

Report

First Meeting of the WHO Advisory Group on Innovative Technologies

Singapore
20-21 June 2009

*This publication contains the report of the 1st Meeting of the WHO Advisory Group on Innovative Technologies
and does not necessarily represent the decisions or policies of the World Health Organization*

List of Abbreviations

AFRO	WHO Regional Office for Africa
AGIT	Advisory Group on Innovative Technologies
AMRO	WHO Regional Office for the Americas
CENETEC	National Centre for Health Technology Excellence (Mexico)
EHT	Essential Health Technologies
EMRO	WHO Regional Office for the Eastern-Mediterranean
EURO	WHO Regional Office for Europe
GIHT	Global Initiative for Health Technologies
GMDN	Global Medical Device Nomenclature
HT	Health Technology
HTA	Health Technology Assessment
HTAi	Health Technology Assessment International
HTM	Health Technology Management
ICT	Information and Communication Technology
IFMBE	International Federation for Medical and Biological Engineering
IHF	International Hospital Federation
INAHTA	International Network of Agencies for Health Technology Assessment
IOMP	International Organization for Medical Physics
ISO	International Organization for Standardization
IT	Information Technology
LMIC	Low- and Middle-Income Countries
MDGs	Millennium Development Goals
MoH	Ministry of Health
RSS	Resource-Scarce Settings 1
SEARO	WHO Regional Office for South East Asia
WB	World Bank
WHA	World Health Assembly
WHO	World Health Organization
WPRO	WHO Regional Office for the Western Pacific

¹ For purposes of this project, synonymous with developing countries

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1. Executive Summary

The overall goal of the Global Initiative on Health Technologies (GIHT) is to help make available the benefits of core health technologies at an affordable price, particularly to communities in resource-limited settings.

The meeting was organized in view of an upcoming Call to the international business and scientific communities to develop new and/or adapt existing technologies addressing key health problems in low- and middle income countries.

The meeting brought together 50 participants from more than 20 countries including the 23 members of the Advisory Group on Innovative Technologies (AGIT), 4 officers from two WHO Regional Offices and 4 officers from WHO Headquarters. The full list of participants is given in Annex I and the agenda of the meeting appears in Annex II, while a summary of the preceding Priority Medical Devices project is given in Annex III.

Presentations from eight Collaborating Institutions included candidate key problems based on disease burden data and country needs that could be addressed through a Call. The meeting experts were tasked with identifying priority candidate health problems based on the presentations and background papers from the collaborating institutions. The meeting participants were also invited to propose criteria for inclusion in the Call and suggest criteria for selection of candidate technologies submitted in response to the Call, as well as to provide general advice to WHO on how to proceed with the Call.

Representatives of the collaborating institutions and industry observers met to identify a list of potential participants in the Call and discuss factors that would encourage industry to invest in health technologies for low- and middle income countries. Industry observers were also tasked with identifying the background information needed for the Call.

The recommendations of the meeting comprise a framework for selecting key health problems to address and a set of selection criteria for the Call. The next step in the Call process is the launch at a special session at the IFMBE/IOMP World Congress to be held in September 2009 in Munich, Germany. Other directed outreach activities to pre-identified candidate participants and a General Call open to all interested parties are also part of the Call process.

Proposals submitted to WHO through the Call will be screened and graded between October 2009 and March 2010 by the collaborating institutions using agreed-to criteria. A short list of proposals for review and selection will be presented to the Advisory Group at its second meeting to be held in Copenhagen in April 2010. The selected technologies will be disseminated and supporting material for the optimal implementation of these technologies will be prepared, based on input from the Advisory Group.

2. Closed Session (Day 1)

Introduction

Welcome

Dr Steffen GROTH, Director, Department of Essential Health Technologies, opened the meeting by welcoming the participants and outlining the aim of the meeting. He further explained that the meeting would focus on a review of the health / health care problems raised and presented by the WHO collaborating institutions, with a view to prioritizing a limited number of key problems and determining a set of selection criteria. Through the participation of WHO regional representatives and representatives of a variety of stakeholders, a higher degree of engagement and a greater range of perspectives were anticipated.

The participants then briefly introduced themselves. This was followed by the election of Mr. Mladen Poluta as Chairperson, Ms Josee Hansen as Vice Chairperson and Mr Albert Poon as Rapporteur.

Mr Mladen Poluta, as Chairman, provided an introduction to Innovative Technologies and discussed the applicable scope for resource scarce settings. The purpose of the project and its expected outcomes were presented by Mr Bjorn Fahlgren.

WHO Global Initiative for Health Technologies

Background

Successful health care delivery requires effective medical devices and supporting health technologies as tools for prevention, screening, diagnosis, treatment and rehabilitation. Despite the exponential growth in scientific and technological development, low- and middle-income countries are still largely excluded from access to appropriate and affordable health technologies. Furthermore, attainment of the health-related Millennium Development Goals (MDGs) and effective control of many health-related problems will not be possible without certain basic technologies.

The World Health Assembly in its resolution WHA 60.29 (2007) emphasized the role of medical devices and health technologies, as well as their current sub-optimal contribution to health outcomes:

"Understanding that health technologies, and in particular medical devices, represent an economic as well as a technical challenge to the health systems of many Member States, and concerned about the waste of resources resulting from inappropriate investments in health technologies that do not meet high-priority needs, are incompatible with existing infrastructures²".

In order to facilitate equitable access to health care and the necessary core technologies, one of the goals of the WHO Department of Essential Health Technologies is to identify and promote innovative technologies addressing global health concerns and to stimulate their further development. To contribute to the achievement of that goal the Department of Essential Health Technologies has launched a Global Initiative for Health Technologies.

² This is confirmed in the background paper on *Innovation in Medical Devices* (Sarvestani and Kan): "WHO estimates that 70% of medical devices designed for use in the developed world do not work when they reach the developing world".

Goal and Objectives

The overall goal of the Global Initiative for Innovative Health Technologies (GIHT) is to help address important health problems associated with communities in resource-limited settings by making available the benefits of core health technologies, through equitable access and acceptable levels of affordability. This also requires technological innovation, either in the technologies themselves or in the processes designed to facilitate their dissemination, application and utilization.

The two specific objectives of the initiative are:

- I. 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;
- II. To challenge the business and scientific communities to identify and adapt innovative technologies that can have a significant impact on public health in developing countries.

Outputs for Objective I will include needs assessment and gap analysis tools for Member States as well as a technology prioritization model.

Objective II is a follow-up to an earlier WHO project on Priority Medical Devices (see [Annex III](#)).

Activities under this objective will include:

- Establishing partnerships with institutions that have experience in identifying health trends or forecasting and evaluating health technologies;
- identification of key global health concerns and emerging health trends based on disease burden data;
- outreach (including Call) to industry, universities, associations and other role-players to identify suitable technologies to address the identified health concerns;
- selection of innovative 3 health technologies meeting the criteria of this Initiative;
- promotion and diffusion of selected technologies through training, media coverage and other channels.

The project, to be completed by March 2011, will optimize public health outcomes by:

- Increasing understanding among decision-makers about the critical role of health technologies in promoting public health;
- stimulating the development of new technologies;
- expanding the use of existing health technologies that are not widely used, and
- identifying new uses of existing non-health technologies that can have a significant and immediate impact on public health.

Role of the Advisory Group on Innovative Technologies

³ Innovative technologies ideally represent a breakthrough in health care in the sense that they reduce or eliminate the need for currently available technologies (intended for the same clinical purpose) that are less cost-effective, appropriate and/or sustainable. Innovative technologies are likely to be already used in other sectors.

The Advisory Group, comprising a broad grouping of experts, is expected to assist WHO in many of the above-mentioned activities. Specifically, the expected deliverables from this meeting were a prioritized list of health problems, a set of technology selection criteria and any other suggestions for innovative technologies that would assist the Call process and ensure a successful outcome. The next meeting of the Advisory Group is scheduled for 27-29 April 2010 in Copenhagen, Denmark.

Presentation of Health Problems by Collaborating Institutions:

Dr Jie Chen gave a presentation and update on health-related challenges in China. The key message from the presentation was that the disease spectrum in China has changed vastly, with non-communicable diseases (NCD's) emerging as the main health-related risk factors: in 2003, for example, non-communicable diseases (NCDs) accounted for more than 70% of the total economic burden of all disease in China. The leading chronic NCDs were malignant tumor, cerebrovascular disease, hypertension, coronary artery disease and other types of heart disease.

The candidate health problems suggested were (i) cardiovascular disease and cerebrovascular disease; (ii) malignant tumors; (iii) diabetes and (iv) infectious diseases in children and adults, and emerging disease threats. Among children under five, 70% of deaths are due to perinatal conditions, respiratory infections, and infectious and parasitic diseases. For adults, Hepatitis B remains a major problem (primarily due to chronic complications of cirrhosis and liver cancer) as does TB. Emerging disease threats include HIV/AIDS, SARS, Human Influenza and Avian Influenza).

To meet these challenges, the following are needed: cost-effective screening devices for hypertension and malignancies; intelligent insulin pumps; cost-effective methods for treatment of kidney disease; new glycol-haemoglobin detection devices and innovative vaccines.

Ms Adriana Velazquez-Berumen presented Dr Guillermo Carroli's paper titled *The Millennium Declaration: still a long way to go*. The presentation focussed on maternal mortality and morbidity, given that reducing maternal mortality is the 5th Millennium Development Goal (MDG). More than half a million women between the ages of 15 and 49 die every year worldwide as a result of complications arising from pregnancy and childbirth. These deaths are heavily concentrated among the poor, almost all in the developing world. Pregnancy and childbirth related complications are responsible for almost 20% of the global burden of disease among young women worldwide. WHO estimates that, globally, over 300 million women currently suffer from short or long-term complications (such as infertility, anaemia, uterine prolapse and vaginal fistula) arising from pregnancy or childbirth, with around 20 million new cases every year.

It is estimated that more than 2 million young women globally live with untreated obstetric fistula, most of them in parts of sub-Saharan Africa and Asia. It has also been estimated that between 50,000 and 100,000 new women are affected each year. The speaker presented challenges around the issue of vaginal fistulas and the associated severe health, social and economic problems for the women thus affected. There was discussion on the use of fistula plugs for reconstruction and the use of devices facilitating delivery, such as the Odon device.

Attention should also be given to the respective roles of primary, secondary and tertiary-level care according to WHO's Integrated Management for Pregnancy and Childbirth

(2006) with emphasis on community involvement, the role of NGOs for support of patients, education and culture change.

The point was also made that health inequities can be seen at three levels, viz. large disparities in health status, differential access to and use of health care services, and disproportionate exposure to health risks, and all of these should be taken into account. At present there is a wide variation in clinical practice and high rates of inappropriate care. These gaps are due in part to limitations in the generation and use of scientific evidence and addressing these gaps requires better use of existing research.

Finally, the meeting was reminded that less than 10% of global expenditure on health-related R&D is devoted to the major 90% of health problems of the world's population (Commission on Health Research for Development, 1990).

Mrs Rosa Maria Ceballos gave a presentation on Metabolic Syndrome in Mexico: Situational assessment and some technological challenges. There has been an increase in chronic diseases due to rural migration to cities, behaviour modification and the inversion of the population pyramid. Of particular concern is the so-called Metabolic Syndrome, comprising a group of chronic diseases: obesity, diabetes, hypertension and dyslipidaemia. Three proposals have been made, related to the:

- design of applications for the management of information related to diagnosis and treatment of patients with Metabolic Syndrome;
- design of self-help measures for the metabolic control of patients with Type 2 diabetes at the primary level of health care, and
- early detection of ocular fundus alterations in patients with diabetes mellitus and hypertension by using tele-ophthalmology.

The importance of addressing the financial burden of disease to the health care system, communities, families and individuals was also emphasized.

Dr Adham Ismail presented a paper on behalf of Dr. Laurence SLUTSKER of the WHO Collaborating Centre for Prevention and Control of Malaria, CDC, USA dealing with:

- development of novel insecticide-impregnated materials to improve the delivery of insecticide into rural homes and thereby reduce malaria transmission;
- the lack of adequate diagnostic testing devices for febrile patients in malaria endemic areas (often febrile patients are treated presumptively for malaria, without appropriate disease-specific diagnosis); and
- improving case management: the provision of prompt and effective treatment for ill persons is important to reduce morbidity and mortality, but clinical guidelines are often not followed; one possible solution is the implementation of electronic patient records.

Mr Stig Becker presented on the work of the Swedish Institute of Assistive Technology (SIAT) and highlighted issues around diabetes, dementia and obesity.

Diabetes: More than 360 million are expected to have diabetes by 2030, with the major increase in developing countries (type 2 diabetes is also common in the young). Diabetes may lead to sensory loss, damage to limbs, foot disease, blindness, kidney failure, early death, etc. The challenge is to reduce the costs for individuals and society. Solutions include improved syringes, blood glucose meters and insulin pumps, and increased access to appropriate assistive devices.

Dementia: More than 34 million people worldwide are expected to suffer from Alzheimer's disease by 2025. It is a chronic and progressive disease; care costs and efforts are expected to rise dramatically. Solutions include interventions that will reduce costs and/or help individuals to be independent and secure, as well as encouraging industry to develop and design technology for daily life that is usable by all (principle of universal design).

Obesity: An epidemic of obesity has swept over Europe during the last 20 years. Effects on the individual include decreased mobility, loss of self-confidence, problems with personal hygiene and experiencing an inferior quality of life. Products in the general market should be available in sizes and designs suitable for obese persons.

Dr Pascience Kibatata presented a paper on the inadequacies of emergency, surgical and anaesthetic equipment in Tanzania, confirmed by a survey using the WHO Tool for Situational Analysis for Emergency and Essential Surgical Care. The survey revealed a significant need for anaesthesia machines, oxygen concentrators and suction devices; these devices could be made available either as separate units or as an integrated unit.

The speaker suggested that emergency, surgical and anaesthetic equipment designed for resource-scarce settings should optimally: be robust and user friendly; be light-weight and/or portable; include basic patient monitoring; require low maintenance, and have the option of being powered by battery or solar power instead of mains electricity.

The speaker also believes that the 4th and 5th Millennium Development Goals will not be achieved without an integrated health care approach, especially in resource-scarce settings. Improving emergency, anaesthetic and essential surgical care through the development of appropriate, basic health technologies is an essential step in realising that integration.

It was also noted that of the more than 200 million major surgical procedures conducted annually, one third are conducted in developing nations. Also, 11% of the global disability (DALY) burden can be attributed to the failure to treat common conditions that lend themselves to surgical intervention.

Mr Stephen Mwangi presented a paper on *Safe Drinking Water*. The speaker noted that a vast proportion (close to half) of the population in developing countries suffers at any given time from water-borne diseases such as diarrhoea, cholera, Guinea worm, bilharzias and typhoid. The speaker identified the need for a water-purification device that would be affordable to individuals in rural areas; able to filter particulate matter, clean water and inhibit micro organisms, and made from locally available material. The meeting agreed that the provision of drinking (potable) water should be seen as part of the health care challenge and a basic need of any health system.

Mr Iyad Mobarek presented a paper on behalf of Dr Vivian Coates of the ECRI Institute on *Barriers to Providing Health care in the Developing World*. ECRI Institute emphasizes a scientific approach to technology solutions and has established a world-wide information network for knowledge-sharing. ECRI has identified, amongst others, the following obstacles to health care provision in developing countries:

- supportability, reliability and sustainability of medical technology, and
- deficiencies in infrastructure.

Underlying difficulties in delivering care that are outside health system control include:

- inadequate roads and transportation;
- centralized power generation that is often unreliable;
- general economic conditions;

- population educational levels, and the
- effects of climate change

Dr Coates called for:

- standardized user interfaces on medical devices/equipment;
- standardization by health care authorities and providers to a group or type of equipment / technology, and
- harmonization of standards for medical devices and health technologies.

Breakout Session 1

Three Working Groups were formed by the Advisory Group experts to prioritize candidate health problems based on proposals (in the form of presentations and background papers) from the Collaborating Institutions. Representatives of Collaborating Institutions and Observers from Industry formed a separate group to identify potential participants in the Call and more generally to formulate suggestions for addressing various aspects of the project.

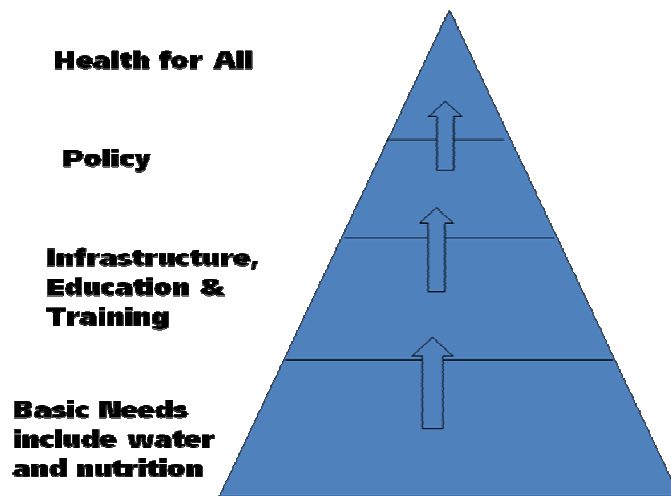
Group Presentations

The Advisory Group experts were of the view that they could not identify a definitive list of health problems for purposes of the project. However, criteria presented in the format of non-prioritized lists could be considered as a framework for selecting key health problems to address in the Call:

- a) high burden of disease in terms of incidence and prevalence and severity of health problems;
- b) screening for diseases, both communicable and non-communicable, that correspond to high levels of disability, such as slow onset handicap/loss of faculties (hearing, seeing, etc.) and mental illness (need for early diagnosis and screening);
- c) high economic impact of the problem;
- d) priority given to root causes of diseases;
- e) addressing needs of vulnerable populations and groups;
- f) challenges that have a higher likelihood of finding a solution;
- g) problems that could be addressed at the primary level of health care delivery;
- h) likelihood of being a major problem (e.g. impact in the near future / next 5 years for Swine flu, microbial antibiotic resistance, global warming, etc.)
- i) morbidity forecasts, e.g. Disability-Adjusted Life Years, for 2030;
- j) basic needs, e.g. sanitation and water purification for rural conditions (drinking) and health facilities;
- k) addressing child health needs;
- l) supporting maternal care, both prenatal and perinatal;
- m) supporting acute trauma care in field conditions;
- n) addressing wound care and pain management, e.g. post-surgical and chronic wounds / bed sores, and
- o) addressing challenges of safety and cross-infection (air-borne and other) in health facilities.

Further, criteria should not be restricted to diseases only but should include health system policies and procedures, health-related information needs, health care delivery processes and health care infrastructure.

This was reinforced by a proposed ‘pyramid of needs’ (analogous to Maslow's hierarchy), as shown below:



The concept of Quality of Care as measured by criteria of equity, effectiveness, safety, timeliness, patient-centeredness and efficiency ⁴ should also be incorporated into the framework.

The following comments and suggestions were made from the perspectives of Industry and the Collaborating Institutions:

1. Medical device/equipment utilization data is currently not available.
2. Industry needs to know what is needed in order to provide a solution.
3. Recommended listings of essential equipment by level of care and/or type of hospital/health facility (or by packages/sets of clinical interventions) should be developed and/or refined.
4. Best practices relating to policy, technology management and procurement should be shared, as should developments around harmonization and standardization.
5. Technical specifications for commonly-used medical devices with certain specific features at different levels of complexity (basic, medium and high) should be created.
6. WHO should share the draft guidelines for medical device procurement and maintenance with Industry for their comment and inputs.
7. There is a need for better infrastructure and skilled human resources for acceptance, installation and commissioning of medical devices; alternatively, it can make sense to design equipment adapted to the lack of such infrastructure.
8. There is a need to explore innovative ways of financing, logistics and delivery, and maintenance through mechanisms such as public-private partnerships (PPP's).

Collaborating Institutions and Industry are willing to collaborate with WHO in gathering data about availability of technology, needs and generic specifications (survey by country is suggested since ‘one size does not fit all’).

⁴ Institute of Medicine

There was a rich exchange of views and ideas followed by fruitful discussions on each group's proposals. A call was made for the following types of innovation, in addition to those mentioned earlier, to be supported:

- devices and interventions working well in industrialized countries but not affordable in resource-scarce settings;
- innovations addressing lack of infrastructure, e.g. basic operating theatre/room equipment such as suction pumps, lamps, respirators, etc. in conditions where electricity supply is unreliable; as well as addressing the lack of skilled human resources;
- innovations in the area of rehabilitation and assistive technologies, e.g. addressing problems of communication and
- solutions making use of existing technologies creatively, e.g. mobile phones for surveillance / monitoring, reminders, etc.

Participants thanked EHT Director, Dr Groth and Meeting Chairman Mr Mladen Poluta for the excellent leadership and successful conduct of Day 1 proceedings. Meeting was adjourned at 18:30.

3. Closed Session (Day 2)

The Chairman welcomed newcomers to the meeting. The Rapporteur provided a review of the proceedings and discussions from Day 1. Mr. Bjorn Fahlgren briefed the meeting on the objective for Day 2, i.e. discussion and compilation of selection criteria for a Call to stakeholders of industry, institutions, academia and national or local health authorities.

Breakout Session 2

The meeting was divided into 3 working groups of experts for the purpose of brainstorming, discussion and generation of recommendations for selection of innovative health technologies.

Group Presentations

A conceptual framework for the Call as a whole was proposed:

What do we want?	
<i>Category</i>	<i>Criteria</i>
Health	Global Burden of Disease Quality of Life
Health Care	Prevention, Diagnosis, Treatment, Rehabilitation Affordability Fit for use
EnvironmentDemography	Sustainability
How do we want it?	
<i>Category</i>	<i>Criteria</i>
The Carrot	Selling the WHO brand Notion of partnering Country information Highly selective
Role of WHO	As an industry consultant As a strategic partner Sharing information transparently Providing expert lists for specific diseases
The Process	A transparent review process Public Private Partnership (PPP)

A list of non-prioritized selection criteria was proposed, as follows:

- (i) Patient / staff safety, e.g. risk of infection minimal:
 - safety from infections, blood contamination
 - warnings for risk of infection
 - easy to safely maintain / clean / sterilize / dispose of
 - device self-checks for risk of infections
 - minimize medical waste in a cost-effective manner
- (ii) Reliability/durability/robustness
- (iii) Labour-saving, if possible
- (iv) Simplicity of design and intuitiveness:
 - stick to essential features and functionality
 - use principles of universal design
 - human factors: turning dials the same way on different makes; dials pointing the same direction for 'normal' setting; etc.
- (v) Simplicity of operation and maintenance:
 - easy to train, use and maintain
 - low cognitive load for user
 - auto-calibration / self-check
 - simple interface with inbuilt user-friendly help protocols
 - built-in diagnostics with a protocol that assists with trouble-shooting
 - documentation available in all necessary languages, even if over the internet
- (vi) Ability to link in the existing infrastructure:
 - function without a reliable power source
 - standardized connectors/interfaces
 - electromagnetic compatibility
- (vii) Life-cycle issues:
 - life-cycle cost clearly presented as an indicator of affordability (device cost and cost of disposables/consumables should be presented together)
 - estimated vs. actual lifetime of devices ⁵;
 - manufacturer support for the lifetime of the device
- (viii) Common standards:
 - clinical data in/out through standardized interface
 - colour codes of gases
- (ix) Risk of ionizing radiation minimal

⁵ AAMI publishes a list of expected lifetimes for medical devices

Experts also suggested a distinction between mandatory and desirable criteria, as follows:

- Mandatory criteria - safety, efficacy/effectiveness, good value for money (cost-effectiveness), affordability, acceptability (to target population and professionals).
- Desirable criteria—adaptability to resource-poor settings (e.g. energy, human and infrastructure relevance), locally producible and maintainable, neglected/orphan interventions (there is no commercial interest), population focused.

Plenary Discussion

A general discussion on health problems to address and the selection criteria for the Call was conducted. The following general recommendations were made regarding the selection criteria:

- preferably evidence-based but, if not and in public interest, as part of the project WHO should promote evidence generation;
- criteria should be applied only when applicable—different criteria will be relevant to different innovations; and
- priority should be given to interventions tackling the root causes of health problems (e.g. through primary and secondary prevention).

It was also recommended that the following information be collected in support of the selection process:

- needs of member states/countries/regions;
- individual country differences in expected demand;
- disease burden / magnitude of the health problem;
- interventions and packages which would make use of the technology;
- requirements for incorporating the technology package into routine use, and
- potential impact of the technology on disease burden.

Comments from Collaborating Institutions and Industry Observers included the following:

- a complexity classification of technologies would be useful (the level of infrastructure requirements could provide a criterion for classification);
- should focus on some key areas (to be defined) and achieve progress / early success before expanding the scope of activities;
- invite input from other sectors such as telecommunications, construction, transport, etc. and
- technologies that impact positively on the quality of life should be included.

The Chairman concluded the session with a summary of the key issues. The Rapporteur presented a brief summary of the morning's discussions.

The Chairman invited Dr. GROTH to address the floor and close the meeting. The meeting adjourned at 12.30 p.m.

4. Summary of Recommendations

The following summary presents a framework for selecting health problems for the Call to the scientific and business communities as well as the selection criteria for the innovative technologies. The Advisory Group also formulated some general advice to the project team.

The intended use of technologies

When selecting technologies proposed in response to the Call, WHO should use the following questions regarding the intended use or purpose:

1. What is the burden of diseases in terms of incidence, prevalence and severity of health problems?
2. What is the population and demography of vulnerable groups, where applicable?
3. What is the economic impact of the health / health care problem?
4. How well is the problem understood by the health care community and how solid is the scientific basis for its description?
5. Is the problem likely to have a major and possibly growing health impact within the next 5 years?
6. Is the problem a root cause of disease(s)?
7. Is the health problem linked to a lack of appropriate water, lack of infrastructure, education and/or training?
8. Is the focus on prevention, screening, diagnosis, therapy/treatment, rehabilitation, palliation, assistance (compensation of physiological function)?
9. What is the feasibility of finding a technical solution?
10. What is the possibility of solving the problem at primary health care level?

Desirable attributes/properties of technologies

When selecting technologies proposed in response to the Call, WHO should take into account the following properties of technologies:

1. Safety and effectiveness:
 - safety for patient, user and the environment, including risk of infection and exposure to radiation;
 - effectiveness for its stated purpose.
2. Sustainability:
 - life-cycle cost clearly presented, with a view towards affordability in resource-scarce settings;
 - reliability, durability and robustness; and
 - labour-saving, if applicable and possible.
3. Compatibility with context:
 - ability to link to/function within the existing infrastructure, including services and internet/telecommunications connectivity (or lack thereof);

- simplicity of operation and maintenance, including a standardized user interface, consistency of design and intuitiveness;
- where possible, no dependence on consumables;
- where possible, reusable; if not, then safely disposable;
- cultural and social acceptability of the technology;
- user education included and available; and
- possibility of local manufacture or assembly.

Other points/comments made included:

1. Industry requires information on the need and financing actually available to satisfy the needs of different markets.
2. Collated information on – and access to – the pool of existing technologies developed by NGO's should be made available.
3. Greater use should be made of technology horizon-scanning bodies.
4. Human factors engineering experts and users should be more involved in the innovation process.
5. The use of signs, logos and abbreviations used on medical device gives cause for concern, especially in environments where proper documentation and user training are not provided.
6. The Certificate of Need mechanism could be used to promote the introduction of new cost-effective technologies (rather than focus on limiting the diffusion of cost-ineffective or undesirable technologies).
7. Health care funders and consumer organizations should have a voice in the process; mechanisms to support this need to be established (if they don't exist).
8. Creative partnerships between government, industry and academia should be explored, especially at regional levels.

5. Open Session

Day 2 proceedings continued with an open session chaired by Professor Marjukka Mäkelä addressing the question:

“How can assessment of health technologies accelerate their successful introduction in low- and middle income countries?”

The session was opened by EHT Director, Dr Steffen Groth. Mr Bjorn Fahlgren presented an overview of the Global Initiative for Health Technologies and Mr Mladen Poluta presented a summary of the discussions that took place in the closed meeting.

Six presentations on various aspects of - and/or country experiences in - Health Technology Assessment (HTA) were made. This was followed by a discussion on HTA best practices, ways forward and the role of WHO, countries and agencies in promoting the assessment of innovative technologies in developing countries particularly.

Presentations

Under the general question of the session theme, the first two speakers presented tools designed to facilitate and accelerate health technology assessment and its dissemination.

Dr Tuija Ikonen presented a tool developed by the European Network for Health Technology Assessment (EUnetHTA) collaboration and designed to facilitate the transfer of HTA reports prepared elsewhere to a local context, by using a standardized format/ template with common core elements including safety, effectiveness, cost, organisational and societal impact, as well as legal and ethical issues. Prime features of the tool are its modular approach and adaptability.

EUnetHTA in cooperation with EuroScan also publishes a newsletter on high volume, costly and rapidly developing new and emerging technologies. The newsletter also provides information about health technologies that are at an early stage of development and which may have a significant impact on health care in the EU. The information provided is intended to assist decision makers (policy makers, regulators and reimbursers) better anticipate, plan and manage the introduction and diffusion of new health technologies.

Dr Joseph Mathew noted three types of health technology innovation, viz. in concept, context and content, all of which are needed. He presented an assessment tool and decision making algorithm (see Box below) particularly suited to resource-constrained settings. It has the merits of (i) including all the facets of a conventional HTA; (ii) facilitating decisions for all stakeholders; (iii) having much shorter timeframes than formal HTA studies; (iv) being context specific and (v) being much more economical in terms of time, manpower and material resources.

The presentations demonstrated a shared belief that there is need for further standardization of the methods and format of HTA efforts.

/ ...

Box 1: Algorithmic Approach to HTA for Resource-Scarce Settings

- KN = Knowledge of need
- O = Outcome of interest
- W = Who is the target?

- E = Evidence of effectiveness
- S = Safety
- S = Social quotient (ELSI)
- E = Economic issues
- N = Novelty
- T = Time factor
- I = Integration
- A = Alternate options
- L = Likely impact of not using the HT

- S = Sustainability
- U = Universality
- M = Monitoring and Measurement

Example of an assessment on a diagnostic test using the approach:

	Individual	Professional	Policy-maker	Payer
KN	High	High	High	High
O	Diagnostic accuracy	Altering of treatment threshold	Cost-effectiveness Affordability. Sustainability Universality.	Cost. Cost-benefit
W	Myself	Symptomatic people	General population	People in this setting
E	Yellow	Red	Red	Green
S	Green	Green	Green	Green
S	Green	Green	Green	Green
E	Red	Red	Yellow	Green
N	Yellow	Yellow	Yellow	Green
T	Green	Green	Green	Green
I	Green	Green	Yellow	White
A	Yellow	Yellow	Yellow	White
L	Yellow	Yellow	Yellow	Green
S	Green	Green	Yellow	White
U	White	Yellow	Yellow	Green
M	White	Green	Yellow	White
	No	No	No	Yes

A further four speakers presented country experiences of assessment of health technologies.

Dr Paulo Picon (Brazil) described both prospective and retrospective evaluations of prescription of medicines that have produced significant results in terms of quality of care and savings. Although little HTA of medical devices has been conducted in Brazil, this is beginning to change with assessment of selected devices and interventions.

Ms Rosa-Maria Ceballos (Mexico) described CENETEC's (Mexican National Centre of Excellence in Health Technology) successful efforts to optimize integration of health technologies in the Mexican health system, and mainstreaming HTA as an element of decision making. The speaker described the strategies and products devised by her organization aimed at: increasing the use of HTA among decision makers; improving HTA production; fostering collaboration among HTA producers and disseminating the assessment results. CENETEC also promoted the concepts of equity, access and efficiency in the context of health technologies.

Dr Alireza Manesh (Islamic Republic of Iran) described the accomplishments of the HTA secretariat at the Ministry of Health in Iran in terms of training, funding and establishing a national network for HTA. Further activities include establishment of guidelines and standardized formats for HTA reports.

Dr Lazar Mathew (India) stated that, in his view, HTA in India is still at an early stage of development. He provided a comprehensive overview of India's demographics and selected health indicators against a backdrop of the evolution of Indian society in general. The largest disease burden currently is that associated with diarrheal diseases, with TB also being a major challenge. Many so-called 'neglected' diseases are found in rural rather than urban areas. By 2030, 70% of deaths in India are expected to be due to cancer and cardiovascular diseases combined. The speaker outlined the opportunities for innovation in India but noted that over the last 3 decades only 21 drugs have been discovered for neglected diseases compared to more than 150 for coronary artery disease; this is a reflection of the tension in priorities (industry commercial needs vs. societal health needs) which affect many developing nations. He also briefed the meeting on the limited local development of medical devices in India.

Summary of the Session

The Chairperson summarized the session by saying that there are clearly very structured and sophisticated approaches to Health Technology Assessment in many settings, as illustrated by the presentations. There is still a strong need for substantial development of standardization of HTA practices and for increased sharing of HTA information produced in different countries amongst stakeholders in health care systems. Existing tools for information sharing should be used more actively to avoid unnecessary duplication of work.

The Meeting was closed by Dr Steffen Groth with an expression of gratitude to all for their active participation.

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Annex II: Provisional Programme of Work

Saturday 20 June 2009

- | | | |
|-------|---|-------------------|
| 08.30 | Registration | |
| 09.00 | Opening session | |
| | Health Technologies and Primary Health Care Renewal. | Dr Steffen Groth |
| 09.15 | Participants self-introduction, election of Chairperson, Vice-Chair and Rapporteur. | |
| 09.45 | The Global Initiative on Health Technologies: Purpose of project and expected outcomes. | Mr Björn Fahlgren |
| 10.05 | Discussion | |
| 10.15 | Coffee/tea break | |

Presentations of Health Problems by Collaborating Institutions

- | | | |
|-------|---|---|
| 10:30 | WHO Collaborating Centre for Health Technology Assessment and Management | Dr Jie Chen |
| 10:50 | WHO Collaborating Centre for Research in Human Reproduction (CREP), Argentina | Ms Adriana Velazquez Berumen for Dr Guillermo Carroli |
| 11.10 | WHO Collaborating Centre in Health Technology (CENETEC), Mexico | Ms Rosa Ceballos |
| 11:30 | WHO Collaborating Centre for Prevention and Control of Malaria, CDC, USA | Dr Adham Ismail for Dr Laurence Slutsker |
| 11:50 | Discussions | |
| 12.20 | Lunch | |

Presentations of Health Problems by Collaborating Institutions (continued)

- | | | |
|-------|--|--------------------------------------|
| 13.30 | Swedish Institute of Assistive Technology | Mr Stig Becker |
| 13.50 | St Francis Designated District Hospital | Dr Pascience Kibatata |
| 14.10 | The Mombasa Polytechnic University College | Dr Stephen Mwangi |
| 14.30 | WHO Collaborating Centre for Patient Safety, Risk Management and Health Care Technology ECRI Institute | Mr Iyad Mobarek for Ms Vivian Coates |
| 14.50 | Discussion | |
| 15.20 | Coffee/tea break | |
| 15.40 | Breakout session | |

Experts: Prioritization of candidate health problems based on proposals and background papers from collaborating institutions.

Representatives of Collaborating Institutions and Observers: Identification of potential participants in the Public Call.

- 17.00 Presentation by working groups of discussions and outcomes from breakout session.
- 17:30 Discussion
- 18.00 Adjourn
- 19.30 Dinner at the Pearl River Palace

Sunday 21 June 2009

- 08.30 Review of Day 1 Proceedings Rapporteur
- 08:45 Introduction to breakout session Mr Björn Fahlgren
- 09.10 **Breakout session:**
Experts: Establishment of selection criteria for technologies to be applied in the Public Call
Representatives of Collaborating Institutions and Observers: Selection criteria and the consequences if they are met/not met.
- 10.15 Coffee/tea break
- 10.30 Presentation by working groups of discussions and outcomes from breakout session.
- 11.00 Discussion
- 11.30 Establishment of selection criteria for technology proposals. Plenary
- 12.00 Summary and Conclusions Rapporteur
- 12.20 Closing Comments Dr Steffen Groth
Chairperson
- 12.30 Adjourn / Lunch

Open Session

How can assessment of health technologies accelerate their successful introduction in low- and middle income countries?

Chair: Professor Marjukka Mäkelä

Innovative technologies bring benefit to patients. At the same many innovative technologies never become mainstream health care tools and the initial investment made is perceived to be lost. Can the risk associated with investment in innovative technologies be reduced, particularly in the context of low- and middle income countries?

13.20	Opening session by Dr Steffen Groth, Director, Essential Health Technologies. Introduction to the Global Initiative on Health Technologies.	
13.40	Overview of the Global Initiative for Health Technologies' project for innovative technologies and Summary of the outcome of the closed session.	Mr Björn Fahlgren and Mr Mladen Poluta
14.00	Assessing Innovative Health Technologies in Developing countries	Dr Joseph Mathew
14.20	Innovation in resource scarce settings: Adapting results of HTA performed elsewhere to local conditions - EUNnetHTA tool for adaptation of studies to local conditions	Dr Tuija Ikonen
14.40	Discussion on the importance of assessing innovative technologies of developing countries.	Chairperson
15.00	Coffee/tea break	
15.20	Assessing health technologies - Experiences from Brazil	Dr Paulo Picon
15:40	Assessing health technologies - Experiences from Mexico	Mrs Rosa Maria Ceballos
16.00	Assessing health technologies - Experiences from Iran	Dr Alireza Olyae Manesh
16.20	Assessing health technologies - Experiences from India	Dr Thalakkotur Lazar Mathew
16:40	Discussion on best practices and ways forward, and the role of WHO and countries in promoting the assessment of innovative technologies in developing countries.	
17.20	Summary of the Open Session	Chairperson
17.30	Close of the meeting	Chairperson

Annex III: Priority Medical Devices (PMD) Project

Background

In 2007 the World Health Organization (WHO), in collaboration with the Government of the Netherlands, launched the "Priority Medical Devices" project to determine whether medical devices currently on the market were meeting the needs of health care providers and end-users throughout the world and if not, to propose research to identify—and action to remedy—inadequacies or shortcomings. The aim of the project is to bring medical devices to the attention of policy makers and to help guide both industry and government public health spending.

The main **objective** of the Priority Medical Devices project is to identify gaps in the availability of preventive, diagnostic, therapeutic and assistive medical devices on the market. Mapping of gaps in the medical devices supply constitutes a priority for governments and key stakeholders because of the associated disease or disability. In addition, potential barriers to innovation were assessed and a research agenda and action plan generated.

The objective is being achieved by conducting a comprehensive review through scientifically sound methodology, a survey and expert consultations to incorporate stakeholder needs and to account for socio-demographic factors. The methodology used takes into account of the following key items:

- present burden of disease and disability and the associated clinical guidelines;
- potential future burden of disease and of disability, given the changing demography in many countries;
- cross cutting issues like training design, context, regulatory framework; and
- drivers and barriers to innovation and research.

Outcomes include:

- A generic methodology to identify "gaps" in the availability of preventive, diagnostic, therapeutic and assistive medical devices. These gaps will include medical devices that (i) are or may not be currently available; (ii) if available, not necessarily widely used; (iii) if used, not to the extent that is desirable; or (iv) that may be inappropriate for the context in which they are used.
- Identification of the main barriers to innovation and diffusion of medical devices and where possible, suggestion of solutions to either reduce or overcome these.

This first phase of the PMD project pointed to the next steps in a continuous process of developing tools for assessing the availability, accessibility and appropriateness of medical devices. The final report of the project, *Medical Devices: managing the mismatch* is expected to be published in February 2010. Additionally there will be a number of background reports available on key issues such as: Characteristics of medical devices; Availability matrix; Neglected diseases; ICF—bridging GBD and assistive devices; Barriers to innovation and diffusion; and Future needs and technology trends.