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20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 – WWW.WHO.INT

Report

In Search for Equity in Medical Devices Accessibility

WHO Centre for Health Development (WKC)
Kobe, Japan
13-14 July 2010

منظمة الصحة العالمية • 世界卫生组织

Organisation mondiale de la Santé • Всемирная организация здравоохранения • Organización Mundial de la Salud



List of Abbreviations

ADB African Development Bank
AFRO WHO Regional Office for Africa
AGIT Advisory Group on Innovative Technologies
AMRO-PAHO WHO Regional Office for the Americas
EDMA European Diagnostic Manufacturers
EHT Essential Health Technologies
EMRO WHO Regional Office for the Eastern-Mediterranean
EURO WHO Regional Office for Europe
GIHT Global Initiative for Health Technologies
GMTA Global Medical Technology Alliance
HIV Human Immunodeficiency virus
IVD In Vitro Diagnostics
JFMDA the Japan Federation of Medical Devices Association
JICA the Japan International Cooperation Agency
MoH Ministry of Health
NPO Non Profit Organization
SEARO WHO Regional Office for South East Asia
WHA World Health Assembly
WHO World Health Organization
WPRO WHO Regional Office for the Western Pacific

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1. Executive Summary

The meeting took place in the WHO KOBE centre from 13 to 14 July 2010. It brought together participants from development agencies, WHO offices, industry, and academia.

The main objectives of the meeting were:

- to update the participants on the role of WHO regarding equity and universal access to health technologies necessary for primary health care delivery;
- to outline the challenges and opportunities for achieving equitable access while taking into account ethical considerations in particular in environments such as urbanized areas and for particular diseases chosen: e.g. cancer as example in both low- and high- resource settings;
- to consider technological innovation: e.g. e-health and m-health as means to achieve equitable access in low- and middle- income countries;
- to examine from an equity perspective the usefulness of predefined lists of recommended medical devices for specific purposes that serve as standards for services and as reference for health technology metrics at different resource levels;
- to identify health technology experts, governments, organizations, industries and other stakeholders

The program included presentations on topics related to the expected meeting outcomes and breakout sessions for working groups to propose recommendations that were discussed and adopted in the plenary sessions.

The presentations gave an overview of current WHO projects on priority medical devices and innovative health technologies, topics including urban health and cancer, the role of WHO Collaborating Centres, and an update on current developments and trends of medical technology industries to increase innovation, affordability, appropriateness and equity.

The breakout sessions provided opportunities for group work and exchange on lists of medical devices for specific purposes, establishment of a coordinated research agenda, transfer of knowledge and technology to low resource settings.

The meeting concluded by recommending to establish a strategic framework for advancing equitable access to medical devices comprising the following components:

- Proposing a coordinated research agenda in order to evaluate the usefulness of medical devices in low medical resource settings;
- taking actions to guide funding for appropriate devices and for improvement of access to medical devices and;
- developing and disseminating lists of priority medical devices intended for resource limited settings.

2. Meeting contents:

The agenda included an opening session and plenary sessions in day 1 and 2 as breakout sessions in working groups as follows. For reference please find attached agenda in annex 1 and the list of participants in annex 2

2.1 Meeting opening

2.1.1 Welcome remarks

Dr Kumaresan made opening remarks. He welcomed participants and stressed the importance of access to health care. He emphasized equity in medical devices availability, affordability and accessibility of all people.

2.1.2 Opening remarks

Dr Mugitani mentioned about health from personal perspective and addressed the importance of health and access to health care in a timely fashion.

2.1.3 Equity in Medical Device Accessibility

Dr Steffen Goth, Director, Department of Essential Health Technologies, introduced and explained the objectives of the meeting. He then made a presentation on "Ethics as a framework for healthcare". He advocated for a coordinated research agenda for appropriate health technologies to be established for the promotion of projects in developing countries.

3. Presentations

3.1.1 Urbanization, health and equity

Dr Francisco Armada, from the WHO Kobe Center, discussed the reduction of health inequity in urban settings. He reviewed activities of WKC since its establishment in 1995, focused on urban health and equity in access to health care referring to the commission on social determinants of health, and mentioned the World Health Day 2010 which gave renewed momentum to urban health. Furthermore, he introduced URBAN HEART a programme for establishing urban health metrics. He emphasized the importance of urban community network working together with WKC and using the URBAN HEART "package".

3.1.2 International projects to overcome the inequity in access to medical devices

Dr Sueo Machi adviser to the Ministry of Education, Culture, Sports, Science and Technology of Japan, proposed ways to improve medical devices accessibility in developing countries. Based on his experiences at IAEA and other agencies, he pointed out following key points:

- Cost reduction of medical devices
- Funds for procurement of medical devices
- Donation of medical devices from developed countries
- Utilization of used refurbished medical devices from developed countries.

Furthermore, he proposed potential roles of WHO for improving medical devices accessibility in developing countries as follows:

- Encouraging developed MS to increase humanitarian aids
- Disseminating statistics of inequity in medical devices accessibility in developing countries to MS, NPO and the public
- Facilitating and encouraging donation of devices by NGO and NPO
- Approaching funding agency such as UNDP and JICA to facilitate their support to MS
- Facilitating soft loan of WB, EBRD, ADB etc. for developing countries
- Assisting MS to establish medical technology infrastructure in terms of expertise, human resources (through expert service, training courses and distant learning)
- Establishment of regional network: Regional centre of advanced high cost devices, collaboration of developed and developing countries in the region

3.1.3 Equity - Information for decision making

Ms Ana-Lucia Ruggiero from the American Regional Office of WHO (AMRO-PAHO) overviewed the possibilities for information technologies in health care systems. The speaker stressed the power of outreach to populations that would otherwise not be reached and also the value of making information about the health system available through IT tools. Information technologies in health care systems, both provide the information necessary to measure equity in health care and provides solutions for improving equity. The presentation was in itself an example of the possibilities information technologies as Ms Ruggiero used Elluminate Live, software developed for holding teleconferencing, classes and meetings. It permits to work in teams at different locations.

3.1.4 Priority Medical Devices - Interim Report

Dr Josee Hansen from the Health Care Inspectorate of the Netherlands overviewed the Priority Medical Devices Project (she presented from Netherland via Skype). She mentioned that objectives of the project are as follows:

- Identify the gaps in medical devices
- Develop a methodology to identify the gaps
- Identify barriers to innovation
- Propose a research option

She pointed out that major findings which were identified through the implementation of the project were mismatches as follows:

- A sector which is market driven rather than addressing public health care needs
- Lacking needs assessment
- Inadequate guidelines
- Lack of clinical outcome data
- Lack of a single nomenclature system
- Lack of training
- Lack of management systems

She also proposed research topics in order to overcome the mismatches as described above, and introduce research option in each specific disease such as tuberculosis, HIV/AIDS, diabetes mellitus and road traffic injuries.

3.1.5 Lists of medical devices - When are they useful?

Mrs Adriana Velazquez-Berumen from the Essential Health Technologies department Geneva presented the case of lists of medical devices for different kinds of health interventions and levels of health care. The speaker cited examples of countries that have used such list for harmonization and standardization purposes facilitating the management of facilities and planning and enabling measurement and comparison between different facilities in the framework of a health system.

WHO has engaged in establishing such lists for the district hospital and envisages to push further forward, with estimation of needs and cost, information related to listed medical devices. The speaker insisted on the potential of medical device lists for simplified and optimized management in health systems and the challenges in terms of making lists relevant and adaptable for all different settings.

3.1.6 Innovative Health Technologies

Mr Björn Fahlgren from the Essential Health Technologies department Geneva outlined the project “Call for innovative health technologies that address global health concerns” within a framework of GIHT. He introduced the definition of “innovative” as follows.

To qualify for consideration, a technology must be deemed “innovative” by providing the evidence that the solution:

- Has not previously existed;
- Has not previously been made available in low- and middle-income countries;
- Is safer and/or simpler to use than earlier solutions; and/or
- Is more cost effective than previous technologies.

Also he introduced the aim and scope of the project, and process for the call of innovative health technologies, and reported those 15 technologies, including 8 technologies in commercialized/-able products and 7 technologies in non- commercialized/-able products. Examples of selected technologies include:

- Reusable neonatal suction system
- Transcutaneous bilirubin measurement system
- Transcutaneous anaemia monitoring system
- Single use assistive vaginal delivery system

All the selected technologies and the information from the call are posted on WHO website: http://www.who.int/medical_devices/call_selected_innovative_tech/en/index.html for further reference. The goal is to make them available in resource limited settings.

3.1.7 Cancer - Situation analysis and proposals

Dr Andreas Ullrich from the Chronic Diseases Prevention and Management department reviewed the essential elements of effective cancer control (he presented from WHO/HQ, Geneva via telephone). He pointed out the importance of the contribution of health technologies for cancer control according to level of care (primary health care (PHC), district hospital and tertiary care), and emphasized the following points:

- EHT (devices at all level of care) are essential for effective cancer control
- Partnerships in cancer control can support access to devices and services
- Equity in access to devices relevant to cancer control requires:
 - Systematic planning based on evidence
 - Health system strengthening at all levels of care
 - Leadership and inter disciplinary collaboration
 - Decentralization of care as possible. PHC plays an important role in early detection

3.1.8 eHealth and mHealth as solutions for achieving the millennium development goals

Professor Kendall Ho from the University of British Columbia reviewed eHealth and mHealth, as possibly effective methods to overcome the inequity of medical devices. He defined eHealth as information technologies for health service delivery, education, research and knowledge translation. He pointed out that combination of eHealth and medical devices would be available for applications (health access and improvement), surveillance (prioritization and monitoring), communication (transparency and engagement), knowledge exchange (capacity and change), device development (utilization and replication) and evaluation (building evidence).

3.1.9 Equity concerns in the health service delivery

Dr Janet Hatcher Roberts from the University of Ottawa reviewed health systems perspective on equity and technology. She reviewed inequity of population, distribution of world health, distribution of poverty, distribution of underweight children, HIV prevalence, and distribution of health workers and nurses. She emphasized needs to get better at transferring and adapting models that will promote a fair distribution of access and availability of appropriate technologies, devices and services for health care and strengthen the systems infrastructure to improve accountability.

She also mentioned that well trained health professionals, nurses, doctors, and community health workers to be in the right place at the right time doing the right thing with appropriate equipment is an essential component of a health systems approach, in order to strengthen the delivery of appropriate technologies and devices. Furthermore, she emphasized needs to promote a sustainable health system.

3.1.10 Information for decision makers, in equity, accessibility and use of health technology

Ms Alejandra Prieto de la Rosa from the Centro Nacional de Excelencia Tecnológica en Salud in Mexico presented on information for decision makers in equity, accessibility and use of health technology, based on experiences in Mexico.

She presented the health technology aspects in the National Health Program 2007-2012 as the following:

- To develop planning, management and evaluation instruments for the National Health System
- To organize and integrate health care services delivery at the National Health System
- To extend access and improve quality, efficiency and continuity of medical health care through Tele-health services
- To support the delivery of health services by developing infrastructure and essential equipment, and
- To stimulate the financing and establishment of policies for the renovation and maintenance of medical equipment by developing biomedical engineering areas into health units.

She also reviewed availability of major medical equipment in Mexico, and emphasized the necessity for the improvement of health technology management, assessment and application and increase the use of health technology information among decision makers.

3.1.11 The Needs for equity

Dr Jean-Bosco Ndiokubwayo from WHO Regional Office for Africa reviewed the needs for equity of healthcare system, including medical devices in AFRO. He mentioned that health technology is one of the weakest components of the national health system, and the absence of suitable health technology policies in most AFRO countries is at the root of the problem. At the same time, costs for health system are increasing and the gap between needs and resources is widening. He concluded that access to health technologies and medical devices requires higher public investment and priority allocation to deficit areas, in order to decrease inequities.

3.1.12 Inequity in access of medical devices

Dr Nicholas Adjabu from WHO Country Office in Kenya presented on inequity in the access of medical devices in Kenya. He pointed out factors that can promote or limit access to medical devices were availability on the market, cost, decision making process, infrastructure and environmental factors, capacity to utilize the devices, timely replacement, cost recovery or system for reimbursement and transparency and fairness in the medical devices market. He mentioned that availability of safe, innovative, useful and affordable medical devices depend on the economy and the business environment, worsening this is the lack of regulations to minimize the marketing of the substandard medical devices and competent personnel in the area of medical devices.

3.1.13 The Japanese perspective (on developments and trends of the medical device industry)

Mr Masaaki Naito representing the Japan Federation of Medical Devices Association (JFMDA) reviewed activities of and reviewed medical devices market of Japan, including imports and exports. He pointed out that Japan's exports are less than imports, and promoting more exports to balance trade is a role of JFMDA. Also he emphasized the importance of medical device innovation through promotion of collaboration with academia.

3.1.14 The perspective of the diagnostics industry (on developments and trends of the medical device industry)

Mr Bruce Ellsworth representing the European Diagnostic Manufacturers Association (EDMA) gave an overview of the in vitro diagnostic industry. He started by describing the essential role of in vitro diagnostics (IVDs) in each stage of prevention, diagnosis and therapy of disease. He also proposed need for coordinated research agenda with focus on innovation of IVDs. Furthermore, he emphasized the importance of diagnostic technology transfer to low resource settings and recommended in order to increase private sector investment in low resource settings the following courses of action:

- Increase training on IVDs for medical students, healthcare providers and technicians to broaden access
- Use of transparent rules and methods for government procurement could improve the investment environment
- Capacity building programs for regulators on Global Harmonization Task Force (GHTF), which respond to growing needs for International Harmonization in medical device and diagnostic regulations, encourage convergence in regulatory practices related to ensuring the safety, effectiveness, performance adequacy and quality of devices and diagnostics.

3.1.15 The Global Medical Technology Alliance perspective (on developments and trends of the medical device industry)

Ms Anne Trimmer presented on behalf of the Global Medical Technology Alliance (GMTA), which taken European Diagnostic Manufacturers Association the initiative to promote improved access to medical technologies. She mentioned that GMTA welcomes opportunity to work with WHO on its programmes on Essential Health Technology. GMTA supports the focus of WHO to work on effective contribution made by medical technology and mechanisms to ensure access, public/private collaboration will assist in delivering benefits to patients and healthcare systems. Three key requirements are harmonized regulatory systems, transparent and ethical procurement processes and appropriate health technology assessment.

4. Perspectives (Day 2)

Through panel discussion on perspectives from funding agencies and governmental agencies, representatives from The African Development Bank (ADB) and The Japan International Cooperation Agency (JICA) made presentations.

4.1.1 Perspective from funding agencies and governmental agencies

Mr Tsinko Ilunga introduced activities of ADB in the field of health system, public health and health promotion, including medical devices. He outlined the goal (to reduce poverty in regional member countries) and vision (to be the leading development finance institutions in Africa), and pointed out objectives of ADB lending for health as follows:

- Assist Regional Member Countries (RMCs) in tackling prevailing health problems
- Assist RMCs to develop and implement health policies and strategies
- Assist RMCs to strengthen their health systems, in particular Human Resources for Health

He introduced areas of interventions by ADB up to 2008 in areas of health system, public health and health promotion. Furthermore, he pointed out that priority areas of intervention of ADB are as follows:

- Direct health investment through the public sector (strengthening health systems, training of biomedical engineers and technicians, introduction of procurement reforms in the health sector, introduction of health care financing e.g. insurance, strengthening of research capacity in bio-sciences and strengthening of capacity to regulate the sector and dialogue with stakeholders)
- Direct health investment through the private sector (including equity participation, health manpower and training and health care). Supportive environment for health (including safe drinking water and sanitation, food security, infrastructure, such as roads and telecommunication systems, actions to cope with climate change and social protection.

Mr Tomoya Yoshida reviewed activities of Japan International Cooperation Agency (JICA), which is an independent administrative institution that coordinates Official Development Assistance (ODA) for the government of Japan.

He introduced that basic policies of JICA are: human security and sustainable capacity development. Its focal areas in health sector are: health system strengthening, human resources for health, improvement of maternal and child health and of reproductive health and infectious disease control.

He introduced several examples of grant aid project by JICA in health sector, and challenge concerns for the continuous use of the medical equipment in developing countries. He emphasized that establishing preventative maintenance system, as well as training of human resources are important for better management/maintenance of the medical equipment.

4.1.2 Coordinated research agenda methodology proposal

Dr Noboru Takamura outlined coordinated research agenda on medical devices. Proposed coordinated research programme (CRP) could be organized as a network of participating institutions. It would be formed for innovative technologies chosen to be evaluated for its appropriateness and efficacy under the conditions of developing countries. He mentioned that institutions within the network would cooperate to reach the identified evaluations goal, but may also address individual evaluation problems under the larger evaluation theme that is agreed by the participants of the network. Also he suggested that WHO's role would be to support the network and convene research coordination meetings.

About coordination of CRP, he proposed as follows:

- WHO in its unique position as a technical international organization would take the lead and coordinate this research effort. WHO could aim to involve several research institutions to contribute, both from developed countries and low- and middle-income countries.
- WHO could invite selected research bodies to contribute to specific research questions.
- WHO might also be open to proposals from institutes or individuals for participation in this programme if relevant. Awards made under this programme would take into account the value of the proposed project to the overall research aim.

4.1.3 Transfer of knowledge considerations

Dr Kendall Ho reviewed issues to consider for knowledge transfer. He pointed out following points for reviewing telemedicine:

- Collaboration, participation, Capacity building
- Context (resources, needs, SWOT)
- Simplest, most cost efficient to fulfill needs
- Evaluation towards scalability, transferability
- Social benefits beyond health

5. Group work

The meeting participants were divided into three groups. Each one of the groups needed to consider one of the following topics: Coordinated research agenda, Transfer of knowledge and technology to low resource settings and Lists of medical devices.

Each group was asked to attempt to answer three questions for each topic:

- What are the practical actions that could achieve improved access to medical devices?
- What could a strategy for access to medical devices look like?
- What could be done to specifically address urban health issues?

1) Coordinated research agenda

Group 1: proposed organization of coordinated research agenda is attached in Annex. This group pointed out the role of each participant as follows:

- Coordinator (P staff or from institution who obtained budget); setting a theme
- Consulting group (from institutions, funding bodies); implementation of research project (practical research, not basic and epidemiological researches).

Also, several topics were shown to be samples of research agenda (Practical actions that could achieve improved access to medical devices, optimal strategy for improving access to medical devices and urban health issues).

2) Knowledge transfer

Group 2: presented the solution to promote knowledge transfer of medical devices. This group proposed that the following actions should be taken:

- Understanding the needs from hospital
- Accurate monitoring system to judge need and manage inventory
- Donor coordination to guide funding for appropriate devices, and
- Setting up mobile devices system ink mobile devices to telemedicine

Also this group proposed that in urban settings actions should be taken towards:

- Better understanding of urban disease patterns
- Setting up continuum of care clinics to provide good quality/standard of care, and
- Establishing a process to fund access.

3) List of medical devices

Group 3: presented practical actions and strategy to improve access to medical devices.

This group proposed practical actions to improve access to medical devices as follows.

- To develop and disseminate list of priority medical devices /priority diseases.
- Support the implementation and use benefit of the reference lists to local settings.
- Need to add technical specifications, staffing and reference cost

Also, this group proposed to define the basic health needs of the country at macro level, to use the reference lists to determine the devices needs and to prioritize gap, shortfall of devices required.

6. Recommendations

In the end of the meeting the following points are recommended:

1. Establish coordinated research agenda in order to evaluate the usefulness of medical devices in low- and middle- resource settings
2. Take actions to guide funding for appropriate devices and improvement of access to medical devices.
3. To develop and support dissemination of lists of priority medical devices in resource limited settings.

Annex: 1

In Search for Equity in Medical Devices Accessibility 13-14 July 2010 WHO Centre for Health Development (WKC), Kobe, Japan

List of Participants

AMRO/PAHO REGION

Ms Alejandra PRIETO DE LA ROSA

Centro Nacional de Excelencia Tecnológica en Salud
CENETEC
Ministry of Health
Av. Reforma No. 450, Piso 13
Col. Juarez, Del Cuauhtémoc
Mexico D.F.
MEXICO

Professor Kendall HO

Chair of the U21 Health Sciences
UN MDG Steering Committee
Director, eHealth Strategy Office
Faculty of Medicine
University of British Columbia
Vancouver
CANADA

Mrs Janet HATCHER ROBERTS

WHO Collaborating Center for Technology
Assessment, Knowledge Transfer for Health Equity
Centre for Global Health
Institute of Population Health
University of Ottawa
1 Stewart St., ON
CANADA K1N 6N5

EMRO REGION

Mr Tshinko ILUNGA

The African Development Bank
Rue D Ghana
Tunis, Belvedere
BP 323-1002, Tunis
TUNISIA



Dr Iyad MOBAREK

WHO Country Office/Jordan
Technical Officer of Health Technology
Amman, Jordan

EURO REGION

Mrs Josee HANSEN

The Netherlands Health Care Inspectorate
Chief Inspector
2595 The Hague
THE NETHERLANDS

Dr Kirsten HAVEMANN

The Research Unit
Technical Advisory Service
Ministry of Foreign Affairs
Asiatisk Plads 2
DK-1448 København K.
DENMARK

WPRO REGION

Mr Eizen IREI

Director
Japan International Cooperation Agency
JICA Hyogo
1-5-2 Wakihama Kaigan Dori, Tyuou-ku
651-0073 Kobe
JAPAN

Mr Tomoya YOSHIDA

Assistant Director
Project Management Division 2
Financing Facilitation and
Procurement Supervision Department
Japan International Cooperation Agency
Nibancho Center Building 5-25, Nibancho,
Chiyoda-ku, Tokyo 102-8012
JAPAN

Dr Sueo MACHI

Adviser to the Ministry of Education
Culture, Sports, Science and Technology of Japan
Senior Adviser to Japan Atomic Energy Agency
Coordinator, Forum for Nuclear Cooperation in Asia (FNCA)
Tokyo
JAPAN



Dr Masato MUGITANI

Ministry of Health
Tokyo
JAPAN

INDUSTRY

Mr Masaaki NAITO

Japanese Federation of Medical Device Associations
8F B, Iidabashi Square Bldg., 3-2,
Shimomiyababi-cho, Shinjuku-ku
162-0822 Tokyo
JAPAN

Mr Bruce Ellsworth

European Diagnostic Manufacturers
Association (EDMA)
Place des Maieurs, 2
1150 Brussels
Belgium

Ms Anne TRIMMER

Chief Executive
Medical Technology Association of Australia
Level 12, 54 Miller Street
North Sydney NSW 2060
AUSTRALIA

WHO CENTRE FOR HEALTH DEVELOPMENT (WKC), KOBE, JAPAN

Dr Jacob KUMARESAN

Director

Dr Francisco ARMADA

Technical Officer

Dr Jostacio LAPITAN

Technical Officer



WHO REGIONAL OFFICE FOR AMRO-PAHO

Mrs Ana Lucia RUGGIERO

Information Systems Management MSC
Equity, Health & Human Development Listserv
Information Knowledge Management Area DD/IKM
Washington D.C
UNITED STATES OF AMERICA

WHO REGIONAL OFFICE FOR AFRO

Dr Jean-Bosco NDIHOKUBWAYO

Programme Manager
Blood Safety, Laboratories
And Health Technologies
Health Systems & Services Cluster

Mr Nicholas ADJABU

Kenya Country Office

WHO REGIONAL OFFICE FOR WEST PACIFIC

Dr Gayatri GHADIOK

Regional Adviser
Essential Health Technologies

WHO DEPARTMENT OF CHRONIC DISEASES PREVENTION AND MANAGEMENT

Dr Andreas ULLRICH



**World Health
Organization**

20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 – WWW.WHO.INT

DEPARTMENT OF ESSENTIAL HEALTH TECHNOLOGIES

Dr Steffen GROTH
Director

Mrs Adriana VELAZQUEZ-BERUMEN
Diagnostic Imaging and Medical Devices

Mr Björn FAHLGREN
Diagnostic Imaging and Medical Devices

Dr Noboru TAKAMURA
WHO Kobe Centre

Annex 2: Agenda

In Search for Equity in Medical Devices Accessibility 13-14 July WHO Centre for Health Development (WKC), Kobe, Japan

Tuesday, 13 July 2010

- 08.00 Participants registration
- 09.00 Welcome remarks
Dr Jacob Kumaresan
WHO Centre for Health Development (WHO Kobe Centre)
- 09:20 Opening remarks
Dr Masato Mugitani
Assistant Minister for Global Health of Ministry of Health, Labour and Welfare
- 09.40 Equity in Medical Devices Accessibility - Is Innovation a Solution?
Objectives and expected outcomes of the meeting
Dr Steffen Groth
Department of Essential Health Technologies
- 10.00 Urbanization, health and equity:
Challenges ongoing work of WHO Centre for Health Development
Dr Francisco Armada
WHO Centre for Health Development (WHO Kobe Centre)
- 10.20 International projects to overcome the inequity in access to medical devices:
Dr Sueo Machi
Advisor to Ministry of Education, Culture, Sports, Science and Technology, Japan
- 10.40 **Coffee break**

WHO Developments

- 11.00 Equity - Information for decision making
Ana-Lucia Ruggiero, Pan America Health Organization
- 11.15 Priority Medical Devices Project - Interim Report
Ms Josee Hansen
Ministry of Health the Netherlands
- 11.45 Lists of medical devices - When are they useful?
Mrs Adriana Velazquez Berumen
Department of Essential Health Technologies
- 12:00 Innovative Health Technologies
Mr. Bjorn Fahlgren
Department of Essential Health Technologies
- 12.15 Discussion
- 12.30 **Lunch:** At JICA Restaurant, 1st floor of JICA Hyogo building
- 13.30 Cancer situation analysis and proposals:
Dr Andreas Ullrich
WHO Department of Chronic Diseases Prevention and Management
- 13.45 eHealth and mHealth as solutions for achieving the millennium development goals (MDGs)
Professor Kendall Ho
University of British Columbia
- 14.00 Discussion
- The role of WHO Collaborating Centres
- 14.15 Equity concerns in the health service delivery,
Dr Janet Hatcher Roberts
*Director of the WHO Collaborating Centre for Knowledge Translation and Health
Technology Assessment in Health Equity, Ottawa, Canada*
- 14:30 Information for decision makers, in equity, accessibility and use of health technology
Ms Alejandra Prieto
National Center for Health Technology Excellence, Mexico
WHO Collaborating Centre for Health Technology



14:45 Discussion

15:00 The needs for equity

Dr Geeta Mehta

Regional Adviser Blood Safety and Clinical Technology South East Asian Regional Office

15.15 Inequity in access of medical devices

Dr Nicholas Adjabu Kenya Country Office

15.30 Discussion

15.45 **Coffee break**

16:15 **Update on current developments and trends of medical technology industries to increase innovations, affordability, appropriateness and equity**

16.15 The Japanese perspective

Mr Masaaki Naito

Japanese Federation of Medical Device Associations

16:30 The perspective of the diagnostics industry

Mr Bruce Ellsworth

European Diagnostic Manufacturers Association EDMA

16:45 The Global Medical Alliance Perspective

Ms Anne Trimmer

Global Medical Technology Alliance

17.00 Discussion

18.00 Adjourn

Reception

Wednesday, 14 July 2010

08.30 Panel discussion: Perspective from funding agencies and governmental agencies:

Mr Tsinko Ilunga
The African Development Bank

Mr Tomoya Yoshida
The Japan International Cooperation Agency

Discussion

09.15 Coordinated research agenda methodology proposal

Dr Noboru Takamura
Department of Essential Health Technologies

09.30 Transfer of knowledge considerations

Dr Kendall Ho
University of British Columbia

09.45 Discussion

10.00 Coffee Break

10.30 Open discussion to define the issues to overcome the inequity of medical devices in developing countries

11.15 Open Discussion to establish the strategies to overcome the inequity of medical devices with a focus on urban and rural specific needs

12.00 **Lunch:** At JICA Restaurant, 1st floor of JICA Hyogo building

13.00 Break out session:

The break out groups will make suggestions for recommendations on the three topics below and attempt to answer the following questions.

Topics for break out session:

- 1) Coordinated research agenda
- 2) Transfer of knowledge and technology to low resource settings
- 3) Lists of medical devices

Questions to answer in the context of the theme of the working groups:

- What are the practical actions that could achieve improved access to medical devices?
- What could a strategy for access to medical devices look like?
- What could be done to specifically address urban health issues?

15.00 Coffee break

Presentations by groups:

- 15.20 Presentation regarding the best strategy for establishing a coordinated research agenda to overcome the inequity of access to medical devices
- 15.40 Discussion
- 16.00 Presentation on strategies for transfer of knowledge and technology to low resource settings
- 16.20 Discussion
- 16.40 Presentation on strategies for establishing and using lists of medical devices for improving access to medical devices
- 17.00 Discussion
- 17.20 Summary of the meeting and recommendations.
- 17.50 **Conclusion, thanking and closure.**
- 18.00 Closing remarks- Adjourn**



**World Health
Organization**

20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 – WWW.WHO.INT

Annex 3: Background document for the meeting.

In Search for Equity in Access to Medical Devices

Diagnostic Imaging and Medical Devices Unit (DIM)
Department of Essential Health Technologies (EHT)
World Health Organization

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Executive Summary

Medical devices constitute a major factor with respect to access to health care.

The access to medical devices although necessary is not sufficient for people to have access to necessary health care services.

The issue of access to safe and effective medical devices needs to be looked upon differently, depending on whether the setting is urban or rural, depending on the financial resources at the setting.

A large number (hundreds or thousands) of new medical devices are placed on the market every year. Are they all innovative their use justified by solid evidence and their utilization affordable and cost effective? Unfortunately not, for some devices the evidence is scarce and the sheer number of new technologies is such that they can hardly be adopted in resource limited settings.

WHO's objective is to facilitate access to health technologies. However consultation on the future role of technologies in particular innovative technologies for combating health inequity in urban areas of low- and middle- income countries is of great value for the implementation of primary health care reform especially with respect to universal coverage and service delivery concepts.

Current WHO initiatives that address improving access and equity with respect to health technologies include the Global Initiative on Health Technologies and the Priority Medical Devices project of the department of Essential Health Technologies as well as the Urban HEART project of the WHO Kobe Centre which aims to provide an assessment of and a response to inequities in access to health care in urban settings.

It is important to remember that health technologies, in particular medical devices, represent an economic as well as a technical challenge to the health systems of many Member States, and sometimes are associated with the waste of resources resulting from inappropriate investments in health technologies, in particular medical devices, that do not meet high-priority needs, are incompatible with existing infrastructures, are irrationally or incorrectly used, or do not function efficiently.

Member States and donors need to contain burgeoning costs by establishing priorities in the selection and acquisition of health technologies, in particular medical devices, 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.

The consultation is expected to outline the next steps in terms of efforts for improving access to safe and effective health care technologies and how to enhance equity (see annex I for objectives and outcomes of the meeting).

1. Introduction

Health technologies in the form of medical devices are indispensable for delivering healthcare at all levels. In 2006, the United States, the European Union and Japan each spent almost US\$ 300 per capita on medical equipment. In the rest of the world, the average of such expenditure is in the order of US\$ 6 per capita, and in sub-Saharan Africa - a market with much potential for expansion - it is US\$ 2.5 per capita. The countries that spend the most on healthcare spend more than a hundred times more on health technologies per capita than the poorest countries, leading to great inequities in terms of access to safe and effective health technologies.

The difference in spending is in itself a clear indication of inequity but unfortunately there are contributing factors reinforcing the disparity in health outcomes. Settings with limited economical resources continue to invest in and maintain obsolete technologies rather than adopting better new solutions. Furthermore, new innovative technologies developed are not aimed at developing countries and therefore are unsuitable for such markets in terms of requirements on quality infrastructure, spare parts, consumables and maintenance, not to mention the skill required for their use. It appears that the poor not only have little resources but also possibly get little in return for the resources used.

The term “health technologies¹” refers to the application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of lives. Health technologies form the backbone of services aimed at the prevention, diagnosis and treatment of illness and disease. Such technologies are considered essential when they efficiently meet the basic healthcare needs of the majority of the population at an affordable price.

The disparity in health care spending between high- and low-income countries leads to great inequities in terms of access to safe and effective health technologies. In addition, low- and middle-income countries are often excluded from the possibility to implement the latest medical device solutions. This is the case because most innovative health technologies are designed by and for developed nations and hence are unsuitable for use in resource-limited settings in terms of infrastructure, requirements for spare parts, consumables and maintenance, not to mention the level of skill required for their proper use.

However, many novel technologies do have the potential to be adjusted in order to suit resource-limited settings. Key technologies need to be carefully identified and guidance on their adaptation as well as on their integration into the existing health systems needs to be provided. Furthermore, the medical device industry, academic institutes and other organizations operating in the realm of health technologies need to be challenged and incentivized to focus on the development of devices that are accessible to all.

¹ Resolution 60.29, "Health Technologies", World Health Assembly May 2007

2. Current WHO Activities

The strategic objective 11 of the WHO Medium Term Strategic Plan is: "To ensure improved access, quality and use of medical products and technologies" and in order to facilitate equitable access to health care and the necessary core technologies.

In alignment with the World Health Assembly Resolution 60.29 "Health Technologies" in May 2007 resolution WHA62.12 on Primary Health Care, including health Systems Strengthening the World Health Organization has already engaged in a variety of activities aimed at facilitating access to safe and effective medical devices for all. The goal is to increase service delivery, have patient-centered solutions to be able to have universal coverage by using safe, effective, appropriate and accessible medical devices.

2.1 The Global Initiative on Health Technologies

Health technologies have a critical role in the prevention, diagnosis and treatment of illness and disease. Yet, access to health technology remains a challenge particularly in developing countries.

The World Health Organization's Global Initiative for Health Technologies (GIHT) project conducted by the Department of Essential Health Technologies and funded by the Bill and Melinda Gates Foundation seeks to make available the benefits of core health technologies, including innovative technologies, at an affordable price, particularly to communities in resource-limited settings, in order to effectively control important health problems.

The GIHT has two objectives:

Objective 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;

1. Development of guidelines for the formulation of National Health Technology Programmes;
2. development of a methodology and relevant tools to help Member States to conduct an assessment of health technologies;
3. identification of national, regional and global standards for countries to identify current gaps and future needs in order to prioritize health technologies;
4. development of tools to assist countries to integrate the prioritized needs into national policies, action plans and programmes;
5. development of supporting e-tools.

Objective 2:

To challenge the business and scientific community to identify and adapt "innovative" technologies that can have a significant impact on public health.

1. Identify and collaborate with institutions and WHO Collaborating Centres;
2. identification of key global health concerns, guided by the Global Burden of Disease and the disability Adjusted Life Year;
3. outreach/call to the business and scientific community;
4. identification of the "Innovative Technologies".

The call aims at identifying and evaluating innovative medical devices, either commercialized or under development, which focus on global health concerns and that are accessible, appropriate and affordable for use in low- and middle-income countries.

The selected generic technologies were posted on the WHO web site by the 30 June 2010. In connection with the posting of the selected technologies on the web site WHO provides the possibility for interested parties to request information from the applicants who may in turn contact interested parties in a way to encourage dissemination and availability of this innovative technologies in developing countries which will help target global health concerns.

2.2 Priority Medical Devices

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, the project assessed potential barriers to innovation as well as generated a research agenda.

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, took into account of the following key items:

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

The expected outcomes of the project are as follows:

1. A generic methodology to identify "gaps" in the availability of preventive, diagnostic, therapeutic and assistive medical devices. These gaps will include medical devices that are or may be:
 - a) Currently not available;
 - b) if available, not necessarily used worldwide;
 - c) if used, not to the extent that is desirable or;
 - d) that may be inappropriate for the context in which they are used.
2. Identification of the main barriers to innovation and diffusion of medical devices and where possible, suggestion of solutions to either reduce or overcome these.
3. A proposed research agenda.
4. The promotion of medical devices as important tools for improving health care.

2.3 Urban Health Equity Assessment and Response Tool (Urban HEART)

The Urban Health Equity Assessment and Response Tool (HEART) aids decision-making to address health inequities in cities. It is based on the principles elicited by the WHO Commission on Social Determinants of Health and the World Health Report 2008 on Primary Health Care.

Urban HEART was developed as a collaborative effort between WKC and regional offices, a group of external experts (Urban HEART Advisory Group), and city/national officials from 17 cities in 10 countries. It aims to identify and analyse differences in health opportunities between people living in various parts of cities or belonging to different socioeconomic groups, and to decide on viable and effective strategies, interventions/actions that should be used to reduce inter-and intra city health inequities.

Populations are moving to cities, looking for opportunities for working and learning and better infrastructure, but the level of health services coverage is not optimal and so therefore the need for innovative, affordable, easy to use health technologies that should be available and accessible in the health care facilities in urban areas, especially in the highly populated cities in low income countries.

However ill-health is not only an issue for the poorest of the poor, according to the report of the Commission on Social Determinants of Health²: "Poor health is not confined to those worst off. In countries at all levels of income, health and illness follow a social gradient: the lower the socioeconomic position, the worse the health".

Going forward, in 2010-11, the major focus will be to document and disseminate experiences of cities that piloted Urban HEART, and scale up the use of the tool in interested cities in WHO Member States. A formal documentation of the successes, challenges and follow-up of the testing of Urban HEART will be completed and disseminated in workshops and international conferences such as the International Conference on Urban Health 2010. Further, an evaluation of the process and outcomes of the Urban HEART testing will be completed by 2011.

² Report from the Commission on Social Determinants of Health © World Health Organization 2008

Urban HEART is being scaled up in collaboration with WHO regional offices in 20-25 countries during 2010-11. Specific activities will include further training of officials and upgrading the resources available to Urban HEART sites. WKC will continue to provide technical support through WHO regional offices to cities implementing Urban HEART.

3. Next Steps for Facilitating Access to Primary Health Care in Urban and Rural settings

3.1 Establishing a coordinated research agenda program on innovative health technologies

In response to Resolution 60.29 Health Technologies and the situation outlined above, WHO started the Global Initiative on Medical Devices in 2008. Building on the success of its current activities (e.g. Call for innovative technologies that address global health concerns, health technology policies, guidance and management tools, PMD report) and to further advance its efforts along these lines, WHO proposes a coordinated research agenda covering the following areas:

- Multinational Clinical Evaluation of appropriateness and efficacy of technologies under the conditions found in resource-limited settings.
- Evaluation of possibilities for technology transfer.
- Data collection on availability, state and use of select medical devices in low- and middle-income countries.

3.1.1 Proposal

The following is a suggestion to support the establishment of a small WHO programme for coordinated research on innovative health technologies that address global health care concerns.

The coordinated research programme (CRP) could be organized (see annex III for more detail) as follows:

A network of 10-12 participating institutes will be formed for each innovative technology chosen to be evaluated for its appropriateness and efficacy under the conditions of developing countries. Institutions within the network will cooperate to reach the identified evaluations goal, and could also address individual evaluation problems under the larger evaluation theme that will be agreed on by the participants of the network.

WHO's role will be to support the network and to organize Research Coordination Meetings (RCM) two to three times during the maximum three-year lifetime of each CRP. WHO will also supervise the drafting of an overall evaluation report at the end of the programme. The proposed programme represents an effective means of bringing together researchers from developed and developing countries alike to stimulate relevant research and to provide evidence-based guidance for clinical use of innovative technologies in resource-limited settings.

3.1.2 Outcome of the Co-ordinated research agenda

The project contributes to providing access to health care delivery by providing:

- a method for evaluating innovative health technologies with respect to their suitability for the conditions in developing countries thus accelerating their successful integration in health systems;
- guidance on factors contributing to successful integration of health technologies;
- an international network for evaluation of innovative health technologies;
- pilot studies of the method on a number of technologies.

3.2 Establishing lists of medical devices for different resource levels

Medical devices as a neglected area are becoming significant economic and technical challenges to national health systems of Member States. Today, More than 8000 generic medical device groups and several thousands of registered care procedures are in use, with new innovative technologies introduced into practice everyday. In fact, technological changes in healthcare particularly medical devices have contributed dramatically to the escalation and inequality of global health expenditure.

At the same time, access to safe, effective and appropriate health technologies remains one of the most distinct differences between rich and poor countries. On one hand, countries with limited funding or donations lack critical international collaboration and practical instrumentation experiences to successfully set up facilities targeted at levelled health care targets. On the other hand, even within such limited budgets and resources, there are wasted investments in medical devices that: (1) do not meet priority needs (2) too complex to handle, (3) incompatible with the existing infrastructure and services or (4) too costly to maintain in service.

The medical device lists were designed to meet these unmet needs. It will support our MS countries' prioritized needs with evidence based lists for the purposes of budgeting, procurement, economic and architectonic structuring and inventory management. The anticipated outcome of the project will integrate elements of:

1. WHO recommended medical device nomenclature specification.
2. Clinical Practice Guidelines or care pathways related.
3. By level of care, and indicators use.
4. Cost/effectiveness information.
5. Global burden of disease and;
6. cost/pricing factors.

Device lists will be delivered based on diseases and facility levels to be better tailored to countries' public health priority and action plans.

3.3 Technology Transfer

In order to provide access to health care in low- and middle- resource settings it will be necessary to adopt new technologies in these settings.

This will entail transfer of technology both regarding user skills and knowledge necessary for selecting, using, training and maintaining medical devices.

Issues for technology transfer and uptake are being studied by the WHO as a very important area, including IP issues.