity, learning from countries with developed health technology assessment systems and considering different models.	**- WHO to develop health technology assessment tool. - WHO to provide information regarding HTA on their website with links to collaborating centres and other institutions with which WHO shares a MoU in order to support access to information.**	**- WHO to support the development of HTA units at the Ministry of Health through the exchange of information and best practices from existing health technology agencies. - WHO to coordinate workshops on how to develop HTA such that HTA is included as a tool for decision making.**
8	WHO: Promote health technology assessment as an integral part of health system research and strengthening, and assist developing countries in conducting health technology assessment.		
9	WHO: Help Member States to identify tools for prioritizing devices by using the health technology assessment process.	- WHO to disseminate the use of existing tool kits that will assist newly formed HTA agencies/units in conducting a health technology assessment .	- WHO to coordinate workshops that will enable newly formed HTA agencies/units to develop recommendations and establish priorities.
Health technology management			
10	WHO: Support free access to nomenclature systems.	- WHO to develop the ideal characteristics of a nomenclature system to share with key stakeholders in order to define a single medical devices nomenclature system.	- WHO to work with external organizations and come to a consensus on selecting or creating a single WHO nomenclature system.
11	WHO: Urge industry to tag medical devices with a nomenclature reference.	- WHO to compare the information available on unique identification numbers.	- WHO to work with all stakeholders, including industry to select the best method to tag medical devices.
12	WHO: Develop tools for needs assessment incorporating multiple dimensions (e.g. human resources, epidemiology, etc).	- WHO to develop a needs assessment tool.	- WHO to facilitate the implementation of the needs assessment process (thereby enabling better planning) at the country level.
Health technology regulation			
13	WHO: Facilitate opportunities for capacity building based on cooperation between regulatory authorities.	- WHO to update the regulations guideline in 2011. - WHO to develop a network for regulatory authorities.	- WHO to update information relating to regulation on the WHO website. - WHO to promote collaboration between regulators. - WHO to coordinate regional workshops on the topic of regulation.
15	Promote an exchange system for information on regulatory action.		
14	WHO: Facilitate capacity building for post-market surveillance and adverse event reporting in low-income countries.	- WHO to review existing adverse event reporting and post-market surveillance systems for the eventual selection of one system. - WHO to make available links to adverse event reporting and post market surveillance information as well as regulatory action taken on their website.	- WHO to provide guidelines, tools and capacity building for adverse event reporting and post-market surveillance. - WHO to select one system for adverse event reporting and post-market surveillance

Second outcome: Best practices, available resources, tools and guidelines compiled

The Priority Medical Devices project and the work done under the auspices of the Global Initiative on Health Technologies identified some best practices. Similarly, during the course of the Global Forum, participants shared their experiences, successes and challenges. This information will be published in a best practice compilation. Both the Priority Medical Devices project and the Global Initiative on Health Technologies developed a public health approach to medical devices and identified the need to focus on the availability, accessibility, appropriateness and affordability of medical devices - concepts discussed at the Global Forum and overwhelmingly supported by participants. Inclusion of accountability in this list of "A's" was proposed in the final session of the Global Forum.

For the purposes of knowledge sharing, detailed information on medical devices presented in the Priority Medical Device project's eight background papers was also included in the CD-ROM given to conference participants and widely disseminated. This information is available through a dynamic e-resource library, which includes documents on best practices, available resources, tools and reference documents on medical devices for integration into national health plans. As a result of the Global Forum, this e-resource,

the "WHO health technologies e-documentation center", has become a more comprehensive source of information to best suit the needs of those who use this service[1].

Furthermore, information from the Baseline Country Survey on Medical Devices (14) has provided valuable insight into the current situation regarding medical devices in individual countries. In addition to providing essential information, the results of the survey have served as a needs assessment to better inform all stakeholders about priority areas for action, which have been included in the Global Forum recommendations. Information provided by this ongoing survey will be included in each country profile on the WHO website and will be used as a benchmark to help decision-makers and encourage country action at the national, regional and global levels.

The collaborative work of the Global Initiative on Health Technology has involved developing tools to integrate appropriate and affordable medical devices into the health system delivery component of national health plans, in order to reach universal health coverage. Some of these tools were discussed in the parallel sessions of the Global Forum and have been included in the final recommendations agreed by all participants.

In addition, members of the TAGHT have also been working to update and revise guidelines on the regulation, assessment, donations, procurement, maintenance, policies, management and use of medical devices (see Table 4). This work has also focused on developing lists of medical devices by clinical practice guidelines and by health-care facilities. The draft guidelines were presented for consultation on the CD-ROM given to Global Forum participants and also discussed during the course of the meeting. WHO will publish these reference documents in 2011.

Table 4. Reference documents in development

No.	Subject area
1	Health technology assessment
2	Medical device regulations
3	Needs assessment
4	Medical device procurement
5	Guidelines for health-care equipment donations
6	Health-care equipment maintenance
7	Health-care equipment inventory management
8	Computerized Maintenance Management System
9	Policy framework for health technology management
10	Medical devices nomenclature
11	Medical devices by health-care setting
12	Medical devices by clinical practice guidelines

1 The e-documentation center is available at http://www.who.int/medical_devices

Third outcome: Establishment of a network of interdisciplinary professionals

To date, many countries, organizations, groups and individuals from different sectors, have been involved in and helped to inform and develop all of the WHO collaborative work on medical devices. This has resulted in several networks of stakeholders including: the TAGHT; the AGIT; the Advisory Group and Steering Committee of the Priority Medical Devices project; and the Steering Committee and International Organizing Committee of the Global Forum. In addition, WHO has established four email listservs (focusing on eHealth, health technology assessment, regulation, and health technology management) and an online community for health technology focal points in 144 countries. Furthermore, participants at the Global Forum and those who were interested in attending, were invited to join the aforementioned listservs after the Global Forum.

Second Global Forum on Medical Devices

The Second WHO Global Forum on Medical Devices is planned for 2012. Participants will share progress made on all activities to date related to the 15 priority recommendations and the implementation of resolution WHA60.29 on health technologies as well as decide on additional priority actions. See Appendix J for a draft programme summary.

Conclusion

In some countries, action to improve access to health technologies began more than 20 years ago, but in many others such action has only recently started. The Global Initiative on Health Technologies, resolution WHA60.29 on health technologies, the Priority Medical Devices project and the First WHO Global Forum on Medical Devices have all helped raise awareness of the need for affordable, appropriate, accessible and available medical devices – and as discussed at the Global Forum, the need for a robust accountability process.

All stakeholders are invited to implement the actions outlined in this report (with particular emphasis on the regulation, assessment and rational management of medical devices, the use of appropriate and innovative technologies, and implementation of a public health approach to medical devices) before the Second Global Forum on Medical Devices in 2012. At this event, a new and updated action plan for the next steps towards ensuring adequate access to safe, effective and appropriate medical devices in health systems in all countries will be reviewed and discussed. Presentations on the implementation of resolution WHA60.29 on health technologies, 5 years after its approval, will be given by stakeholders and Member States. Additionally, more action points will be identified and implementation plans developed, as necessary.

In order to adequately address the important role of medical devices in the management of high-burden health problems and in health system strengthening, continuous action, targeted advocacy, fundraising, donor support and strong leadership are all essential. Men, women, children and newborns should not continue to die or suffer because the medical devices required to save their lives or improve their quality of life remain unavailable, inaccessible, inappropriate or unaffordable. For the sake of the health of poorer and all populations, we must not waste time: we have to act together – now.

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Appendix A

Welcome address by Abhisit Vejjajiva, Prime Minister of Thailand

His Excellency Abhisit Vejjajiva
Prime Minister of Thailand

Inauguration address at the First WHO Global Forum on Medical Devices
Bangkok, Thailand
9 September 2010

Your Excellency Dr. Margaret Chan,
Director General of the World Health Organisation,
Your Excellencies the Ministers of Health, honourable guests, ladies and gentlemen,

1. On behalf of the Royal Thai Government and people of Thailand, I would like to welcome all of you to Thailand for the First Global Forum on Medical Devices. I am honoured to be with you at this distinguished gathering of delegates from Member States of the World Health Organisation, as well as scholars and representatives of health professions, international agencies, civil society organisations, and the industry.

2. Protecting the health of the population is a crucial responsibility of all governments. Healthy people are every nation's valuable assets, as a productive workforce drives forward the economy. More importantly, having a healthy state of the body and the mind is a fundamental right of everyone in every society. As defined by the World Health Organisation, "health" is "a state of complete physical, mental and social well-being, and not merely the absence of disease or infirmity". Ensuring people's health clearly requires the collaborative efforts of various sectors in society, as well as the global community. Moreover, in today's medical care, medical technology and devices have assumed increased importance, in the quality and cost of healthcare services.

3. I am therefore very glad that this First Global Forum on Medical Devices is being held in Thailand. I am also pleased to learn that all of you who are gathered here are dedicated policymakers, officials, practitioners and experts from organisations in different sectors around the world, who are ready to share your knowledge and expertise, as well as your wealth of experiences, in our collective efforts to address the needs for appropriate policies and systems concerning medical devices.

4. The value of this kind of exchange cannot be exaggerated. Deliberations, discussions and lessons learned in various international conferences in the past have enhanced awareness of existing problems, generated new ideas, inspired proper solutions, and led to the undertaking of actions amongst policymakers and other key stakeholders in different countries. With your contributions, I am confident that this Forum will be recognised as a crucial milestone in health policy development at both national and international levels.

Excellencies,

Distinguished Participants,

5. The issue of medical devices and equipment is not a stand-alone issue. As a means to promote people's health, these technologies are normally introduced in the healthcare systems, while some of them are used by households, on a self-care basis. Therefore, in most instances, it is difficult to address problems related to medical devices and other health technologies without taking into account the culture, infrastructure and other characteristics of the health systems in particular countries. In the same vein, in making essential medical devices available to the population in need of them at affordable prices, it is important to consider this effort in the global and national contexts, where issues relating to research and development and production capacity, technology transfer, and trade regulations are also involved.

6. In this connection, I would like to commend the organising committee of this conference for incorporating all important aspects of medical devices – including innovation, prioritization, regulation, evaluation, procurement, usage, and so on – into the meeting agenda. It is also important that this conference will touch upon many topics particularly relevant to low- and middle-income countries, as well as policy issues that are relevant in any setting, regardless of the country's economic status.

7. I wish to highlight here two issues, namely, "universal access" and "equity", where lessons can be drawn from Thailand's health system. The Thai Constitution recognises access to health care as a basic right of all Thais, and thus our universal health coverage plan was established in 2002. We learn, however, that despite strong political commitments and multi-sectoral efforts, translating these policies into actions, and achieving equitable access to health services in practice, is not easy. Limited resources have compelled us to find ways to allocate and use them efficiently. Technology assessment, selection and management, including bulk purchasing, are among effective solutions adopted at the national level and in hospitals. The unaffordable price of healthcare products, which are, in some instances, associated with patents, is also an important barrier to their accessibility. I am delighted that the issues of 'Intellectual Property and Innovation' and 'Technology Transfer' will be discussed in this Forum, which will help improve access to a number of essential medical devices.

8. To reaffirm the importance of universal health coverage, I would like to call upon distinguished delegates, scholars, industry members, representatives from international organisations and donors to jointly commit themselves to "building fairness and reducing inequity" to ensure access to affordable, safe and effective medical devices, and to quality health care for all.

9. There are other challenges we must confront. The first one is the so-called issue of 'rational' versus 'irrational' use of medical devices and public education on this issue. Irrational use of medical devices has resulted in high costs without reasonable health gains. Policy decisions need to be supported by evidence proving the "value for money" of medical devices. Thus, it is fundamental to build up adequate capacity on Health Technology Assessment in our countries. Another challenge involves regulation. Like medicines, medical devices should be cost-effective, efficacious, safe and of good quality---hence every country needs to develop strong regulatory structures to ensure that these requirements are met. At the same time, systems should be established for the safe and effective disposal of outdated or expired medical devices that may pose risk for users. The last challenge is the strengthening of R&D and manufacturing of medical devices in developing countries, so that their citizens can access the technologies they need at affordable prices. I fully support the initiative to tackle all of these challenges, and to jointly build upon our strengths.

10. As well-devised health policies alone do not guarantee equitable access to quality services and essential technologies, it is my hope that this meeting will create fertile grounds for future networks and cooperation to strengthen policy development and implementation capacity with regard to medical devices, amongst Member States and domestic and international institutions.

11. Here in Thailand, we have long been addressing the need for multi-sectoral and interorganisational integration of health policies, as well as public-private partnership in order to efficiently tackle major health issues. I am certain that the lessons learned and experiences shared in this conference will be very helpful to all countries. For Thailand, our commitment is to see the establishment of the National Medical Device Systems Development Committee.

12. In closing, I wish to express my deep appreciation to the World Health Organisation, Madam Director General and her team for having taken the initiative in convening this Conference, and in providing Thailand with the opportunity to take on the important role as co-host. I wish all participants an enjoyable stay in Thailand, and great success in the meeting's deliberations. Thank you very much and Sawasdee Krub.

www.thaiembassy.sg/announcements/inaugural-address-by-his-excellency-abhisitvejjajiva- prime-minister-of-thailand-at-th

Appendix B

Inauguration address by Dr. Margaret Chan, Director-General of WHO

Medical devices: an area of great promise

Dr Margaret Chan
Director-General of the World Health Organization

Opening address at the Global Forum on Medical Devices
Bangkok, Thailand
9 September 2010

Your Excellency, Prime Minister Abhisit, honourable ministers, distinguished delegates, representatives of professional societies, patient groups, and industry, ladies and gentlemen,

I am pleased to welcome you to this first Global Forum on Medical Devices. I thank the government of Thailand and its Ministry of Public Health for hosting and supporting this event.

You represent a diversity of disciplines, interests, and country experiences. This diversity is important given the complexity of the task before us. This is the first meeting of its kind, and you will be exploring some new territory where the best way forward for public health is largely uncharted.

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.

The medical devices industry produces high-tech high-cost diagnostic and therapeutic equipment, but it also produces the basic supplies and devices that keep any health facility running smoothly on a daily basis.

The field also includes devices that aid functional ability, like wheelchairs, hearing aids, eyeglasses, intraocular lenses, and artificial limbs. The vital role of such devices in improving the quality of life is obvious, though often overshadowed by the attention given to more spectacular devices.

We are here to help set the agenda for a more rational approach to the acquisition and use of medical devices in their full range of applications.

We are here, in part, because of concern about runaway health care costs and pressure to contain these costs. As noted in a 2007 World Health Assembly resolution, health technologies, and medical devices in particular, represent an economic as well as a technical challenge to health systems.

That resolution expressed concern about the waste of resources caused by investments in medical devices that do not meet high-priority needs, are incompatible with existing infrastructures, are irrationally or incorrectly used, or do not function efficiently. This tells us some of the pitfalls.

But we are also here because the unquestionable benefits of medical devices are so unevenly distributed. I wonder if there is any other area that illustrates so profoundly the great difference in the ability of wealthy and developing countries to reap the benefits of advances in medicine and technology.

As one example, a recent WHO survey showed that the availability of mammography, an important screening tool for breast cancer, is one per 47 000 people in high-income countries, but one per 5.7 million people in low-income countries. The availability of CT scanners is one per 170 000 people in high-income countries, but one per 3.8 million in low-income countries.

In some countries, shortages of needles, syringes, and sterilizing equipment mean that up to 40% of injections are unsafe. As yet another example, some 30 developing countries do not possess a single radiotherapy machine for cancer treatment.

I believe you will agree: too many people are being excluded from the benefits of medical devices, and this is a challenge we need to address.

I can suggest some reasons for this great imbalance.

The most obvious one concerns resources and costs. Technological advances nearly always come at a price higher than conventional technologies, and some medical devices are obviously priced for the financially privileged few.

One figure illustrates the magnitude of the affordability problem. Worldwide, annual government expenditure on health ranges from well over $7,000 per person to less than $10. Low levels of expenditure on health help explain why many medical devices are considered luxuries.

Yet high cost alone is not the only explanation, the only excuse for such inequitable access. Many badly needed and affordable devices, like electrocardiographs, are still not widely used in low-income settings. This may reflect how priorities are set, with medicines and vaccines having a higher place in budgets.

A second problem is inherent to the industry. These are medical devices, produced for a medical market, largely focused on financially profitable diseases, and almost exclusively designed for use in wealthy settings.

Currently, most medical equipment used in low-resource settings is imported from industrialized countries. About 70% of the more complex devices do not function when they reach their destination.

A third problem follows logically and is deeply familiar: lack of capacity. I mean lack of infrastructure and funds for recurring costs. I mean erratic power supplies, uncertain water quality, a crippling shortage of health personnel, limited training capacity, difficulties getting spare parts, and limited budgets for maintenance and for purchasing consumables.

Under such conditions, a technological miracle can rapidly become the worst nightmare of service providers: wasted resources and risks to patient safety.

Faced with such harsh realities, we need to ask: what does a true “cutting edge” technology mean for the developing world?

The biggest breakthroughs are likely to come with technologies that use alternative power supplies, resist heat, humidity, and dust, relieve the workload, require little maintenance, and can be operated, with no risk to patient safety, by personnel with little specialized training.

Or with something so simple as glucose meters and test strips that perform well in the hot and humid homes of diabetes patients. Or with robust portable machines that extend the advantages of technology beyond the hospital setting or take it from cities to rural areas.

This is a challenge, but not an insurmountable one. During outbreaks, WHO has seen how portable PCR machines can vastly increase the speed and precision of containment operations.

You will be discussing technology transfer, which can help, and donations, which can be problematic. Developing countries are littered with unused, obsolete equipment and devices. Recent studies suggest that only 10% to 30% of donated equipment ever becomes operational.

A fourth reason is possibly the most important. That is, a failure to look at this rapidly evolving industry from a public health perspective. When we take a public health perspective, one priority is clear. First take care of the basics.

If we think about the health-related MDGs, and about what hinders progress, it becomes easier to define some basic needs. Blood transfusion services to prevent women in labour from bleeding to death. Anaesthesia machines, oxygen bags, and basic surgical equipment. Rapid point-of-care diagnostics for malaria and tuberculosis. Resuscitation equipment for newborns with breathing problems. Generators that keep equipment running when the electrical power shuts down.

I know you will be discussing MDG-related issues during the meeting, and will have many other ideas and experiences to contribute.

And we have another big-picture issue we need to address. 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.

Ladies and gentlemen,

You are tasked with setting an agenda for a more rational approach to medical devices. This is not an easy task.

It is tempting to seek guidance from years of largely successful efforts to rationalize the use of pharmaceutical products.

We can certainly draw some guiding principles from experience with essential medicines, namely the importance of focusing on priority health needs, and on affordable devices that match those needs. We can certainly repeat the commitment to fair and equitable access.

We can also identify some similar obstacles that limit the appropriateness of medical devices to priority needs in the developing world. Market forces, all by themselves, will not automatically shift the R&D agenda for medical devices towards unmet needs in the developing world.

As with pharmaceutical products, explicit policies are needed to move the power of innovation more directly into the service of international health development.

But here the similarities end. The diversity of medical devices is much greater than that of medicines. The pace of new product development is faster, and the lifecycle of some medical devices can be as short as 18 months.

The regulatory pathways are different. The approval process for medical devices is often less rigorous. Factors affecting the safety of medical devices are more numerous, including the competence and skills of product users. The potential for human error when a person swallows a pill is quite different from that when staff operate highly complex equipment.

Systems for reporting adverse medical device events and for conducting post-marketing surveillance are not yet so well advanced. These, too, are pitfalls in the midst of great promise.

Despite the challenges, a key achievement of this meeting is its strong public health approach. The organizing and steering committees have put together a public health agenda. The agenda is firmly focused on needs assessment and improved access to priority devices, especially in low-resource settings.

You will be considering the potential of these devices to reduce gaps in health outcomes, to relieve some of the pressures of the workforce crisis, to improve service delivery, and to strengthen health systems.

You will take a close look at the enabling environment: the role of health technology assessment, the management of medical devices through national health plans and strategies, and the need for strong regulation and enforcement.

You will explore the convergence of advances in information and communication technologies with advances in medical technologies. As practical guidance, you will consider a process of priority setting at the national level and look for ways to harmonize regulatory pathways.

Ladies and gentlemen,

Medical devices require, and deserve, their own unique agenda. I wish you a most productive meeting.

Thank you.

Appendix C

Participation in baseline country survey and/or WHO meetings

		PARTICIPANTS	1ST TAGHT MEETING 21-23 APRIL 2009, GENEVA	2ND TAGHT MEETING 8-9 NOVEMBER 2009, RIO DE JANEIRO	3RD TAGHT MEETING 20-22 JUNE 2010, CAIRO	1ST GLOBAL FORUM ON MEDICAL DEVICES 9-11 SEPTEMBER 2010, BANGKOK	BASELINE COUNTRY SURVEY ON MEDICAL DEVICES
AFRICAN REGION	1	Algeria					
	2	Angola				X	X
	3	Benin				X	X
	4	Botswana				X	X
	5	Burkina Faso				X	X
	6	Burundi				X	X
	7	Cameroon	X			X	X
	8	Cape Verde					X
	9	Central African Republic					X
	10	Chad					X
	11	Comoros				X	X
	12	Congo				X	
	13	Côte d'Ivoire				X	X
	14	Democratic Republic of the Congo				X	X
	15	Equatorial Guinea				X	
	16	Eritrea				X	X
	17	Ethiopia	X	X		X	X
	18	Gabon					X
	19	Gambia				X	X
	20	Ghana				X	X
	21	Guinea				X	X
	22	Guinea-Bissau				X	X
	23	Kenya	X	X	X	X	X
	24	Lesotho					
	25	Liberia					X
	26	Madagascar				X	X
	27	Malawi					
	28	Mali				X	X
	29	Mauritania					X
	30	Mauritius					X
	31	Mozambique				X	X
	32	Namibia	X	X		X	X
	33	Niger				X	X
	34	Nigeria				0	
	35	Rwanda					
	36	Sao Tome and Principe				X	X
	37	Senegal	X			X	X
	38	Seychelles				X	X
	39	Sierra Leone				X	X
	40	South Africa				X	X
	41	Swaziland				X	X
	42	Togo				X	X
	43	Uganda			X	X	X
	44	United Republic of Tanzania				X	X
	45	Zambia				X	X
	46	Zimbabwe				X	X

PARTICIPANTS			1ST TAGHT MEETING 21-23 APRIL 2009, GENEVA	2ND TAGHT MEETING 8-9 NOVEMBER 2009, RIO DE JANEIRO	3RD TAGHT MEETING 20-22 JUNE 2010, CAIRO	1ST GLOBAL FORUM ON MEDICAL DEVICES 9-11 SEPTEMBER 2010, BANGKOK	BASELINE COUNTRY SURVEY ON MEDICAL DEVICES
REGION OF THE AMERICAS	47	Antigua and Barbuda					X
	48	Argentina				O	X
	49	Bahamas					X
	50	Barbados					
	51	Belize				X	X
	52	Bolivia (Plurinational State of)					X
	53	Brazil		X		X	X
	54	Canada				O	X
	55	Chile				X	X
	56	Colombia				O	X
	57	Costa Rica				X	X
	58	Cuba				X	X
	59	Dominica					X
	60	Dominican Republic					X
	61	Ecuador					
	62	El Salvador	X	X			X
	63	Grenada					X
	64	Guatemala					X
	65	Guyana					X
	66	Haiti					
	67	Honduras					X
	68	Jamaica		X		X	X
	69	Mexico	X	X		X	X
	70	Nicaragua	X	X			X
	71	Panama					X
	72	Paraguay				X	X
	73	Peru					X
	74	Puerto Rico*					
	75	Saint Kitts and Nevis					X
	76	Saint Lucia					X
	77	Saint Vincent and the Grenadines					X
	78	Suriname				X	
	79	Trinidad and Tobago				X	X
	80	The United States, USA		O		X	X
	81	Uruguay					
	82	Venezuela (Bolivarian Republic of)					

		PARTICIPANTS	1ST TAGHT MEETING 21-23 APRIL 2009, GENEVA	2ND TAGHT MEETING 8-9 NOVEMBER 2009, RIO DE JANEIRO	3RD TAGHT MEETING 20-22 JUNE 2010, CAIRO	1ST GLOBAL FORUM ON MEDICAL DEVICES 9-11 SEPTEMBER 2010, BANGKOK	BASELINE COUNTRY SURVEY ON MEDICAL DEVICES
EASTERN MEDITERRANEAN REGION	83	Afghanistan				X	X
	84	Bahrain				X	
	85	Djibouti				X	
	86	Egypt			X	O	
	87	Iran (Islamic Republic of)					
	88	Iraq				X	X
	89	Jordan		X	X	X	X
	90	Kuwait					
	91	Lebanon					X
	92	Libyan Arab Jamahiriya (the)					X
	93	Morocco					X
	94	Oman					X
	95	Pakistan				X	
		Palestinian Authority			O		
	96	Qatar					
	97	Saudi Arabia					X
	98	Somalia					
	99	Sudan	X	X	X	X	X
	100	Syrian Arab Republic				X	
	101	Tunisia		O	X	X	
	102	United Arab Emirates					
	103	Yemen					X

		PARTICIPANTS	1ST TAGHT MEETING 21-23 APRIL 2009, GENEVA	2ND TAGHT MEETING 8-9 NOVEMBER 2009, RIO DE JANEIRO	3RD TAGHT MEETING 20-22 JUNE 2010, CAIRO	1ST GLOBAL FORUM ON MEDICAL DEVICES 9-11 SEPTEMBER 2010, BANGKOK	BASELINE COUNTRY SURVEY ON MEDICAL DEVICES
EUROPEAN REGION	104	Albania		X	X	X	X
	105	Andorra					
	106	Armenia				X	X
	107	Austria				0	X
	108	Azerbaijan				X	X
	109	Belarus					X
	110	Belgium		0		0	X
	111	Bosnia and Herzegovina					X
	112	Bulgaria					X
	113	Croatia				X	X
	114	Cyprus					X
	115	Czech Republic					X
	116	Denmark				X	X
	117	Estonia				X	X
	118	Finland					X
	119	France		0			X
	120	Georgia				X	X
	121	Germany				0	X
	122	Greece					
	123	Hungary					X
	124	Iceland					X
	125	Ireland					X
	126	Israel					X
	127	Italy				X	X
	128	Kazakhstan					
	129	Kyrgyzstan				X	X
	130	Latvia					X
	131	Lithuania					X
	132	Luxembourg					X
	133	The former Yugoslav Republic of Macedenia					
	134	Malta					X
	135	Monaco					X
	136	Montenegro				X	X
	137	Netherlands	X			X	X
	138	Norway				0	X
	139	Poland				X	X
	140	Portugal				X	X
	141	Republic of Moldova		X		X	X
	142	Romania					X
	143	Russian Federation					X
	144	San Marino					X
	145	Serbia					X
	146	Slovakia					X
	147	Slovenia					X
	148	Spain				X	X
	149	Sweden					
	150	Switzerland		0		X	X
	151	Tajikistan				X	
	152	The United Kingdom				X	X
	153	Turkey					X
	154	Turkmenistan				X	
	155	Ukraine				X	
	156	Uzbekistan					

		PARTICIPANTS	1ST TAGHT MEETING 21-23 APRIL 2009, GENEVA	2ND TAGHT MEETING 8-9 NOVEMBER 2009, RIO DE JANEIRO	3RD TAGHT MEETING 20-22 JUNE 2010, CAIRO	1ST GLOBAL FORUM ON MEDICAL DEVICES 9-11 SEPTEMBER 2010, BANGKOK	BASELINE COUNTRY SURVEY ON MEDICAL DEVICES
SOUTH-EAST ASIA REGION	157	Bangladesh					
	158	Bhutan				X	
	159	Cook Islands					
	160	Democratic People's Republic of Korea					
	161	India				0	
	162	Indonesia				X	X
	163	Maldives				X	X
	164	Myanmar					
	165	Nepal		X	X	X	X
	166	Niue					
	167	Sri Lanka		X			X
	168	Thailand				X	X
	169	Timor-Leste				X	X
WESTERN PACIFIC REGION	170	Australia				X	X
	171	Brunei Darussalam				X	X
	172	Cambodia				X	X
	173	China				X	X
	174	Fiji					X
	175	Japan				X	X
	176	Kiribati				X	X
	177	Lao People's Democratic Republic		X		X	X
	178	Malaysia		X			X
	179	Marshall Islands					
	180	Micronesia (Federated States of)				X	X
	181	Mongolia				X	
	182	Nauru				X	X
	183	New Zealand				0	X
	184	Palau					
	185	Papua New Guinea					X
	186	Philippines		X		X	X
	187	Republic of Korea					
	188	Samoa				X	
	189	Singapore				X	X
	190	Solomon Islands					
	191	Tokelau*					
	192	Tonga					X
	193	Tuvalu					
	194	Vanuatu				X	
	195	Viet Nam				X	

X = Includes government representation
0 = Observer or general participant representation
* = Associate members

Appendix D

Organizing committees for the First WHO Global Forum on Medical Devices

Steering committee

Chair, Secretariat
Carissa Etienne, Assistant Director-General, Health Systems and Services
Steffen Groth, Director, Essential Health Technologies
Adriana Velazquez Berumen, Coordinator Diagnostic Imaging and Medical Devices Unit
World Health Organization

Members

Jennifer Barragan, World Health Organization
Deirdre Dimancesco, World Health Organization
Yadin David, International Federation for Medical and Biological Engineering (IFMBE)
Björn Fahlgren, World Health Organization
Josee Hansen, Ministry of Health, Welfare and Sport, the Netherlands
Peter Leeflang, Ministry of Health, Welfare and Sport, the Netherlands
Guy Maddern, International Network of Agencies for Health Technology Assessment (INAHTA)
Laura Sampietro-Colom, Health Technology Assessment International (HTAi);
Yot Teerawattananon, Ministry of Public Health Thailand
Sripen Tantivess, Ministry of Public Health Thailand
Bart Wijnberg, Ministry of Health, Welfare and Sport, the Netherlands

International organizing committe

Salma Abbasi, E-Worldwide Group
Barry Allen, International Union of Physical and Engineering Sciences in Medicine (IUPESM)
David Banta, Consultant
Simao Campos, International Standards Organization (ISO)
Monique Dory, Medicines Sans Frontiere (MSF)
Kalipso Chalkidou, National Institute of Public Health and Clinical Excellence (NICE)
Martha Emma Escandon, National Centre for Health Technology Excellence (CENETEC)
James Fitzgerald, Pan-American Health Organization (PAHO/WHO)
Charles A. Gardner, Forum for Health Research
Timothy Hancox, International Standards Organization (ISO)
Myriam Henkens
Kendall Ho, University of British Columbia
Sabina Hoeksta-van den Bosch, Ministry of Health, Welfare and Sport, the Netherlands
Adham Ismail, Eastern Mediterranean Regional Office, WHO
Jennifer Jackson, American College of Clinical Engineering
Ed Kelly, Patient Safety, WHO
Chapal Khasnabis, Assistive Devices, WHO

Paul LaBarre, PATH
Blerta Maliqui, Making Pregnancy Safer, WHO
Joseph Lazar Mathew, Health Technology Assessment International
Geeta Mehta, South East Regional Office, WHO
Iyad Mobarek, Jordan Country Office, WHO
David Porter, Consultant
Sarah Russell, Health System and Services, WHO
Roger Schmitt, HDS, WHO
Peter Smith, International Organization of Medical Physics
Ludo Scheerlinck, UNICEF
Herbert Voigt, International Federation for Medical and Biological Engineering
David Watson, ECRI Institute
Jomkwan Yothasamut, HITAP, Ministry of Health, Thailand

Local Organizing Committee

Chair Suwit Wibulpolprasert
Office of the Permanent Secretary, Ministry of Public Health

Members

Biomedical Instrument Division, Siriraj Hospital
Bureau of International Health, Ministry of Public Health
Bureau of Policy and strategy, Ministry of Public Health
Department of Medical Sciences, Ministry of Public Health
Department of Medical Services, Ministry of Public Health
Food and Drug Administration, Ministry of Public Health
Foundation for Consumers
Health Consumer Protection Project, Chulalongkorn University
Health Intervention and Technology Assessment Program, Ministry of Public Health
Health System Research Institute
Medical Device Control, Food and Drug Administration, Ministry of Public Health
National Health Security Office
National Health Commission Office
National Science and Technology Development Agency
Thai Health-Global Link Initiative Project, Mahidol University
The International Health Policy Program, Ministry of Public Health
The Medical Council of Thailand
Thai Medical Device Technology Industry Association
Social Security Office
World Health Organization Thailand

Appendix E

Programme of the First WHO Global Forum on Medical Devices

Programme at a glance— 9-11 September 2010

ATHENEE CRYSTAL BALLROOM

	Day 1—Thursday 9 September	Day 2—Friday 10 September	Day 3—Saturday 11 September
07:00	**Check-in**		
	Inauguration session Mr Abhisit Vejjajiva, Prime Minister of the Kingdom of Thailand		
08:30		**Future trends in medical devices of relevance to low resource settings** • Space medical technology innovation and its global applications • The future of health technology • Q&A [French & Spanish interpretation]	**Improving access, quality, and affordability of medical devices through…** • Academia • Professional organizations • Technology transfer • Medical technology industry • Q&A [French & Spanish interpretation]
08:50	Dr Margaret Chan, Director-General, WHO [French & Spanish interpretation]		
09:10			
09:15		**In search of appropriate and innovative technologies** • Local Solutions • Innovation for impact: a collaborative venture • Appropriate technologies • Global health innovations • Q&A [French & Spanish interpretation]	
09:20	**Global status on medical devices** • Situational global analysis of medical devices • Mismatches in medical devices • Medical device needs in a developing country [French & Spanish interpretation]		
10:05			**Ethical practice** [French & Spanish interpretation]
10:30	*Coffee break* and **poster session A**	*Coffee break* and **poster session B**	*Coffee break*
11:15	**Medical devices and universal access** • Health systems strengthening and financing medical devices: suggestions for change • Empowering decision makers • Q&A [French & Spanish interpretation]	**Strategies to promote safe, affordable, quality medical device use** • Health technology assessment • Regulation of medical devices • Medical devices management • Q&A [French & Spanish interpretation]	**Closing session** Summary of recommendations Day 1, 2 and 3
12:00			Way forward
12:15	*Lunch*	*Lunch*	Closing message
12:30			*Lunch*
13:45	**The role of medical devices to improve health service delivery** Track 1: Millennium Development Goals 4, 5 and 6, Room A, [French interpretation] Track 2: Meeting the needs, Room B, [Spanish interpretation] Track 3: The convergence of eHealth and medical devices: implications for the future, Room C	**Health technology assessment, regulation, and management of medical devices when evaluating the needs** Track 1 (HTA): Assessment for innovative and emerging technologies, Room A, [French interpretation] Track 2 (HTR): Pre-market approval including preclinical and clinical evaluation, Room B, [Spanish interpretation] Track 3 (HTM): Needs assessment: epidemiological needs, inventories, and medical device lists, Room C	**Post conference workshops & meetings** **Technical workshops in English (registration required)** Track 1: Health Technology Assessment, Room A Track 2: Medical Devices Management, Room B Track 3: Medical Devices Regulation, Room C Track 4: e-Health, Room D
14:00			
14:45		**Prioritization, selection, and harmonization** Track 1 (HTM): Equipment incorporation: selection, procurement, and donations, Room A, [French interpretation] Track 2 (HTA): HTA of medical devices: national prioritization processes, Room B, [Spanish interpretation] Track 3 (HTR): Harmonization of regulation – challenges and benefits, Room C	
15:15	*Coffee break* and **poster session A** (continued)		
15:45			
16:00	**Safe, accessible and affordable medical devices** Track 1: Towards safe and appropriate radiation treatment, Room A, [French interpretation] Track 2: Safe medical devices for the patient, the health worker and the environment, Room B, [Spanish interpretation] Track 3: WHO call for innovative technologies that address global health concerns, Room C	*Coffee break* and **poster session B**	Meeting of the Global Medical Technology Alliance
16:30			
17:00		**Assessment and management: a continuous process** Track 1 (HTR): The need for adverse event reporting and post-market surveillance, Room A, [French interpretation] Track 2 (HTM): Healthcare technology operation: training, safe use, and maintenance, Room B, [Spanish interpretation] Track 3 (HTA): The need for continuous HTA in developing countries and the role of international organizations, Room C	
17:30			
19:30–22:00	*Reception and dinner at the venue*		

Programme day 1—Thursday, 9 September 2010

ATHENEE CRYSTAL BALLROOM

07:00–08:30	**Check-in**		
08:30–08:50	**Inauguration session** [French & Spanish interpretation] Welcome address Mr Abhisit Vejjajiva, Prime Minister of the Kingdom of Thailand		
08:50–09:10	Inauguration address Dr Margaret Chan, Director-General, WHO		
09:20–10:30	Technical session [French & Spanish interpretation] **Global status on medical devices** Chair: Dr Carissa Etienne, WHO Film Situational global analysis of medical devices Dr Steffen Groth, WHO Mismatches in medical devices Mrs Josee Hansen, Ministry of Health, Welfare, and Sport, Netherlands Medical device needs in a developing country Dr Pascience Kibatala, Saint Francis Designated District Hospital, Ifakara,Tanzania		
10:30–11:15	*Coffee break* and **poster session A**		
11:15–12:15	**Medical devices and universal access** [French & Spanish interpretation] Chair: Mr Bart Wijnberg Co-Chair: Dr Geeta Mehta Keynote addresses: Health systems strengthening and financing medical devices: suggestions for change Dr Charles Ok Pannenborg, The World Bank Empowering decision makers Mr Andrew Dillon, National Institute for Health and Clinical Excellence Q&A		
12:15–13:45	*Lunch*		
13:45–15:15	**The role of medical devices to improve health service delivery**		
	Track 1: Millennium Development Goals 4, 5 and 6 [French interpretation] Chair: Dr Joseph Mathew Co-Chair: Dr Nicholas Adjabu ■ MDGs and the role of medical devices, Dr Helene Möller, UNICEF ■ Clinical Practice Guidelines, Dr. Maki Esther Ortiz-Dominguez, Ministry of Health, Mexico ■ Self care, Dr Wiwat Rojanapithayakorn, WHO, Mongolia	Track 2: Meeting the needs [Spanish interpretation] Chair: Mr Mladen Poluta Co-Chair: Dr Adham Ismail ■ The patient perspective, Mr Jeremiah Mwangi, International Alliance of Patients' Organizations ■ Sustainable intensive care unit for newborns, Mr Luciano Moccia, East Meets West Foundation ■ Improving the availability of medical devices, the Ghana experience, Mr John Zienaa, Ghana Health Service ■ Filling the human resource development gap, Dr Saide Jorge Calil, Universidade Estadual de Campinas, Brazil	Track 3: The convergence of eHealth and medical devices: implications for the future Chair: Mrs Jennifer Jackson Co-Chair: Dr Noboru Takamura ■ Telemedicine, Dr Marc Nyssen, International Federation for Medical and Biological Engineering ■ Improving healthcare IT systems through interoperability, Ms Lisa Spellman, HIMSS – Integrating the Healthcare Enterprise ■ eHealth for the Millennium Development Goals, Dr Kendall Ho, University of British Columbia, Canada
15:15–16:00	*Coffee break* and **poster session A** (continued)		
16:00–17:30	**Safe, accessible and affordable medical devices**		
	Track 1: Towards safe and appropriate radiation treatment [French interpretation] Chair: Dr Peter HS Smith Co-Chair: Mr Pablo Jiménez ■ Radiation safety, Dr Caridad Borrás, Universidad Federal de Pernambuco, Brazil ■ Access to radiotherapy, Mr Graeme Morgan, Dr Joanna Izewska, International Atomic Energy Agency ■ Palliative care and medical devices, Dr Barry Allen, International Union for Physical and Engineering Sciences in Medicine	Track 2: Safe medical devices for the patient, the health worker and the environment [Spanish interpretation] Chair: Dr Renato Garcia Co-Chair: Dr Selma Khamassi ■ Syringes, Dr Arshad Altaf, Vanderbilt Institute for Global Health & Bridge Consultants Foundation, Pakistan ■ Mercury, Ms Faye V Ferrer, Health Care Without Harm Southeast Asia; Mr Prasert Surmsuk, Siriraj Hospital, Mahidol University, Thailand	Track 3: WHO call for innovative technologies that address global health concerns Chair: Dr Kathleen Slenko Co-Chair: Mr Björn Fahlgren ■ Selected technology representatives Mr Jorge Ernesto Odon, Argentina Mr José Carlos Lapenna, Brazil Dr Qimin You, China Mr Hermann Kranzl, Germany Dr Sangeeta Das Bhattacharya, India Mr Aman Midha, India Ms Sarah Burgarella, Italy Mr Mark Smith, New Zealand Mr Jens Petter Ianke, Norway Dr Rahul Panicker, United States Ms Anna Young, United States
19:30–22:00	*Reception and dinner at the venue*		

Programme day 2—Friday, 10 September 2010

ATHENEE CRYSTAL BALLROOM

08:30–09:15	**Future trends in medical devices of relevance to low resource settings** [French & Spanish interpretation] Chair: Ministry of Health, TBD Co-Chair: Ms Jennifer Barragan Space medical technology innovation and its global applications Dr Chiaki Mukai, Astronaut, JAXA Space Biomedical Research Office The future of health technology Ms Renata Bushko, Future of Health Technology Institute Q&A		
09:15–10:30	**In search of appropriate and innovative technologies** [French & Spanish interpretation] Chair: Ministry of Health, TBD Co-Chair: Dr Iyad Mobarek Local solutions Prof Dr Oluyombo Awojobi, Awojobi Clinic Eruwa, Nigeria Innovation for impact: a collaborative venture Dr Kristian Olson, Center for Integration of Medicine and Innovative Technology, Massachusetts General Hospital, Harvard University, United States Appropriate technologies Mr Paul LaBarre, PATH Global health innovations Dr Peter A Singer, McLaughlin-Rotman Centre for Global Health & Grand Challenges Canada Q&A		
10:30–11:15	*Coffee break* and **poster session B**		
11:15–12:15	**Strategies to promote safe, affordable, quality medical device use** [French & Spanish interpretation] Chair: Ministry of Health, TBD Co-Chair: Mr Pablo Jiménez Health technology assessment Dr Laura Sampietro-Colom, Health Technology Assessment International Regulation of medical devices Dr. Ruth Lopert, Therapeutic Goods Administration, Australia Medical devices management Dr David Porter, United Kingdom Q&A		
12:15–13:45	*Lunch*		
	Health technology assessment, regulation, and management of medical devices when evaluating the needs		
13:45–14:45	Track 1 (HTA): Assessment for innovative and emerging technologies [French interpretation] Chair: Dr Pwee Keng Ho Co-Chair: Dr Iyad Mobarek Speaker: Dr Brendon Kearney, EuroScan	Track 2 (HTR): Pre-market approval including preclinical and clinical evaluation [Spanish interpretation] Chair: Dr Daniel Tan Co-Chair: Mr Björn Fahlgren Speaker: Ms Yuwadee Patanawong, Food and Drug Administration, Thailand	Track 3 (HTM): Needs assessment: epidemiological needs, inventories, and medical device lists Chair: Mr Ronald Bauer Co-Chair: Mr Paul Rogers Speaker: Mrs Maria Luisa Gonzalez Retiz, CENETEC, Ministry of Health, Mexico
	Prioritization, selection, and harmonization		
14:45–15:45	Track 1 (HTM): Equipment incorporation: selection, procurement, and donations [French interpretation] Chair: Mr Ludo Scheerlinck Co-Chair: Dr Nicholas Adjabu Speaker: Mr Sam S B Wanda, Ministry of Health, Uganda	Track 2 (HTA): HTA of medical devices: national prioritization processes [Spanish interpretation] Chair: Dr Berit Morland Co-Chair: Mrs Hayde Reynoso Speaker: Dr Kalipso Chalkidou, National Institute for Health and Clinical Excellence	Track 3 (HTR): Harmonization of regulation – challenges and benefits Chair: Mr Albert Poon Co-Chair: Dr Noboru Takamura Speaker: Dr Larry Kelly, Therapeutic Goods Administration, Australia
15:45–16:30	*Coffee break* and **poster session B** (continued)		
	Assessment and management: a continuous process		
16:30–17:30	Track 1 (HTR): The need for adverse event reporting and post-market surveillance [French interpretation] Chair: Dr Isabelle Demade Co-Chair: Ms Irena Prat Speaker: Dr Giuseppe Ruocco, Ministry of Health, Italy	Track 2 (HTM): Healthcare technology operation: training, safe use, and maintenance [Spanish interpretation] Chair: Mr Ismael Cordero Co-Chair: Ms Jennifer Barragan Speaker: Mr Mladen Poluta, University of Cape Town, South Africa	Track 3 (HTA): The need for continuous HTA in developing countries and the role of international organizations Chair: Dr Chris Henshall Co-Chair: Dr Geeta Mehta Speaker: Dr Yot Teerawattanon, Health Intervention and Technology Assessment Program, Thailand

Programme day 3—Saturday, 11 September 2010

ATHENEE CRYSTAL BALLROOM

08:30–10:05	**Improving access, quality, and affordability of medical devices through…** [French & Spanish interpretation] Chair: Ministry of Health, TBD Co-Chair: Dr Adham Ismail Academia Dr Herbert Voigt, International Federation for Medical and Biological Engineering Professional organizations Dr Peter H S Smith, International Organisation for Medical Physics Technology transfer Dr Rosanna Peeling, London School of Hygiene & Tropical Medicine, United Kingdom Medical technology industry Ms Anne Trimmer, Global Medical Technology Alliance Q&A
10:05–10:30	**Ethical practice** [French & Spanish interpretation] Mr Alexander Capron, University of Southern California Q&A
10:15–11:00	Rapporteur working session
10:30–11:15	*Coffee break*
11:15–12:00	**Closing session** [French & Spanish interpretation] Chair: Dr Steffen Groth, WHO Day 1— Dr Geeta Mehta, SEARO, WHO Day 2— Mr Pablo Jiménez, PAHO, WHO Day 3— Mr Adham Ismail, EMRO, WHO
12:00–12:15	Way forward Dr Carissa Etienne, WHO
12:15–12:30	Closing message Dr Suwit Wibulpolprasert, Ministry of Health, Thailand
12:30–14:00	*Closing lunch*

POST CONFERENCE WORKSHOPS & MEETINGS

	Technical workshops in English (registration required)			
14:00–16:00	Track 1: Health Technology Assessment Room A	Track 2: Medical Devices Management Room B	Track 3: Medical Devices Regulation Room C	Track 4: e-Health Room D
16:00–17:00	**Meeting of the Global Medical Technology Alliance,** Room A			

Appendix F

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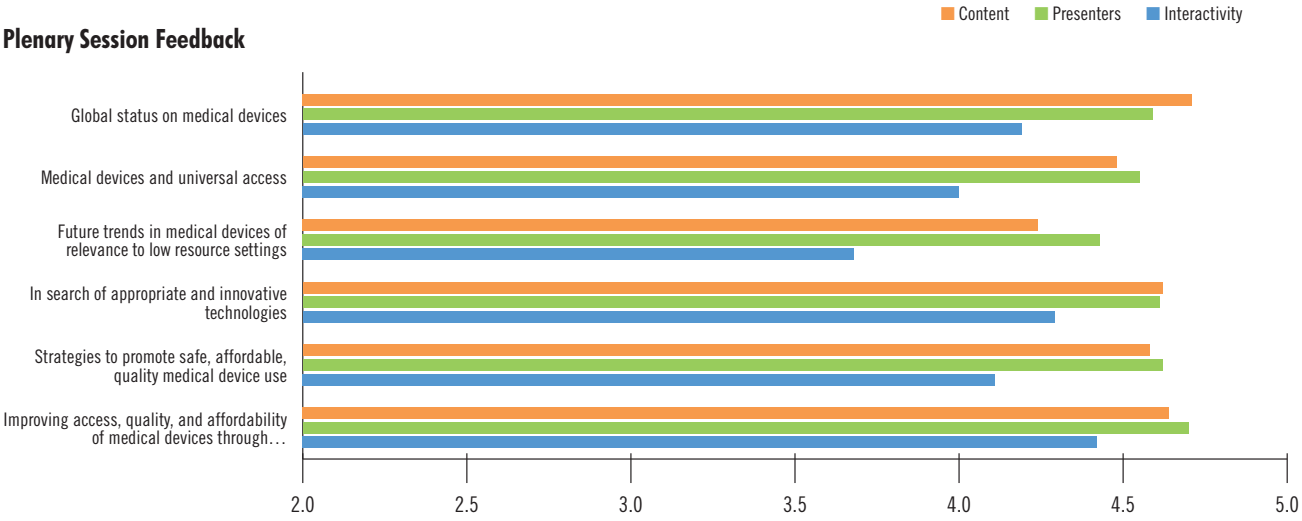
Appendix G

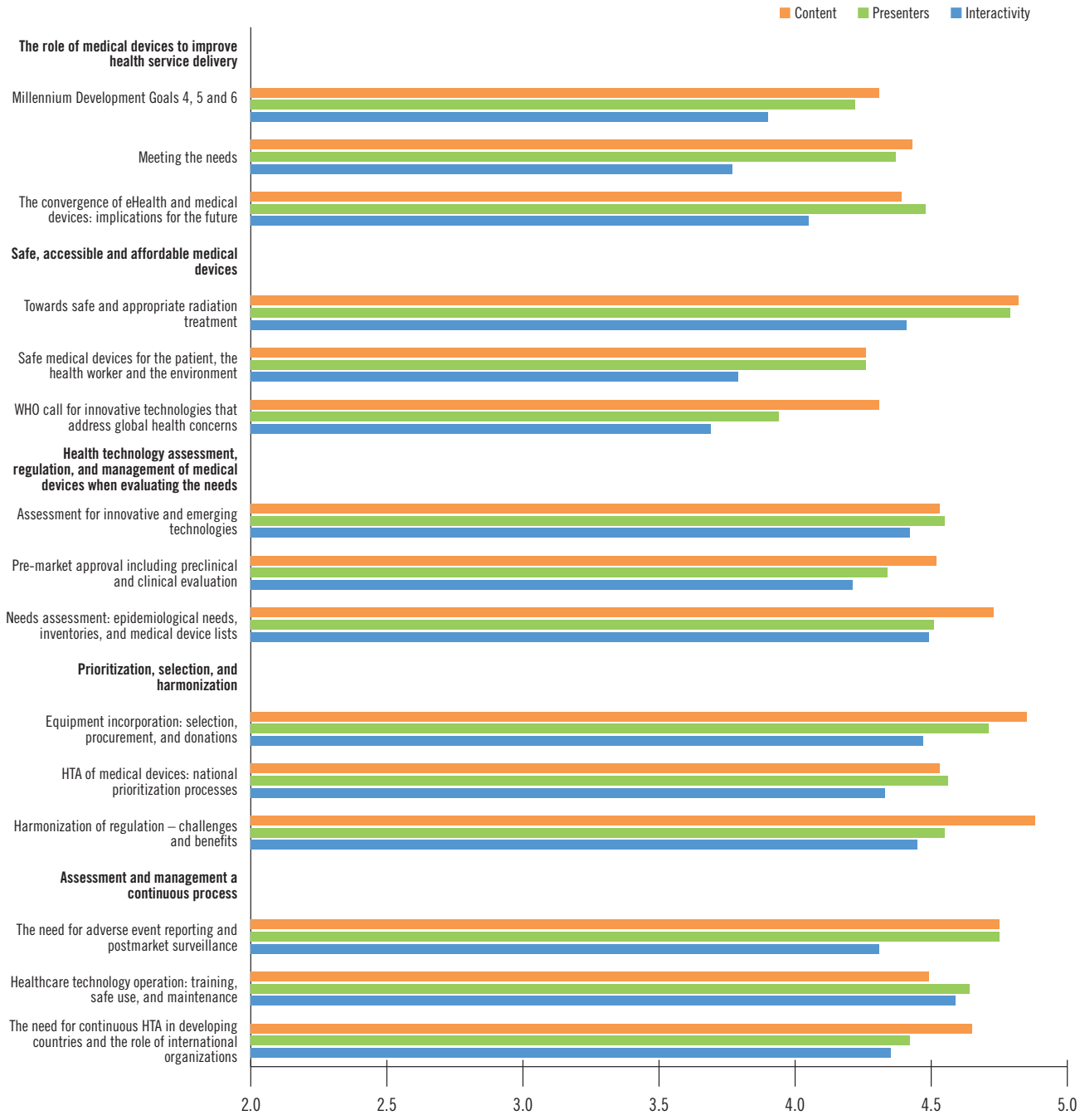
Participant feedback survey results

Below is a summary of the results of a feedback survey given to participants. They were asked to rate the sessions, both plenary and parallel on a scale from 1 to 5 in three different categories:

1. Content was of interest to participant
2. Presenters were knowledgeable about the subject-matter
3. The session was engaging and interactive



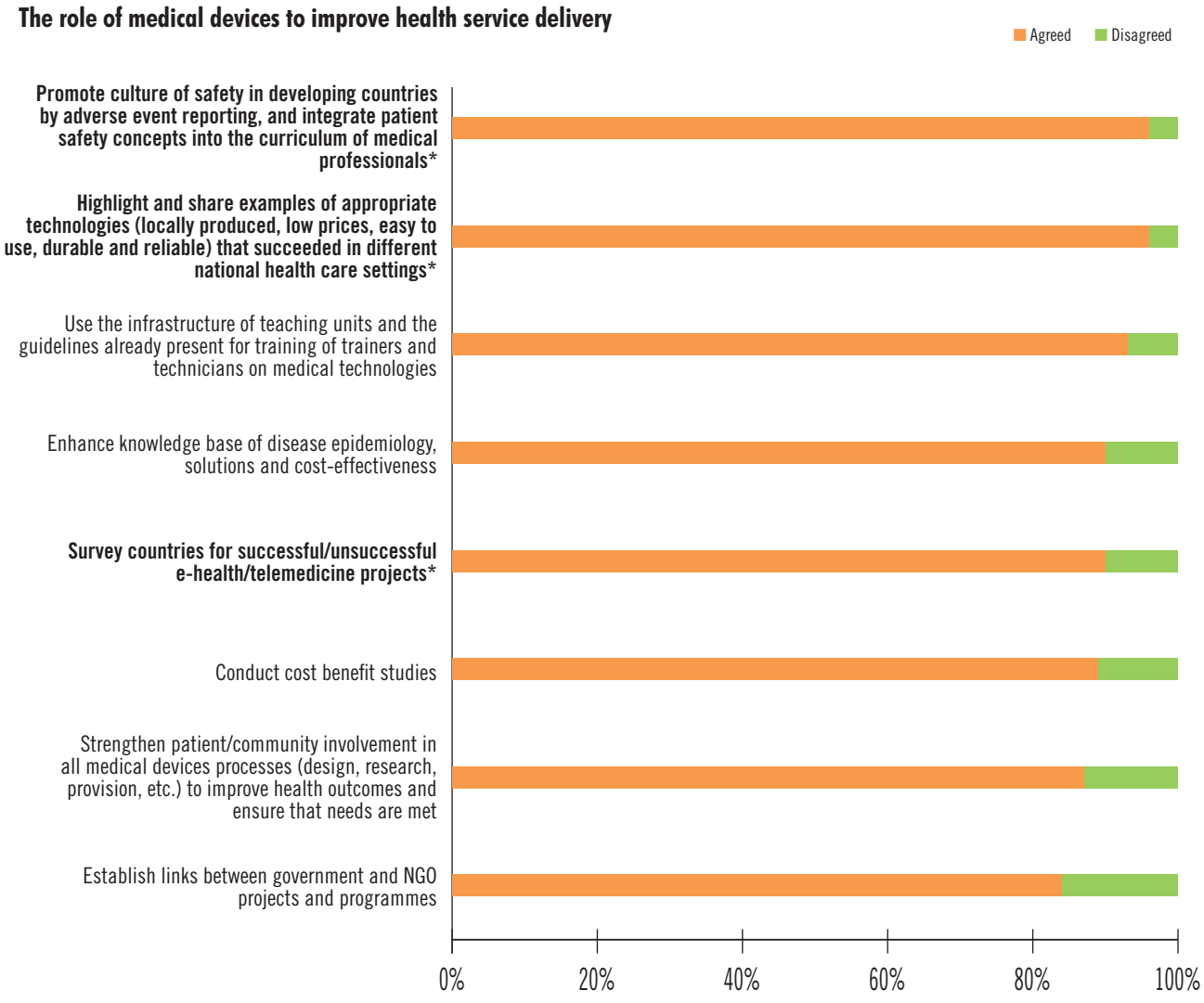
Parallel Session Feedback



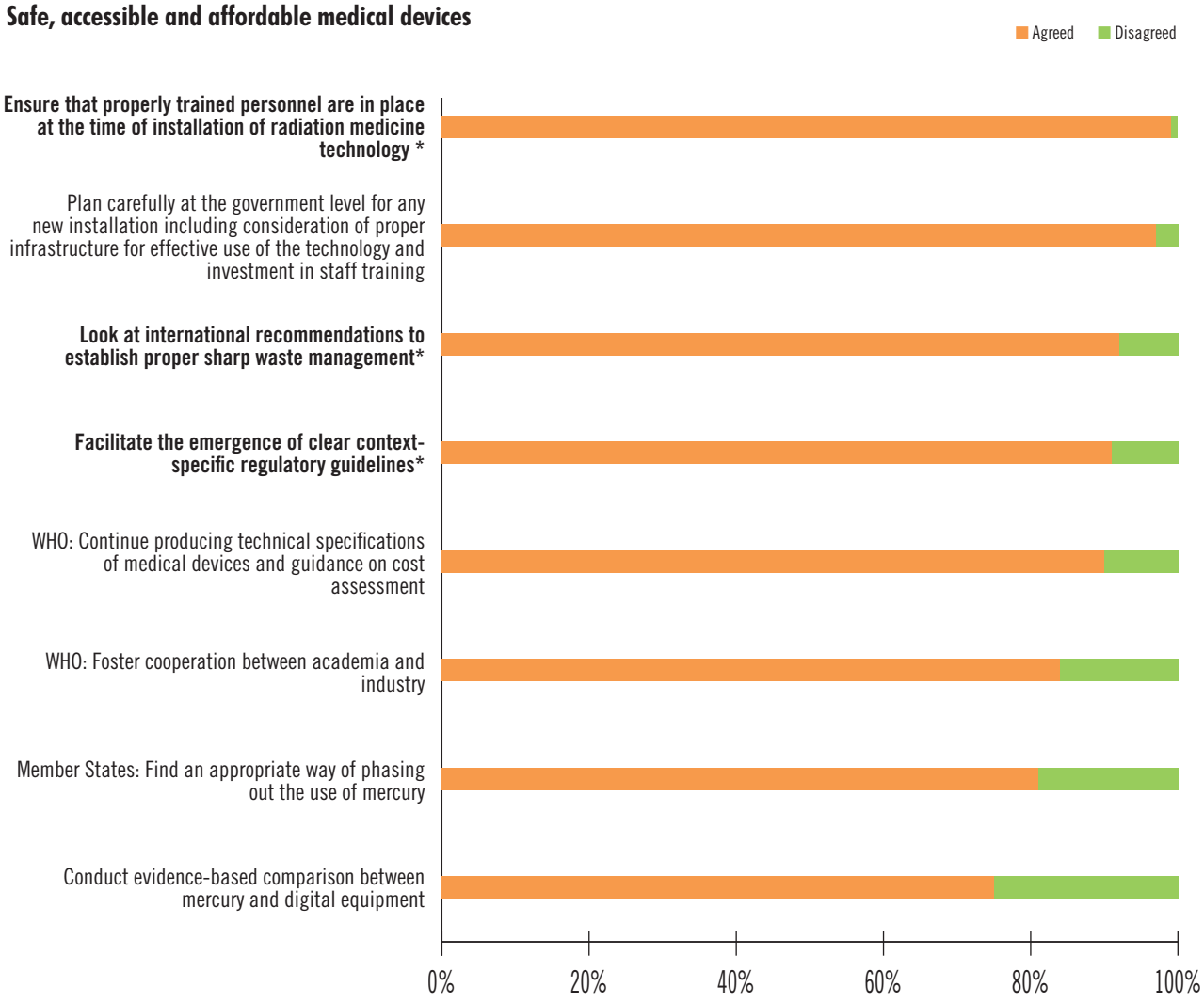
Appendix H

Voting results for the 42 proposed recommendations, by theme

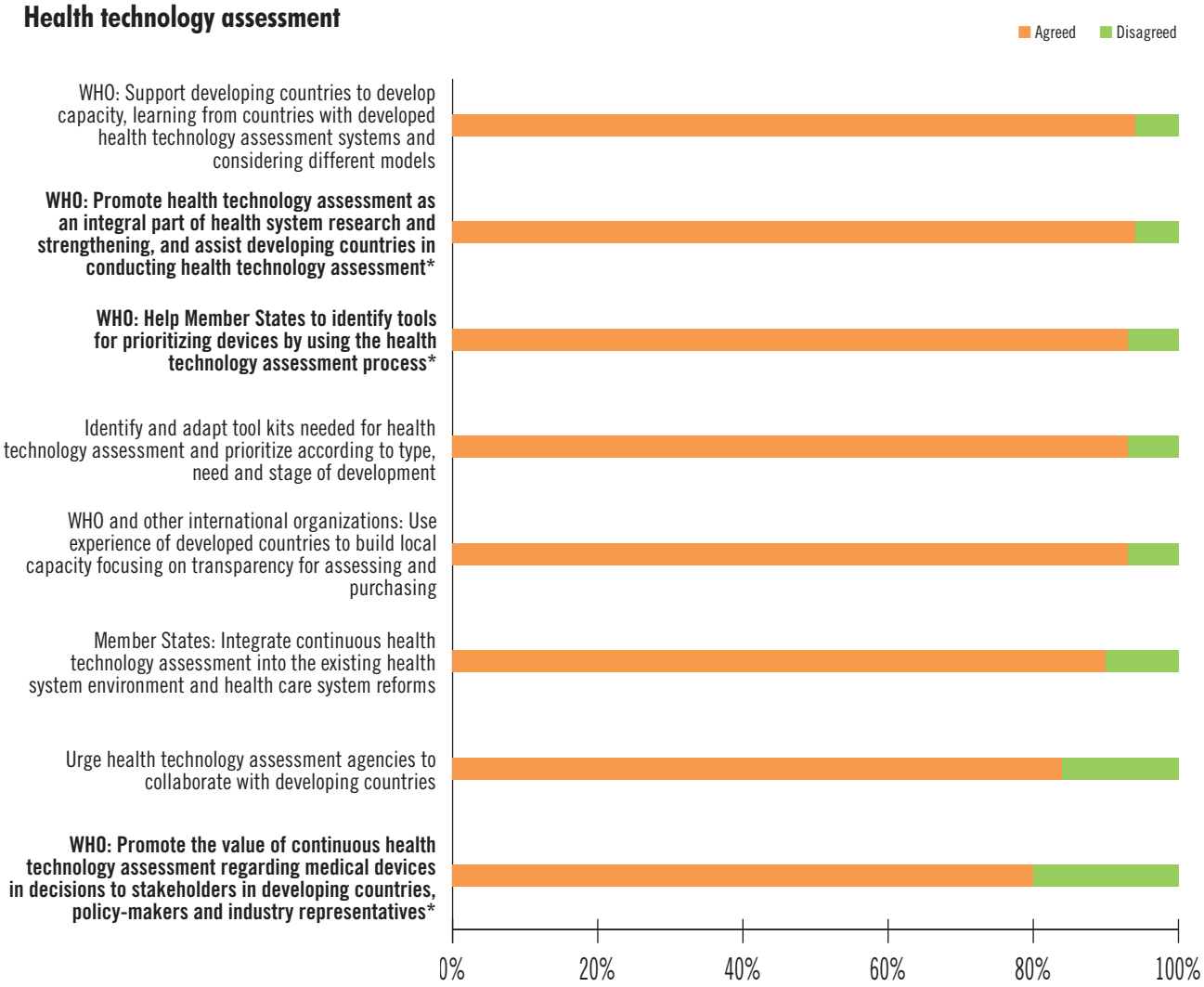
(as percentage of total votes cast)



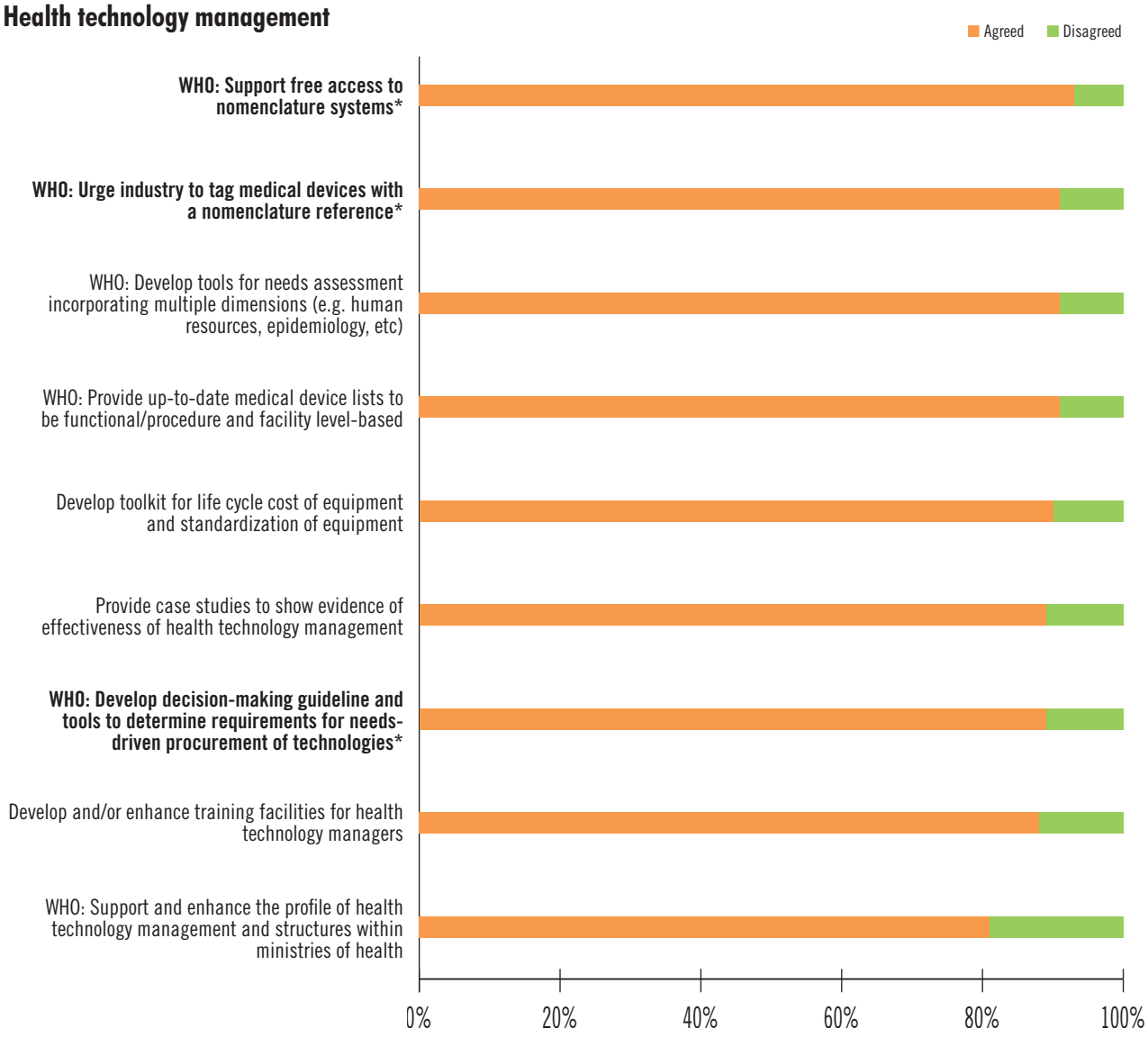
Safe, accessible and affordable medical devices



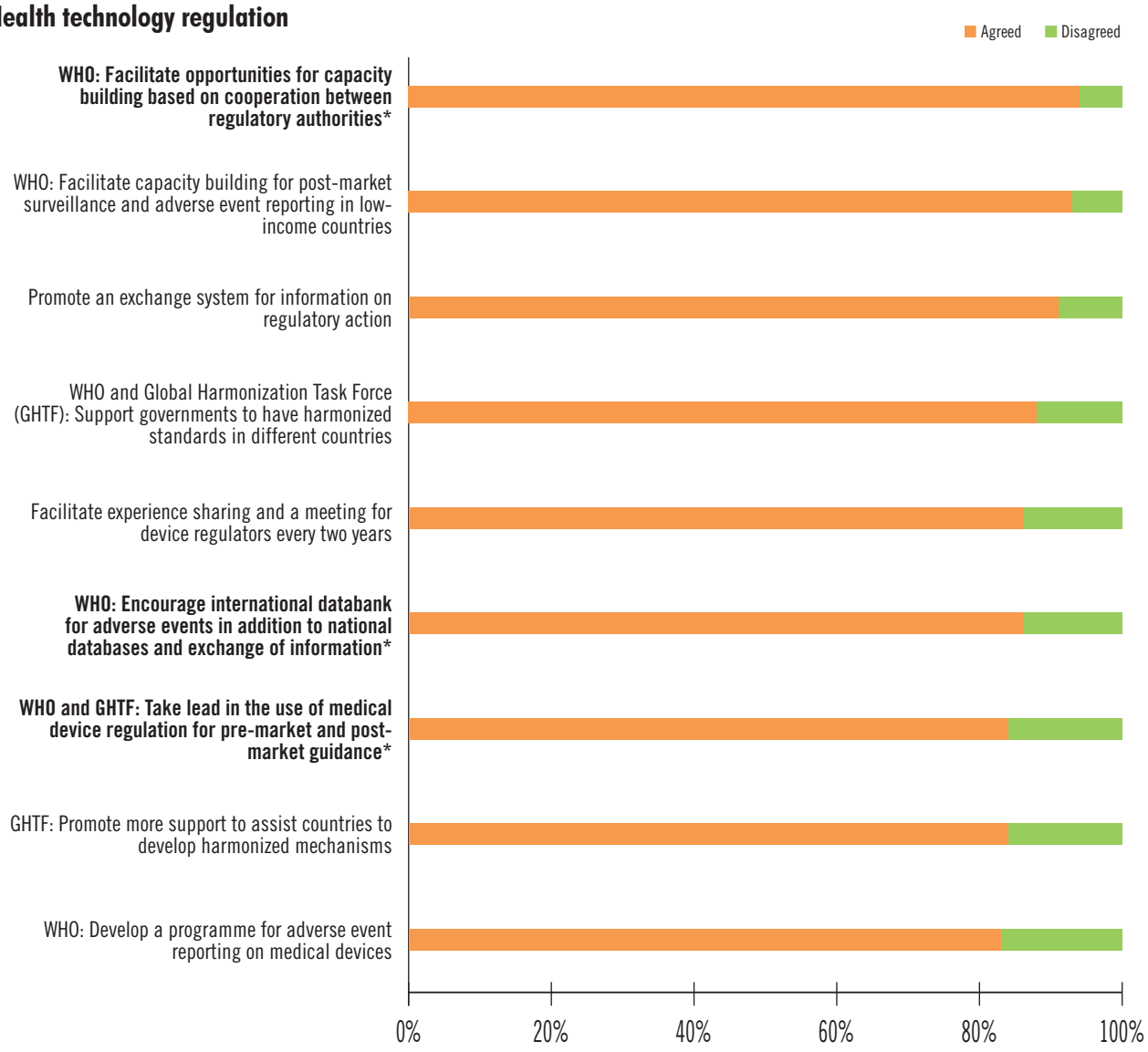
Health technology assessment



Health technology management



Health technology regulation



* The top recommendations as voted for by participants within the individual sessions.

Appendix I

All recommendations suggested by forum participants

Theme	Session title	Recommendation
The role of medical devices to improve health service delivery	MDGs 4, 5 and 6	Promote culture of safety in developing countries by adverse event reporting, and integrate patient safety concepts into the curriculum of medical professionals. Clinical practice guidelines must be evidence based and implementers should be part of the development process. Develop CPGs that are locally relevant, evidence-based and linked to implementation. Empower community and consumers to demand devices that conform to 1. 2. 3. above. Enhance knowledge base of disease epidemiology, solutions, cost-effectiveness. Identify ways to enhance acceptance and use of low cost, low-tech devices like condoms, safe syringes. Increase acceptability of consumers in the use of self care devices. Select medical devices from CPGs. The CPGs should be the basis for the selection of medical devices.
	Meeting the needs	Highlight and share examples of appropriate technologies (locally produced, low prices, easy to use, durable and reliable) that succeeded in different national health care settings. Use the infrastructure of teaching units and the guidelines already present for training of trainers and technicians on medical technologies. Investigate available resources (within the organization) that addresses needs assessment and prioritization. These resources have to be collated and disseminated for member states to benefit from. Conduct a survey on availability and accessibility of medical devices in different countries. Develop guidelines on different healthcare technology aspects, including success stories. Develop, validate and disseminate a framework for integrated healthcare needs assessment. Ensure that technology development does not interfere with healthcare delivery resources. Look into ways of increasing the role of industry, patient organization and others in terms of needs assessment. Strengthen patient/community involvement in all medical devices processes (design, research, provision, etc.) to improve health outcomes and ensure that needs are met.
	The convergence of eHealth and medical devices: implications for the future	Survey countries for successful/unsuccessful e-health/telemedicine projects. Cost/benefit studies. Develop stakeholders taskforce to help align capacity building for global health needs. Focus on appropriate patient-centric record keeping. Good practices/appropriate technologies. Link between government and NGO projects. Open source culture. Study or guideline to understand how to reduce telecommunication costs (infrastructure and bandwidth service).

Safe, accessible and affordable medical devices	Towards safe and appropriate radiation treatment	Ensure that properly trained personnel are in place at the time of installation of radiation medicine technology. Plan carefully at the government level for any new installation including consideration of proper infrastructure for effective use of the technology and investment in staff training. To include comprehensive technology radiotherapy packages. To ensure access to palliative care centers in provincial/district hospitals supported by telemedicine. To ensure the application of International Radiation safety Standards (BSS) in the medical field. To facilitate the human resources development as technology evolves. WHO to continue producing technical specifications of medical devices and guidance on cost assessment.
	Safe medical devices for the patient, the health worker and the environment	Look at international recommendations to establish proper sharp waste management. Maintain sphygmomanometer for calibration. Countries should find an appropriate way of phasing out mercury. Evidence based comparison between mercury and digital equipment. There should be a legislation to regulate medical practices. Phasing out mercury needs to be accompanied with proper training of healthcare workers. Look at options to sterilize plastic syringes before recycling. After proper evaluation eliminate all mercury devices.
	WHO call for innovative technologies that address global health concerns	Facilitate the emergence of clear context-specific regulatory guidelines. WHO to lobby for funding of early research and promote. Engage end users in co-creative design process within an interdisciplinary setting. Foster cooperation between academia and industry. Give more consideration to maintenance and transparency. Promote use of HTA information in the innovation process. Provide guidance/information on local conditions. Recommends to industry to make devices that help patients to help themselves, in the perspective of lack of manpower in health care. WHO to facilitate adaptation of technology to local conditions.
Health technology assessment (HTA)	Assessment for innovative and emerging technologies	WHO: Promote health technology assessment as an integral part of health system research and strengthening, and assist developing countries in conducting health technology assessment. WHO should promote links between MS and HTA institutions. HTA designed for MD.. Life cycle, … Identify and adapt necessary tool kits needed for HTA and be able to prioritize according type, need and stage of development. More coordination with MS and other organization to allocate funds to conduct HTA in developing countries (cost and clinical effectiveness). Urge HTA institutions to collaborate with manufacturers & business communities to work in develpping countries. WHO should work closely with MS to identify existing heath services research institutions to support MS to identify useful technologies.
	HTA of medical devices: national prioritization processes	WHO: Help Member States to identify tools for prioritizing devices by using the health technology assessment process. Is there a need of a global device register? Synergies must be done? Careful management of evidence to restrict access of interventions based on evaluation? Urging the system to do more comparative effective analyzing. WHO and international organizations to use experience of developed countries to build local capacity focusing on transparency for assessing and purchasing. WHO learning from NICE recognizing Pharmaceutical are different from MD and proceed consequently. WHO taking account of interoperability of emerging devices interoperability roadmap. WHO works with international agencies and HTA to develop best practices and a global register.
	The need for continuous HTA in developing countries and the role of international organizations	WHO: Support developing countries to develop capacity, learning from countries with developed health technology assessment systems and considering different models. WHO: Promote the value of continuous health technology assessment regarding medical devices in decisions to stakeholders in developing countries, policy-makers and industry representatives. WHO: support DC for Context specific HTA focusing for example on primary health care. All stakeholders including patients should be involved in priority setting. MD is an important component, HTA is not only for pharmaceuticals. HTA should be used for MD with appropriate methodology. Member Countries: HTA should be integrated into /within the existing health system environment and health care system reforms.

Health technology management (HTM)	**Needs assessment: epidemiological needs, inventories, and medical device lists**	WHO: Support free access to nomenclature systems. WHO: Develop tools for needs assessment incorporating multiple dimensions (e.g. human resources, epidemiology, etc). WHO to provide up to date medical device lists to be functional/procedure and facility level based. Review and update WHO iHTP tool improving user-friendliness and to be made suitable for multiple health settings. WHO to advocate for greater focus of MS MoH on medical device issues (including use of WHO e-centre). WHO to provide guidance on distribution of budgetary resources for medical devices at 3 levels of care. WHO to support access to information on medical device life-cycle and other costs.
	Equipment incorporation: selection, procurement, and donations	WHO: Develop decision-making guideline and tools to determine requirements for needs-driven procurement of technologies. WHO to produce guidelines for equipment donation and must ensure they are fairly new and the consumables must be supplied or source of supply must be identified. Donors to be made responsible for the equipment they donate. Essential list should include specification. Guidelines for procurement of pre-owned equipment. Including contracting and juridical clauses in the guidelines for sourcing. Toolkit for lifecycle cost of equipment and standardization of equipment. Training facility for HTM managers. WHO to develop of generic specification to support procurement. WHO to produce essential list of MD for functional specialties and intervention not just by level of health care.
	Healthcare technology operation: training, safe use, and maintenance	WHO: Urge industry to tag medical devices with a nomenclature reference. WHO promote public awareness of safe/ethical clinical practice. Case studies to show evidence of effectiveness of HTM. Develop expert network to support implementation of guidelines in LIC. WHO to build improved information exchange mechanisms. WHO to develop training program for MEM in rural areas. WHO to promote good management practice with M&E tool. WHO to raise profile of HTM and structures within MoH. WHO to urge Member States to develop new approach and take responsibility for medical devices and asset management. WHO to urge MS to establish minimum HTM budgets.
Health technology regulation	**Pre-market approval including preclinical and clinical evaluation**	WHO: Facilitate opportunities for capacity building based on cooperation between regulatory authorities. Promote an exchange system for information on regulatory action. Facilitate experience sharing and meeting for device regulators every 3 years. WHO to propose a checklist and standards for medical device validation. WHO to propose a global database that regulators could consult. WHO to facilitate cooperation between all stakeholders in capacity building. WHO to put priority on post market surveillance while prioritizing resources. Promote understanding that differences between different settings may justify local requirements.
	The need for adverse event reporting and postmarket surveillance	WHO: Facilitate capacity building for post-market surveillance and adverse event reporting in low-income countries. WHO: Encourage international databank for adverse events in addition to national databases and exchange of information. WHO coordinating conferences of regulators of medical devices (2-3 years). WHO should encourage a PMS plan following the first entry in the market of the medical device. WHO to develop a programme for adverse event reporting on medical devices. WHO to develop guidelines encouraging healthcare workers reporting on adverse events in a "blame free" culture.
	Harmonization of regulation - challenges and benefits	WHO and GHTF: Take lead in the use of medical device regulation for pre-market and post-market guidance. WHO to support a transparent easily verifiable database methods. Continued close relationship with Asian Harmonization Working Party. Contribution to regional training. Definition of manufacture database. Develop liaisons with other regions. GHTF to promote more support to assist countries to develop harmonized mechanism in particular areas beyond WHO justification. MOUs with key bodies eg. ISO, IEC. WHO and GHTF to convince the government to accept global harmonized guidance in different countries. WHO puts them together on a life cycle (holistic) approach.

Appendix J

Draft programme summary for the second WHO Global Forum on Medical Devices

Date: April – June 2012
Venue: TBD

Draft Objectives

1. To share evidence of best practices in the assessment, management and regulation of medical devices that have improved access to safe, quality medical devices.
2. To demonstrate the use of appropriate and innovative technologies that respond to global health priorities.
3. To present the outcomes of the implementation of the World Health Assembly resolution on health technologies (WHA60.29) five years after its approval.

Outcomes

1. Provision and dissemination of evidence on improving access to safe and effective medical devices as well as on positive health outcomes directly or indirectly related to medical devices.
2. Development of key recommendations that stakeholders will implement over the following 2 years.

Overview of Draft Scientific Programme

With the exception of the first session, each of the sessions below would consist of presentations by designated number of Member States on best practices, experiences, and their measured impact on health outcomes. When appropriate, international organizations would also have the opportunity to present issues surrounding their topic of interest. The session would include sufficient time for discussion and development of recommendations.

Key points to be addressed	Key points to be addressed	Pertinent paragraph of WHA 60.29
Outcomes from the First Global Forum on Medical Devices	• Status on the execution of the short- and long-term actions	N/A
Information on health technologies	• Presentation of available country data and statistics • Discussion on prioritization of needs and allocation of resources	to collect, verify, update and exchange information on health technologies, in particular medical devices, as an aid to their prioritization of needs and allocation of resources
National strategies/ plans/ policies on health technologies	• Presentations on implementation of strategies, plans or policies by a biomedical engineer or health technology assessment expert	to formulate as appropriate national strategies and plans for the establishment of systems for the assessment, planning, procurement and management of health technologies in particular medical devices, in collaboration with personnel involved in health-technology assessment and biomedical engineering
Regulation for medical devices	• Presentations on the results of implementing a regulatory framework and process • Presentations on the benefits and challenges of implementing regulatory harmonization	to draw up national or regional guidelines for good manufacturing and regulatory practices, to establish surveillance systems and other measures to ensure the quality, safety and efficacy of medical devices and where appropriate participate in international harmonization
National institutions on health technology	• Description of the organization, processes and impact of a national unit on health technologies • Discussion on interaction with patient associations and professional organizations.	to establish where necessary regional and national institutions of health technology, and to collaborate and build partnerships with health care providers, industry, patients' associations and professional, scientific and technical organizations

Medical devices adapted to national settings and needs	• Presentations on list of medical devices, the required infrastructure for use of the tool, and outcomes from using the tool	to collect information that interrelates medical devices, which deal with priority public health conditions at different levels of care and in various settings and environments, with the required infrastructure, procedures and reference tools
Presentation of guidelines, tools and glossary developed by WHO	• Status of the implementation of documents and tools • Discussion on open work and forward action	to work with interested Member States and WHO Collaborating Centres on the development, in a transparent and evidence-based way, of guidelines and tools, including norms, standards and a standardized glossary of definitions relating to health technologies in particular medical devices
Determining national needs	• Presentations on how countries determine their needs and ensure access to medical devices.	to provide support to Member States where necessary in establishing mechanisms to assess national needs for health technologies in particular medical devices and to assure their availability and use
Methodological tools	• Presentations on medical device needs determination in a specific setting.	to develop methodological tools to support Member States in analysing their health technologies in particular medical devices needs and health-systems prerequisites
Policies on health technologies for priority diseases	• Presentations on the implementation of health technology policies	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
WHO clearinghouse on health technologies	• Outcome of use of WHO clearinghouse tool	to establish and update regularly an evidence- and web-based health technologies database to serve as a clearing house which will provide guidance on appropriate medical devices according to levels of care, setting, environment, and intended health intervention, tailored to the specific needs of country or region
Appropriate health technologies	• Demonstration of innovative technologies and how they are contributing to positive health outcomes	**to provide support to Member States with vulnerable health care systems so as to identify and put in place appropriate health technologies in particular medical devices that facilitate access to quality services in primary health care**

Also being considered are parallel workshops on some or all of the following topics held over the course of one to two days.

Workshop Topic
How to develop a health technology policy
Uses of medical device nomenclature
How to use needs assessment tools
Resources for developing effective procurement systems
How to develop and enforce donation guidelines
How to develop an effective maintenance programme
Guidance on medical devices waste management
Uses of medical devices lists
Economics of medical devices
How to perform pre-market approval
How to develop post-market surveillance programs
How to create a health technology assessment unit
How to evaluate appropriate, innovative medical devices
How to create or improve a health technology unit within a MoH
How to set priorities for procedures, using medical devices
How to define training, capacity building for human resources

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