World Health Organization

Second WHO Global Forum on Medical Devices:

Priority Medical Devices for Universal Health Coverage

22–24 November 2013

Geneva, Switzerland

Designed by Rut Christiani, Rocio Nava Ruelas. And Shruti Sharma

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Acronyms and abbreviations

ACCE	American College of Clinical Engineering
AFRO	African Region
AHWP	Asian Harmonization Working Party
AMRO	Region of the Americas
BME	Biomedical Engineer(ing)
CICG	International Conference Centre Geneva
DITTA	Global Diagnostic Imaging, Healthcare IT & Radiation Therapy Trade Association
EAC	East African Community
EMRO	Eastern Mediterranean Region
EURO	European Region
GHTF	Global Harmonization Task Force
GMDN	Global Medical Device Nomenclature
GMTA	Global Medical Technology Alliance
HTA	Health Technology Assessment
HTAi	Health Technology Assessment International
HTM	Health Technology Management
IAEA	International Atomic Energy Agency
ICDRA	International Conference on Drug Regulatory Authorities
IFHE	International Federation of Hospital Engineering
IFMBE	International Federation for Medical and Biological Engineering
IMDRF	International Medical Device Regulators Forum
INAHTA	International Network of Agencies for Health Technology Assessment
INBIT	Institute of Biomedical Technology
IOMP	International Organization for Medical Physics
ISO	International Organization for Standardization
ISR	International Society of Radiology
ISRRT	International Society of Radiographers and Radiological Technologists
IUA	International Union of Architects
IUPESM	International Union for Physical and Engineering Sciences in Medicine
MDG	Millennium Development Goal
MIMS	Minimum Information Model on Patient Safety
MoH	Ministry of Health
NCD	Non-communicable disease
NGO	Nongovernmental organization
PAHO	Pan American Health Organization
REDETSA	Health Technology Assessment Network of the Americas
SEARO	South-East Asia Region
TAGHT	Technical Advisory Group on Health Technologies
UN	United Nations
UNICEF	United Nations International Children's Emergency Fund
UNFPA	United Nations Population Fund

WFUMB	World Federation for Ultrasound in Medicine and Biology
WHA	World Health Assembly
WHO	World Health Organization
WPRO	Western Pacific Region

Table of contents

List of appendices

Boxes

Figures

Tables

Executive summary

Medical devices are a core component of health systems, and thus required for achieving universal health coverage, and have been recognized as indispensable for health care provision in the World Health Assembly resolution, on health technologies (WHA60.29) in 2007. These health technologies are required in screening, prevention, diagnosis, treatment, rehabilitation and palliative care, but their safe use, rational selection, assessment, effective regulation and innovation remain a very complicated challenge in all settings, due to the enormous diversity, lack of availability, quality, safety, appropriateness and affordability, particularly in low-resource settings. Therefore, even if important awareness has been raised in the last few years, patients still lack access to priority medical devices and thus much work has to be done by health professionals, governments, academia and industry, among many others.

Following the resolution of 2007, the priority medical devices report and the success of the First WHO Global Forum on Medical Devices in Thailand in 2010, WHO became highly committed to the important work related to medical devices. New WHO tools and publications were developed and disseminated to increase awareness in the field in ministries of health, industry and academia. Several workshops and continuous capacity building in various countries and regions led to a high demand from medical device stakeholders, for a second global forum that would follow-up and expand on the topics and recommendations presented previously. Accordingly, in August 2013, WHO determined to convene a Second Global Forum on Medical Devices to take place in Geneva, Switzerland, on 22-24 November 2013.

The objectives of the Forum were to: (i) define methods of increasing access to priority medical devices under the Universal Health Coverage initiative; (ii) share evidence on best practices in health technology assessment, management and regulation of medical devices; (iii) demonstrate the development and use of appropriate and innovative technologies that respond to global health priorities; and (iv) present the outcomes of the implementation of the World Health Assembly resolution on health technologies (WHA60.29) and the status of actions resulting from the First Global Forum on Medical Devices.

Although organized in a short period of time, by the local organizing committee, the Forum resulted in an overwhelming response from the medical device community. The call for papers rendered over 400 abstracts from around the world. Furthermore, this Forum leveraged the expertise from professional organizations, academia, ministries of health, nongovernmental organizations (NGOs), and WHO collaborating centres in order to create a vast programme that included 36 workshops, 25 parallel session presentations, 4 plenary sessions, 116 posters, and 11 films. Although around 700 people registered, the Forum included a total of 572 participants from 103 countries, who participated actively by presenting posters and films, holding round tables, proposing 263 actions to advance in all topics, evaluating the sessions and sharing their expertise. The general feedback was positive; around 90% would like to participate in future events, although most requested more time for presentations and discussions.

The recommendations included: (i) stakeholders to work together to develop affordable appropriate innovative health technologies; (ii) increased use of health technology assessment to make better decisions; (iii) the urgent need to establish better regulatory processes for medical devices; (iv) the need for transparent procurement and technical specifications development; (v) more awareness of aspects on patient safety health technology management among policy decision-makers and at the health facility level, and prioritization of medical devices under the Universal Health Coverage initiative; and (vi) the need to have biomedical engineers responsible for medical devices.
The feedback was generally positive and will help WHO better plan for follow up actions.

This report provides the context in which this Forum was conceived, including activities and publications developed, the status of the actions implemented after the First Forum, the content of the technical program, including abstracts, the proposed actions that WHO and stakeholders will move forward with and the evaluations of the sessions. The results of these proposed actions will be presented at the Third WHO Global Forum on Medical Devices in 2016.

Consequently, in order to implement universal health coverage, and to advance the well-being of the population, appropriate, quality, affordable health technologies need to be available and are thus the responsibility for the health-care community, industry, academia, and policy-makers.

Acknowledgements

The Second WHO Global Forum on Medical Devices demonstrated the commitment of WHO towards improved access to safe, effective and innovative, quality medical devices as a contribution to universal health coverage. This area of work is carried out under the leadership and guidance of: Marie-Paule Kieny, Assistant Director General of the Health Systems and Innovation Cluster; Kees de Joncheere, Director of the Department of Essential Medicines and Health Products; and Gilles Forte, Coordinator of the Policy, Access and Use Unit.

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- The Ministry of Health, Labour and Welfare, Japan, under the WHO project "Towards knowing global needs for medical device"
- The Ministry of Health, Welfare and Sport, the Netherlands, under the WHO project "Follow up to the Priority Medical Devices report"
- The European Commission, under the WHO project " Local production and technology transfer of medical devices, phase two"
- The WHO Health Systems and Innovation cluster under, "Towards mapping of Health Technology Assessment in WHO and globally".
- The Government of Switzerland for providing the International Conference Centre Geneva (CICG), which hosted the Second Global Forum on medical devices.

A special thank you is extended to the Local Organizing Committee, and whose dedication, expertise and invaluable support made the Second WHO Global Forum on Medical Devices a reality:

Local organizing committee (August-November 2013)

General coordination: Adriana Velazquez Berumen

Administrative support:

Karina Reyes Moya (WHO headquarters, Geneva);

Nicole Kruger and Meriem Medbed (WHO Global Conference and Training Centre, in Tunis);

Richard Preston and Reja Sarkis (General Management, Geneva)

Technical programme:

Abstracts: James Abbas (volunteer PhD sabbatical); abstracts support: Panita Looareesuwan, Peng Si and Susanna Chen (WHO interns Medical Devices Unit)

Agenda, programme and datacol registry: Jennifer Barragan (technical officer, WHO)

Country data: Ricardo Martinez Martinez (technical officer, WHO)

Exhibition and films: Keiko Fukuta (WHO intern in Medical Devices Unit)

Posters: Laura Alejandra Velez Ruiz Gaitan (volunteer, biomedical engineer)

Radiology: Miriam Mikhail (technical officer, WHO)

Registration and data management: Olumurejiwa Fatunde (WHO intern, Medical Devices Unit)

Workshops: Yukiko Nakatani, (technical officer, WHO)

Venue Support by WHO interns from other units:

Theresa Sophia Burkard
Frederik Hagelstein
Akiko Kitamura
Suruchi Kumar
Belen Valladares Vaquero

International Conference Centre Geneva: Mr Luca Pellandini.

Programme Committee Members:

Sincere appreciation for their hard work and support is also extended to the Programme Committee members listed in Box 1, who reviewed over 400 abstracts in less than five weeks.

Box 1. Programme committee members

James Abbas	Wilma Doedens	Jan Labuscagne	Mercedes Perez Gonzalez
Adham Ismail Abdel Moneim	Tony Easty	Paolo Lago	Mladen Poluta
Nicolas Adjabu	Olumurejiwa Fatunde	Alexandre Lemgruber	Shamim Ahmad Qazi
Saleh Al Tayyar	Michael Flood	Richard Lilford	Madan Rehani
Helena Ardura-Garcia	Keiko Fukuta	Robert Malkin	Christopher Rerat
Roberto Ayala Perdomo	Andrew Gammie	Ricardo Martinez Martinez	Rebecca Richards-Kortum
Wendy Babidge	Michael Gropp	Paul Merlevede	Amir Sabet Sarvestani
Hanne Bak Pedersen	Iñaki Gutierrez-Ibarluzea	Robyn Meurant	Chris Sargent
Jennifer Barragan	Antonio Hernandez	Mulugeta Mideksa	Jitendra Kumar Sharma
Ronald Bauer	Fred Hosea	Debjani Mueller	Peng Si
Cathy Blanc Gonnet	Pablo Jimenez	Yukiko Nakatani	Kathleen Sienko
Aya Caldwell	Tom Judd	Tomomichi Nakazaki	Slavik Tabokov
Saide Calil	Linga Kalinde Mangachi	Jean-Bosco Ndihokubwayo	Lisa Thomas
Mario Castañeda	Godfrey Katabaro	Dieter Nürnberg	Willy Urassa
Kin Yin Cheung	Brendon Kearney	Marc Nyssen	Adriana Velazquez Berumen
Agnes Chidanyika	Selma Khamassi	Kristian Olson	Alejandra Velez Ruiz Gaitan
Tobey Clark	Niranjan Khambete	Maurice Page	Herbert Voigt
Yadin David	Chapal Khasnabis	Shanti Pal	Sam Wanda
Neelam Dhingra-Kumar	Marianne Klemp	Nicolas Pallikarakis	Susan Wilburn
Karin Diaconu	Ramesh Krishnamurthy	Maria del Rosario Perez	Habib Zaidi

Collaborating organizations

WHO acknowledges the following collaborating organizations that co-organized workshops and parallel sessions (Figure 1).

Figure 1. Collaborating organizations

Global Forum Report

WHO acknowledges the support received from the following individuals in the development and editing of this report.

WHO staff:

James Abbas, Jennifer Barragan and Adriana Velazquez Berumen.

WHO Interns:

For 2013, Olumureji Fatunde, Keiko Fukuta and Panita Looareesuwan.

For 2014, editing and lay out: Rut Christiani, Mohammed Gad, Rocio Nava and Shruti Sharma.

Introduction

Medical devices are critical to the delivery of quality health care, but often even the most essential medical devices are not available. The adoption of the first resolution on health technologies in May 2007 by the World Health Assembly (WHA 60.29) set the framework for an unprecedented focus on health technologies.

In order to bring together all key stakeholders, WHO convened the First WHO Global Forum on Medical Devices in Bangkok, Thailand, on 9－11 September 2010, with 307 participants from 106 Member States. The Forum was conceived as a place to exchange information, network and learn about the ongoing work in the area of regulations, innovations, management and use of medical devices.

After the momentum created by this first Forum WHO continued to work on initiatives to increase access to affordable and appropriate medical devices, as mandated by WHO priorities. These initiatives led to developing publications, workshops and seminars and expanding the efforts to various regions. Due to the request from the First Forum participants as well as other stakeholders, despite limited funding and a very small team, WHO decided to convene and invite all interested parties to co-organize the Second WHO Global Forum on Medical Devices, in Geneva, on 22－24 November 2013. This Forum was meant to serve as a venue in which to share the experiences and best practices that the countries, regions, governments, academia, innovators, and regulators worldwide had developed over the intervening three years. The Forum addressed an even wider range of issues in an effort to increase access to medical devices in support of universal health coverage.

The Forum was planned in an extremely short timeframe having been approved in August 2013, a mere three months prior to the event. Although the call for papers went out in September, it was extended due to an overwhelming response and the review and selection of papers occurred in October. The amount of interest was particularly high from low-income countries. Participants included high-level policy-makers from Member States, nongovernmental organizations (NGO's), health professionals, researchers, academic institutions, professional organizations, biomedical engineering institutions, umbrella organizations in the medical devices industry, and UN organizations.

A total of 572 people from 103 countries attended Forum presentations and participated in discussions on current practices and recent advances in medical device assessment, management, and regulation. The Forum also included discussions on new ideas in human resource development and disseminated information about innovative, appropriate, and affordable devices for low-resource settings in accordance with the WHA 60.29 resolution.

Second WHO Global Forum on Medical Devices: context

Resolutions of the World Health Assembly

The World Health Assembly is the supreme decision-making body for WHO. It generally meets in Geneva in May of each year, and is attended by delegations from all 194 Member States. Its main function is to determine the policies of WHO. There have been specific resolutions that have been approved by the World Health Assembly that give direction on advancements and priorities as dictated by Member States.

Below is the list of the latest resolutions related to medical devices, which supports improving access to safe, effective, and high quality medical devices. The resolutions were passed unanimously by the 194 Member States.

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

Box 2. Resolution WHA60.29 action points for Member States and the WHO Secretariat *(1)*

URGES Member States:

(1) to collect, verify, update and exchange information on health technologies in particular medical devices as an aid to their prioritization of needs and allocation of resources;

(2) to formulate as appropriate national strategies and plans for the establishment of systems for the assessment, planning, procurement and management of health technologies in particular medical devices, in collaboration with personnel involved in health-technology assessment and biomedical engineering;

(3) to draw up national or regional guidelines for good manufacturing and regulatory practices, to establish surveillance systems and other measures to ensure the quality, safety and efficacy of medical devices and where appropriate participate in international harmonization;

(4) to establish where necessary regional and national institutions of health technology, and to collaborate and build partnerships with health-care providers, industry, patients' associations and professional, scientific and technical organizations;

(5) to collect information that interrelates medical devices, which deal with priority public health conditions at different levels of care and in various settings and environments, with the required infrastructure, procedures and reference tools;

Box 2. Resolution WHA60.29 action points for Member States and the WHO Secretariat (cont'd)

REQUESTS the Director-General:

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

(2) to provide support to Member States where necessary in establishing mechanisms to assess national needs for health technologies in particular medical devices and to assure their availability and use;

(3) to develop methodological tools to support Member States in analysing their health technologies in particular medical devices needs and health-system prerequisites;

(4) to provide technical guidance and support to Member States where necessary in implementing policies on health technologies, in particular medical devices especially for priority diseases, according to different levels of care in developing countries;

(5) to work jointly with other organizations of the United Nations system, international organizations, academic institutions and professional bodies in order to provide support to Member States in the prioritization, selection and use of health technologies in particular medical devices;

(6) to establish and update regularly an evidence and web-based health technologies database to serve as a clearing house which will provide guidance on appropriate medical devices according to levels of care, setting, environment, and intended health intervention, tailored to the specific needs of country or region;

(7) to provide support to Member States with vulnerable health-care systems so as to identify and put in place appropriate health technologies in particular medical devices that facilitate access to quality services in primary health care;

(8) to report on implementation of this resolution to the Executive Board and the Sixty-second World Health Assembly through the Executive Board.

In addition the following resolutions relevant to health technologies on universal health coverage were made at the United Nations World Health Assembly on Universal Health Coverage:

1) ***Resolution A/RES/67/81 (2) and A/67/l.36.*** Adopted by the United Nations General Assembly in December 2012, this resolution emphasized "the importance of universal coverage in national health systems" and called "for strengthening collaboration among Member States, in particular through the World Health Organization, through technical assistance and sharing of best practices as well as working with partners, including civil society, to promote effective implementation of universal health coverage on the basis of solidarity at the national and international level. This resolution, urges governments to move towards providing all people with access to affordable and high quality health-care services. It recognizes the role of health in achieving international development goals and calls for countries, civil society and international organizations to include universal health coverage in the international development agenda. The resolution reaffirms leading role of WHO in supporting countries to respond to the challenges of implementing universal health coverage.

1) ***Resolution WHA58.28 (3)*** Adopted by the World Health Assembly in May 2005, this resolution on eHealth acknowledged: "eHealth is the cost-effective and secure use of information and communications technologies in support of health and health-related fields, including health-care services, health surveillance, health literature and health education, knowledge and research," and urged Member States to develop and implement eHealth technologies.

2) ***Resolutions WHA60.30 (4)*** and ***WHA61.21 (5)*** Adopted by the World Health Assembly in May 2007, WHA60.30 requests the WHO Secretariat to prepare background documents and support the Intergovernmental Working Group on Public Health, Innovation, and Intellectual Property for the purpose of developing a plan of action. Resolution WHA61.21 (adopted in May 2008), establishes a global strategy and plan of action that consists of eight elements designed to promote innovation, build capacity, improve access and mobilize resources.

3) ***Resolution WHA62.12 (6)*** Adopted by the World Health Assembly in May 2009, this resolution on primary health care, including health systems strengthening, urges Member States "to improve access to appropriate medicines, health products and technologies, all of which are required to support primary health care".

4) ***Resolution WHA66.7 (7)*** Adopted by the World Health Assembly in May 2013, the resolution on implementing the recommendations of the United Nations Commission on Life Saving Commodities for Women and Children explicitly states "six million lives can be saved within five years by improving access to 13 specific, overlooked commodities and related products". The recommendations urge Member States to put into practice steps that will facilitate universal access to the commodities and improve regulatory efficiency. The commodities include medical devices used in newborn resuscitation, technologies for injectable antibiotics as well as female condoms used for family planning.

The following two resolutions, were approved at the Sixty-seventh World Health Assembly in May 2014 and have a direct impact on the work plan of medical devices both at WHO and for Member States:

1) ***Resolution WHA67.20*** on regulatory systems strengthening to promote access to affordable medical products with assured quality, safety and efficacy. This resolution request WHO to prioritize support for establishing and strengthening regional and subregional networks of regulatory authorities, as appropriate, including strengthening areas of regulation of health products that are the least developed, such as regulation of medical devices, including diagnostics; and to support the building-up of effective national and regional regulatory bodies and networks (see Annex 11, resolution WHA67.20).

2) ***Resolution WHA67.23*** on health intervention and technology assessment in support of universal health coverage. This resolution emphasizes that rigorous and structured research methodology and transparent and inclusive processes, assessment of medicines, vaccines, medical devices and equipment, and health procedures, including preventive intervention, could help to address the demand for reliable information on the safety, efficacy, quality, appropriateness, cost-effectiveness and efficiency dimensions of such technologies to determine if and when they are integrated into particular health interventions and systems. It also urges Member States to strengthen the link between health technology assessment, regulation and management, as appropriate, and requests WHO to assess the state of health technology assessment and support Member States, especially low-income countries and support the exchange of information (see Annex 12, resolution WHA67.23).

It is important that these resolutions are known to policy-makers, which will help advance the innovation, rational selection and assessment, management and safe use of medical devices in the health-care delivery within the Universal Health Coverage Initiative, in order to increase the well-being of the population.

Medical devices in WHO, overview 2010 - 2013

Following the discussion of the First Global Forum, WHO has continued to increase accessibility, affordability, and availability of medical devices through publications, workshops and consultation meetings.

MEDICAL DEVICES PUBLICATIONS

The following publications have been developed and disseminated between 2010 and 2013:

1. As part of the WHO Medical Devices Technical Series, in English, French and Spanish:
    - Development of medical devices policies,
    - Health technology assessment for medical devices
    - In the management of medical devices, the following overview documents:
        - ⇒ Needs assessment
        - ⇒ Procurement process resource guide
        - ⇒ Donations, considerations for solicitation and provision
        - ⇒ Introduction to medical equipment inventory management
        - ⇒ Medical equipment maintenance programme overview
        - ⇒ Computerized maintenance management system
2. In the area of diagnostic imaging:
    - Two manuals of diagnostic ultrasound, in two volumes
3. Related to innovative technologies, a call for innovative technologies led to the first publication on "Innovative technologies that address global health concerns". After this call in 2010, yearly calls have followed, and a process to evaluate the technologies developed by WHO with the support of assessment agencies, and evaluators in collaborating centres, has resulted in a yearly compendium of these health technologies, including assistive devices, ehealth, medical devices and other health technologies, which include the following publications:
    - Landscape analysis of barriers to developing or adapting technologies for global health purposes, 2010
    - Innovative technologies that address global health concerns, 2011
    - Compendium of new and emerging health technologies, 2012
    - Compendium of innovative health technologies for low-resource settings, 2013

    To analyze if local production can increase access of specific technologies, a study was made in 2012:
    - Local production and technology transfer to increase access to medical devices, 2012
4. Addressing the issues on core and priority medical devices, two important publications that contain more than 100 medical equipment characteristics:
    - Core medical equipment,
    - Interagency list of medical devices for essential interventions in reproductive, maternal, new born and child care (*in review, 2014*)
5. Finally, and most importantly, the country profile information has been posted on the WHO website since 2010, which publishes the Member States data collected via the Baseline Country Survey on Medical Devices. It was initiated to be able to find the availability and gaps in policies, procurement guidelines, donations procedures, maintenance and technical specifications and to define health technologies focal points in all Member States. This has been an ongoing project since 2010, with yearly updates. The information published here is available in the Global Health Observatory and the World Health Statistics which is a yearly WHO publication.

All the publications can be accessed following the link in Table 1.

	Cover Image	Title	Year	Language	Website	Bookstore Availability
GENERAL INFORMATION		Baseline Country Survey on Medical Devices	2011	English	Online Link	No
		First WHO Global Forum on Medical Devices: context, outcomes and future actions	2011	English	Online Link	No
		Medical Devices: Managing the Mismatch	2010	English	Online Link	Bookstore
		Dispositifs Médicaux: Ciment résoude l'inadéquation ?		French	Online Link	Bookstore
		Dispositivos Médicos: La gestión de la Discordancia		Spanish	Online Link	Bookstore
		УСТРОЙСТВА МЕДИЦИНСКОГО НАЗНАЧЕНИЯ: УСТРАНЕНИЕ НЕСООТВЕТСТВИЙ		Russian	Online Link	Bookstore
INNOVATION		Local Production and Technology Transfer to Increase Access to Medical Devices	2012	English	Online Link	No

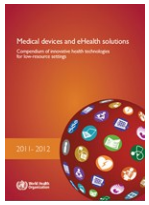
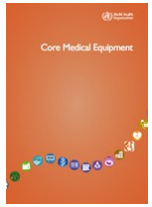
	Cover Image	Title	Year	Language	Website	Bookstore Availability
INNOVATION		Compendium of Innovative Health Technologies for Low-resource Settings	2012	English	Online Link	No
		Compendium of New and Emerging Health Technologies	2011	English	Online Link	No
		Innovative technologies that address Global Health Concerns	2010	English	Online Link	No
POLICY		Development of Medical Policies	2011	English	Online Link	Bookstore
		Dévelopment de politiques relatives aux depositifs médicaux		French	Online Link	Bookstore
		Formulación de políticas sobre dispositivos médicos		Spanish	Online Link	Bookstore
ASSESMENT		Health technology assessment of medical devices	2011	English	Online Link	Bookstore
		Évaluation des technologies de la santé : dispositifs médicaux		French	Online Link	Bookstore
		Evaluación de tecnologías sanitarias aplicada a los dispositivos médicos		Spanish	Online Link	Bookstore

Table 1. WHO publication list of medical devices

	Cover Image	Title	Year	Language	Website	Bookstore Availability
MANAGEMENT		Core Medical Equipment	2011	English	Online Link	No
		Need assessment for medical devices	2011	English	Online Link	Bookstore
		Evaluation des besoins en dispositifs médicaux		French	Online Link	Bookstore
		Evaluación de las necesidades de dispositivos médicos		Spanish	Online Link	Bookstore
		Procurement process resource guide	2011	English	Online Link	Bookstore
		Processus d'acquisition : guide pratique		French	Online Link	Bookstore
		Guía de recursos para el proceso de adquisición		Spanish	Online Link	Bookstore
		Medical device donations: consideration for solicitation and provision	2011	English	Online Link	Bookstore
		Dons de dispositifs médicaux :considérations relatives à leur demande et à leur attribution		French	Online Link	Bookstore
		Donaciones de dispositivos médicos: consideraciones relativas a su solicitud y suministro		Spanish	Online Link	Bookstore

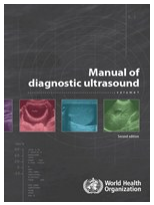
	Cover Image	Title	Year	Language	Website	Bookstore Availability
MANAGEMENT		Introduction to medical equipment inventory management		English	Online Link	Bookstore
		Introduction à la gestion du parc des équipements médicaux		French	Online Link	Bookstore
		Introducción a la gestión de inventarios de equipo médico		Spanish	Online Link	Bookstore
		Medical equipment maintenance programme overview	2011	English	Online Link	Bookstore
		Programme de maintenance des équipements médicaux : présentation générale		French	Online Link	Bookstore
		Introducción al programa de mantenimiento de equipos médicos		Spanish	Online Link	Bookstore
		Computerized maintenence management system	2011	English	Online Link	Bookstore
		Système de gestion de maintenance assistée par ordinateur		French	Online Link	Bookstore
		Sistema computarizado de gestión del mantenimiento		Spanish	Online Link	Bookstore
ULTRASOUND		Manual of diagnostic ultrasound: Volume 2, Second edition	2013	English	Online Link	Bookstore
		Manual of diagnostic ultrasound: Volume 1, Second edition	2011	English	Online Link	Bookstore

Table 1. WHO publication list of medical devices (cont'd)

WORKSHOPS

In three years, from 2010 to 2013, more than 10 regional or country workshops took place using all the guidelines produced and coordinated or organized by the regional WHO office or requested by the Member States. Some examples are country workshops in Egypt, Moldova, Sudan and United Republic of Tanzania.
Workshops, seminars and conferences and initiatives specifically on regulations of medical devices have been supported, by networks, for example:

- Participation in the yearly conferences of the Asian Harmonization Working Party (AHWP) (www.ahwp.info).
- WHO as an observer in the International Medical Devices Regulators Forum (IMDRF), which now has more than five task groups, producing documents that could lead to the convergence of medical device regulation.
- Participating in the International Conference on Drug Regulatory Authorities (ICDRA), which is a WHO event co-organized with Member States. For the first time, sessions on medical devices were initiated in 2012 and are foreseen to continue.

Workshops on health technology assessment, have taken place both in the large health technology assessment conferences organized by Health Technology Assessment international (HTAi) and the International Network of Agencies of Health Technology Assessment (INAHTA) as regional meetings, for example, the Tunisia meeting of all eastern Mediterranean countries in November 2013 organized by the WHO Regional Office, for the Eastern Mediterranean and the Republic of Korea roundtable with HTA leaders organized by the Western Pacific Region in June 2013.

It should be noted that regional offices, along with the regional advisers, have organized conferences, workshops, meetings, webinars and other capacity-building training sessions on subjects related to medical devices and health technologies, in an effort to raise awareness, train users, share expertise or develop networks. One example is REDETSA, a regional network for health technology assessment coordinated by the WHO Regional Office for the Americas and the Pan American Health Organization (PAHO).

GLOBAL COLLABORATION

Relations with non-state actors
In order to support the work that needs to be done in WHO and to reach Member States, more WHO collaborating centres have been designated during this period from 2010 to 2013 and specific memoranda of understanding has been signed with professional organizations or networks, for example with:

- International Organization of Medical Physics (IOMP)
- HTAi
- EUROSCAN
- INAHTA

As a result, the collaboration with NGOs in official relationships with WHO has been strengthened. Consequently, the following professional organizations are supporting WHO and working with Member States:

- International Society of Radiology (ISR)
- International Society of Radiographers and Technicians (ISRRT)

- International Federation of Hospital Engineers (IFHE)
- International Union of Architects (IUA)
- World Federation of Ultrasound for Medicine and Biology (WFUMB)

Although WHO has already provided guidance to Member States to increase access to safe, quality, affordable, appropriate medical devices, much remains to be done by governments, international organizations, academia and the medical device industry. The Second Global forum offered an opportunity for leaders in healthcare to convene and collaborate on these important issues.

Box 3. Links to the organizations and global collaboration

- Asian Harmonization Working Party: www.ahwp.info
- International Medical Devices Regulators Forum: www.imdrf.org
- International Conference on Drug Regulatory Authorities: www.icdra.com.br
- HTAi: www.htai.org
- INAHTA: www.inahta.org
- IOMP: www.iomp.org
- EUROSCAN: www.euroscan.org.uk
- ISR: www.isradiology.org/isr/indeh.php
- ISSRT: www.isrrt.org/issrt/default.asp
- IFHE: www.ifhe.info
- IUA: www.uia.archi/en
- WFUMB: www.wfumb.org

Universal health coverage

In the 2010 World Health Report, WHO proposed universal health coverage as a means to provide quality health services without financial hardship. It defined the three dimensions of universal health coverage as: costs; population covered; and package of interventions (Figure 2). Because medical devices play a significant role in each of these three dimensions, the organizers of the Second Global Forum on Medical Devices chose to focus on Priority Medical Devices for Universal Health Coverage as the overarching theme of the Forum.

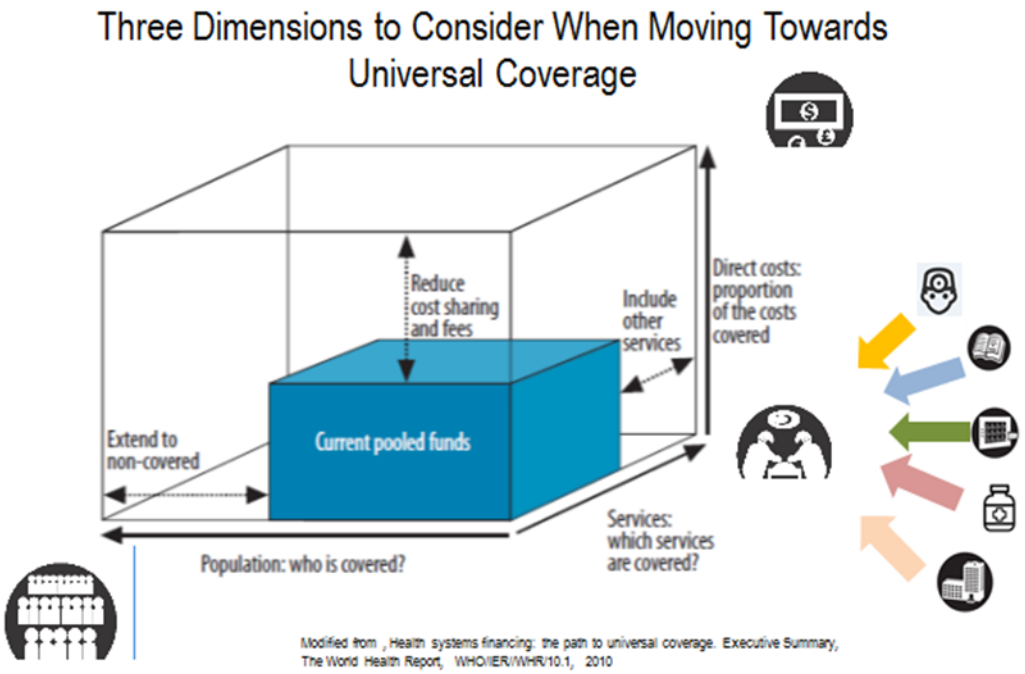


Figure 2. The three dimensions of universal health coverage *(8)*

The programme of the Forum included topics on innovation, regulation, assessment, management and safe use of medical devices as these are issues related to the use of these devices in the health-care delivery services. Discussions were held on the type of medical equipment that should be essential and affordable for procurement or reimbursement and that could address the priority needs of the target population.

The Forum discussed medical devices and their selection, procurement and use to achieve universal health coverage. Many of the sessions discussed innovations in medical devices that could make the technology more effective, more widely available and more affordable. Technical innovation that is occurring across the globe will undoubtedly help to improve medical care for many of the world's people, but profound advances may also be derived from efforts to better integrate technology into health systems. The sessions covered important topics such as: (i) the workforce, specifically the role of biomedical engineers in training to better develop, regulate, select, utilize and maintain medical devices; (ii) information gathering to better determine the impact of medical devices in the health system; (iii) technology management to improve service delivery; (iv) improved methods for medical equipment procurement and financing; and (v) improved leadership and governance, better regulation of medical devices to ensure the safety of patients and health workers and finally the need for appropriate technologies to the different economic and social settings.

In the inauguration address, WHO Director-General, Dr Margaret Chan, raised this need for a comprehensive approach (Appendix 1). She emphasized the need for innovation that makes medical devices more affordable: “The move towards frugal innovation is especially welcome. It reflects a relentless drive, especially by manufacturers in emerging economies, to simplify devices and get the prices down - yet with no compromise of quality, safety or efficacy”. However, she also explained “improving access is an enormous undertaking with a broad scope and great complexity. The scope of issues that need to be addressed… covers economic as well as technical challenges and the need for support from national policies and regulatory control, as well as, evidence”.

In the context of universal health coverage, decisions will have to be taken to select the packages of interventions, the cost of these technologies and the quality of services to be delivered. Therefore, it is of utmost importance to select the specific medical devices required for the continuum of care and to respond to the needs of the population. The use of the medical devices should allow for cost-effective interventions from diagnostics to treatment and palliative care, to allow the best health services and finally the best health outcomes.

The First WHO Global Forum towards the Second Global Forum on Medical Devices

The role of medical devices and its rational selection and use are yet unknown to many policy makers, academicians and health care managers. Therefore the challenges are enormous and there is an extensive agenda that needs to be addressed by all interested parties.

Since the health technologies resolution was approved in the World Health Assembly in 2007, the main activities have included the development of the Priority Medical Devices report, with support from the Government of the Netherlands and the Global Initiative on Health Technologies, funded by the Bill and Melinda Gates Foundation. Both projects were presented at the First WHO Global Forum on Medical Devices *(9)*, which was held in Bangkok, in September 2010, hosting 307 people from 106 Member States who participated and contributed their views on a diverse set of topics.

This event facilitated the exchange of ideas among representatives from Member States and helped to strengthen networks among industry, academia, and government officials.

The primary outcome of the First Global Forum was a list of recommended priority actions. In each session of the Forum, participants were encouraged to submit their recommendations that would help to increase access to quality medical devices. At the end of each session, two rounds of voting were used to produce a prioritized list of recommendations related to the topic of that session. The full set of recommendations and the results of the voting procedures are presented in Appendix H and Appendix I of the report of First WHO Global Forum on Medical Devices *(9)*.

For each of the 15 priority recommendations agreed upon by Global Forum participants, short- and long-term actions were developed through discussions with the WHO Medical Devices Unit and the six WHO regional advisers on health technology. These action items, along with the steps WHO took to implement the recommendations in the years following the First WHO Global Forum on Medical Devices, are listed in Table 2.

No.	Recommendation	Proposed Short-Term Action (2011)	Proposed Long-Term Action (after June 2011)
The role of medical devices to improve health service delivery			
1	Promote culture of safety in developing countries by adverse event reporting, and integrate patient safety concepts into the curriculum of medical professionals.	- WHO medical devices unit to link with patient safety related units within WHO. - WHO to disseminate WHO Patient Safety Curriculum Guide for Medical Schools.	- WHO to work with internal and external partners to improve post-market surveillance, adverse event reporting and technology-related patient safety issues.
2	Highlight and share examples of appropriate technologies (locally produced, low prices, easy to use, durable and reliable) that succeeded in different national health care settings.	- WHO to make available on website a list of examples of appropriate/innovative technologies along with links to other relevant organizations.	- WHO to map the WHO list of innovative technologies to the research agenda of the Priority Medical Devices project. - Collaborating centers to test the "appropriateness" of innovative technologies by region and create a database of the results.
3	Use the infrastructure of teaching units and the guidelines already present for training of trainers and technicians on medical technologies.	- WHO to post a database of biomedical engineering related university programs and professional societies on WHO website.	- WHO to send information, recommendations and guidelines to all universities included in the database.
Safe, accessible and affordable medical devices			
4	Ensure that properly trained personnel are in place at the time of installation of radiation medicine technology.	- WHO medical devices unit to work with the radiation safety unit at WHO, International Atomic Energy Agency (IAEA) and professional organizations, such as the International Organization for Medical Physics (IOMP) to disseminate radiation guidelines.	- WHO to work with IAEA and other organizations on medical imaging and radiation capacity building, including the safe use and installation of medical radiation technologies.
5	Plan carefully at the government level for any new installation including consideration of proper infrastructure for effective use of the technology and investment in staff training.	- WHO to develop a needs assessment tool.	- WHO to facilitate the implementation of the needs assessment process (thereby enabling better planning) at the country level.
6	Look at international recommendations to establish proper sharp waste management.	- WHO to disseminate tools and guidelines on sharps waste management via health technology focal points in member states, industry, patient organizations and academia.	- WHO to assist countries in developing and implementing strategies on sound health-care waste management.
Health technology assessment (HTA)			
7	WHO: Support developing countries to develop capacity, learning from countries with developed health technology assessment systems and considering different models.	- WHO to develop health technology assessment tool. - WHO to provide information regarding HTA on their website with links to collaborating centres and other institutions with which WHO shares a MoU in order to support access to information.	- WHO to support the development of HTA units at the Ministry of Health through the exchange of information and best practices from existing health technology agencies. - WHO to coordinate workshops on how to develop HTA such that HTA is included as a tool for decision making.
8	WHO: Promote health technology assessment as an integral part of health system research and strengthening, and assist developing countries in conducting health technology assessment.		
9	WHO: Help Member States to identify tools for prioritizing devices by using the health technology assessment process.	- WHO to disseminate the use of existing tool kits that will assist newly formed HTA agencies/units in conducting a health technology assessment .	- WHO to coordinate workshops that will enable newly formed HTA agencies/units to develop recommendations and establish priorities.

Table 2. First WHO Global Forum on Medical Devices: recommendations, planned actions, accomplishments

Health technology management			
10	WHO: Support free access to nomenclature systems.	- WHO to develop the ideal characteristics of a nomenclature system to share with key stakeholders in order to define a single medical devices nomenclature system.	- WHO to work with external organizations and come to a consensus on selecting or creating a single WHO nomenclature system.
11	WHO: Urge industry to tag medical devices with a nomenclature reference.	- WHO to compare the information available on unique identification numbers.	- WHO to work with all stakeholders, including industry to select the best method to tag medical devices.
12	WHO: Develop tools for needs assessment incorporating multiple dimensions (e.g. human resources, epidemiology, etc).	- WHO to develop a needs assessment tool.	- WHO to facilitate the implementation of the needs assessment process (thereby enabling better planning) at the country level.
Health technology regulation			
13	WHO: Facilitate opportunities for capacity building based on cooperation between regulatory authorities.	- WHO to update the regulations guideline in 2011. - WHO to develop a network for regulatory authorities.	- WHO to update information relating to regulation on the WHO website. - WHO to promote collaboration between regulators. - WHO to coordinate regional workshops on the topic of regulation.
14	Promote an exchange system for information on regulatory action.		
15	WHO: Facilitate capacity building for post-market surveillance and adverse event reporting in low-income countries.	- WHO to review existing adverse event reporting and post-market surveillance systems for the eventual selection of one system. - WHO to make available links to adverse event reporting and post market surveillance information as well as regulatory action taken on their website.	- WHO to provide guidelines, tools and capacity building for adverse event reporting and post-market surveillance. - WHO to select one system for adverse event reporting and post-market surveillance

Table 2. First WHO Global Forum on Medical Devices: recommendations, planned actions, accomplishments (cont'd)

Second WHO Global Forum on Medical Devices: content

The Second WHO Global Forum on Medical Devices, "Priority Devices for Universal Health Coverage", was convened on 22－24 November 2013 in Geneva at the CICG.

Taking into consideration the needs and challenges in the medical devices sector worldwide and WHO strategic objectives, resolutions and recent publications, WHO proposed the topics and the following objectives for the Second WHO Global Forum on Medical Devices (Box 4).

Box 4. Objectives of the Second WHO Global Forum on Medical Devices

- To define methods of increasing access to priority medical devices under the Universal Health Coverage initiative.
- To share evidence on best practices in health technology assessment, management and regulation of medical devices.
- To demonstrate the development and use of appropriate and innovative technologies that respond to global health priorities.
- To present the outcomes of the implementation of the World Health Assembly resolution on health technologies (WHA60.29) and the status of actions resulting from the First Global Forum on Medical Devices.

Programme overview

In August 2013, the Local Organizing Committee issued a call for abstracts with a tentative agenda and list of possible topics. An outstanding response from the community resulted in 407 abstracts submitted to the 80 members of the Programme Committee in less than five weeks

From this pool of abstracts, the Committee developed a programme that included 4 plenary presentations, 156 oral presentations in parallel sessions, 116 posters, 11 films, and 37 workshops. Thus, the content of the programme was largely formed by submissions from the medical devices community and reflects its priorities, activities and needs.

The Forum began with pre-conference workshops and continued over the subsequent two days with plenary and parallel sessions. Each of the main days of the conference consisted of an opening and closing plenary and five sessions conducted in parallel both in the morning and in the afternoon. Over the course of these three days, the active involvement of the participants was essential to addressing the objectives of the Forum. An overview of the programme is provided below in Figure 3.

Friday 22 November 2013		
09:00-18:00	**Workshop Tracks**	
	WHO/UN Tools to Improve Healthcare Delivery	
	Health Technology Assessment	
	Nomenclature, Standards and Regulations	
	Health Tech Management and Clinical Engineering	
	Medical Imaging and Radiation Safety / Biomedical Engineering	
	Innovation	
	Reproductive, Maternal, Newborn and Child Health / Approaches to Improving Healthcare Delivery	
Saturday 23 November 2013		
09:00-10:00	**Plenary Session 1**	
	"Medical devices for Universal Health Coverage"	
10:30-12:00	**Parallel Sessions**	
	Health Technology Assessment: Networks and Societies around the Globe	** Spanish translation available **
	Health Technology Management: Country Initiatives	
	Regulation of Medical Devices	
	Innovation in Medical Devices	
	Health Care Delivery / Health Care Infrastructure	** French translation available **
12:00-13:00	**Lunch**	
13:00-14:00	**Poster Session 1**	
14:00-15:30	**Parallel Sessions**	
	How to Prioritize Medical Devices	
	Health Technology Management: Country Initiatives	** French translation available **
	Regulation of Medical Devices: Country Initiatives	** Spanish translation available **
	Innovation in Medical Devices for Maternal and Child Health	
	Medical Imaging	
16:00-17:00	**Plenary Session 2**	
	"The unifinished agenda: medical devices are indispensable for reaching the MDG targets"	
17:00-19:00	Film viewing	Social networking / poster viewing
Sunday 24 November 2013		
09:00-10:00	**Plenary Session 3**	
	"Medical devices for the Non-Communicable Diseases (NCD) agenda"	
10:30-12:00	**Parallel Sessions**	
	Health Technology Assessment	
	Policies for Medical Devices / Technical Specifications	
	Safety of Medical Devices	** Spanish translation available **
	Innovative Medical Devices for Low-Resource Settings	
	Human Resources in BME	** French translation available **
12:00-13:00	**Lunch**	
13:00-14:00	**Poster Session 2**	
14:00-15:30	**Parallel Sessions**	
	Local Production in Low-Resource Settings	
	Procurement of Medical Devices	** French translation available **
	Patient safety / Medical Software	
	Innovative Medical Devices for Low-Resource Settings	** Spanish translation available **
	Human Resources for Technology Life Cycle Management / Human Resources in Medical Physics	
16:00-16:45	**Plenary Session 4**	
	"Policies, innovation, regulation, assessment, management and safe use of medical devices for increasing access"	
16:45-17:00	**Closing Session**	
	Summary of recommendations from parallel sessions and closure of Forum	
17:00	**Adjourn**	

Figure 3. Programme overview

The full programme is provided in Appendix 3 and can also be found on the WHO Medical Devices web-site along with all the content of the Forum (Box 5).

Box 5. Website of the Second WHO Global Forum on Medical Devices

http://www.who.int/medical_devices/2nd_gfmd/en/index.html

The website provides access to the programme, videos of the plenary sessions, audio of the parallel sessions, the films that were presented in the film session, and most of the presentations and poster files.

The official languages for submission of abstracts was English but simultaneous translation was made available in the four plenary sessions and for selected parallel sessions in Spanish and French, depending on the language of preference of the submitted papers.

The venue was the CICG, which offered a large plenary meeting room, and several other smaller meeting rooms to accommodate parallel sessions, and open areas for poster presentations and exhibits.

Workshops

The first day (Friday, 22 November 2013) of the Forum included 37 workshops that were presented on the following nine topics (Box 6):

Box 6. Workshop tracks

1. Approaches to improving healthcare delivery
2. Biomedical engineering
3. Health technology assessment
4. Health technology management/clinical engineering
5. Innovation
6. Medical imaging and radiation safety
7. Nomenclature, standards, and regulations
8. Reproduction, maternal, newborn, and child Health
9. WHO/UN tools to improve healthcare delivery

Representatives from WHO, other UN agencies, NGOs in official relationships with WHO, academia, and/or professional organizations co-organized the various workshops with WHO. The final programme, summaries, abstracts and/or reports of the workshops are presented in Appendix 4. It was noted that many submissions were for workshops and many participants enrolled for each workshop in order to obtain more knowledge by subject.

The main conference

The second and third days of the Forum included plenary, parallel, poster and film sessions.

The plenary session topics

Each of the four plenary sessions included brief presentations by invited leaders in their respective fields to address a specific topic. For each session, the presentations were followed by questions and comments from Forum participants and discussion.

Box 7. Plenary session topics

Plenary session topics

1. Medical devices for universal health coverage
2. The unfinished agenda: medical devices are indispensable for reaching the Millennium Development Goal (MDG) targets
3. Medical devices for the noncommunicable disease (NCD) agenda
4. Policies, innovation, regulation, assessment, management and safe use of medical devices for increasing access

The parallel sessions

Taking into consideration the abstracts received, a programme was developed to facilitate the country presentations, academia and health care delivery perspectives to reflect their content in the conference topics. The programme included 156 oral presentations distributed across the following 10 tracks of the parallel sessions:

Box 8. Parallel session topics

Parallel session topics

1. Health care delivery/health care infrastructure
2. Health technology assessment
3. Health technology management
4. Human resources
5. Innovation and local production
6. Medical imaging
7. Medical software
8. Policy
9. Regulation
10. Safety

As the intent of the Forum was to exchange ideas, the timing of the presentations in the parallel sessions was brief to allow time for discussion. The entire programme with the list of all presentations is found in Appendix 3.

Posters

The abstracts that were not selected for presentations or that were submitted for poster presentation were featured on 116 posters organized by theme. Specific times were allotted for poster viewing, but presenters were encouraged to leave their posters up for the duration of the Forum.

Films

The programme also included a new modality of presentation that features the use of an innovative technology, or programmes to increase access to medical devices. Many of these films highlighted devices that were selected for inclusion in the *2013 Compendium of Innovative Health Technologies for Low-Resource Settings.*

As a result of the simultaneity of the Iran nuclear talks in Geneva and the Second Global Forum, reorganization was necessary as security was increased and rooms no longer corresponded with the printed programme.

Attendees

The essence of the Forum was the exchange of ideas between participants from different regions and backgrounds, and to allow them to network and share commonalities.

The Forum was attended by 572 people from 103 countries with 41% of the attendees and 36% of the presenters female.

The attendees came from all six WHO regions. At least 50% of WHO Member States had a representative at the Forum. As can be seen by the density map in Figure 4, the attendees included participants from low - and middle- income countries, but there was a larger representation from high-income countries. The list of countries with the number of attendees from each country is shown in Table 3a-g.

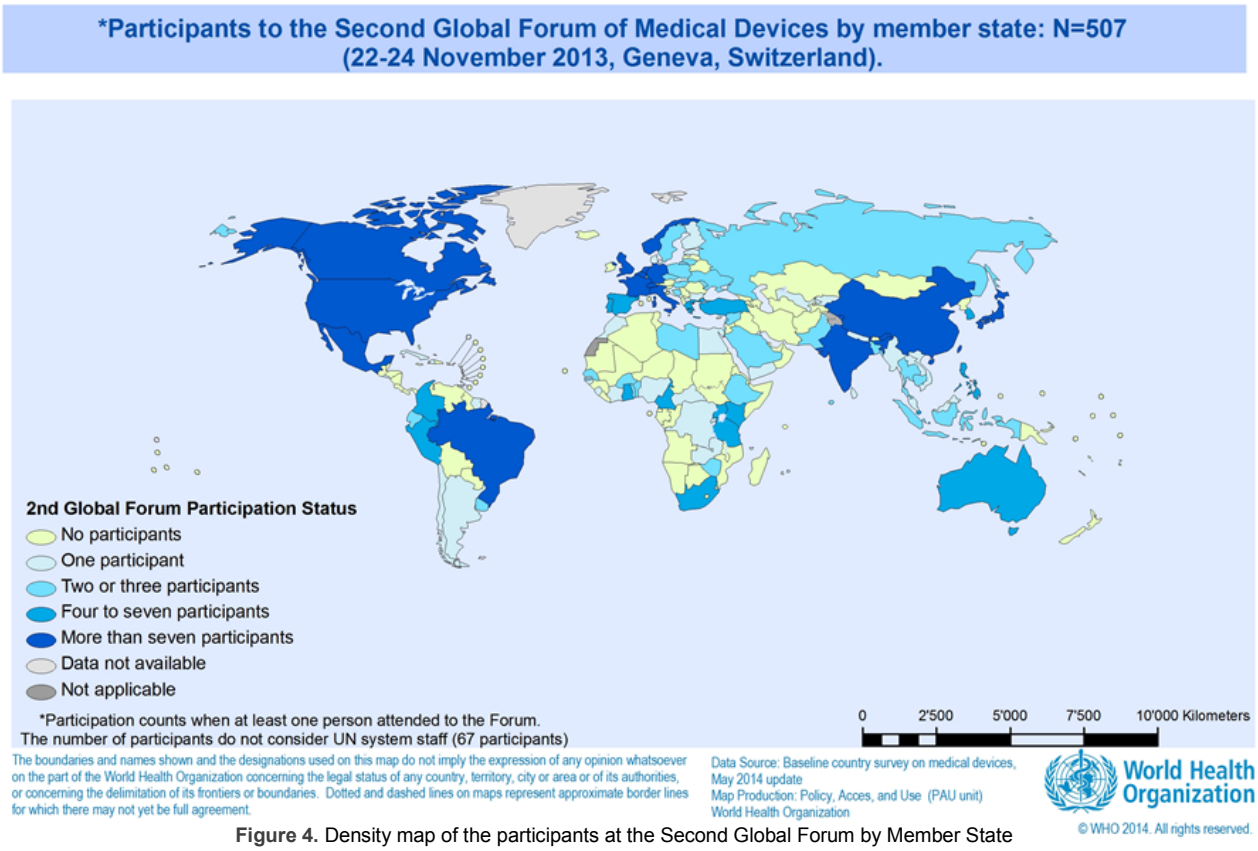


Figure 4. Density map of the participants at the Second Global Forum by Member State

Africa Region (AFR)				
Country	Govern-mental	Other	Total	Number of entities
Benin	2	1	3	1
Burkina Faso	3	0	3	1
Burundi	1	0	1	1
Cameroon	0	4	4	1
Central African Republic	1	1	2	1
Comoros	1	0	1	1
Côte d'Ivoire	1	0	1	1
Democratic Republic of the Con-	0	2	2	1
Ethiopia	1	1	2	1
Gambia	1	0	1	1
Ghana	5	2	7	1
Guinea'Bissau	1	0	1	1
Kenya	3	3	6	1
Mauritius	1	0	1	1
Nigeria	1	0	1	1
Rwanda	0	1	1	1
Senegal	2	1	3	1
Sierra Leone	1	0	1	1
South Africa	2	4	6	1
Swaziland	0	1	1	1
Togo	1	1	2	1
Uganda	1	3	4	1
United Republic of Tanzania	3	1	4	1
Zambia	1	0	1	1
Zimbabwe	1	1	2	1
Total			**61**	**25**

Table 3a Number of participants by country in the African Region

Region of the Americas (AMR)				
Country	Govern-mental	Other	Total	Number of entities
Argentina	1	0	1	1
Brazil	10	12	22	1
Canada	0	9	9	1
Chile	0	1	1	1
Colombia	2	2	4	1
Cuba	1	0	1	1
Ecuador	3	0	3	1
El Salvador	1	0	1	1
Haiti	1	0	1	1
Mexico	2	7	9	1
Panama	0	1	1	1
Peru	0	4	4	1
Suriname	1	0	1	1
Trinidad and Tobago	1	0	1	1
United States of America	2	62	64	1
Uruguay	1	1	2	1
Total			**125**	**16**

Table 3b Number of participants by country in the Region of the Americas

Eastern Mediterranean Region (EMR)				
Country	Govern-mental	Other	Total	Number of entities
Afghanistan	0	1	1	1
Egypt	0	1	1	1
Kuwait	0	1	1	1
Lebanon	1	1	2	1
Libya	2	0	2	1
Morocco	0	1	1	1
Pakistan	0	3	3	1
Saudi Arabia	3	0	3	1
Syrian Arab Republic	2	0	2	1
Tunisia	0	2	2	1
Yemen	1	0	1	1
Total			**19**	**11**

Table 3c Number of participants by country in the Eastern Mediterranean Region

European Region (EUR)				
Country	Govern-mental	Other	Total	Number of entities
Belgium	1	11	12	1
Bosnia and Herzegovina	3	0	3	1
Bulgaria	0	1	1	1
Croatia	0	1	1	1
Czech Republic	0	2	2	1
Denmark	0	1	1	1
Estonia	1	0	1	1
Finland	1	0	1	1
France	0	18	18	1
Germany	2	7	9	1
Greece	1	3	4	1
Hungary	0	3	3	1
Israel	1	2	3	1
Italy	3	18	21	1
Kyrgyzstan	1	0	1	1
Lithuania	2	0	2	1
Moldova	2	0	2	1
Montenegro	4	0	4	1
Netherlands	0	7	7	1
Norway	9	1	10	1
Poland	3	0	3	1
Portugal	2	1	3	1
Russia Federation	2	0	2	1
Slovakia	1	0	1	1
Spain	3	4	7	1
Sweden	1	1	2	1
Switzerland	1	51	52	1
The Former Yugoslav Republic of Mac-	0	1	1	1
Turkey	6	0	6	1
Ukraine	2	0	2	1
United Kingdom	2	40	42	1
Uzbekistan	1	0	1	1
Total			**228**	**32**

Table 3d Number of participants by country in the European Region

South-East Asia Region (SEAR)				
Country	Govern-mental	Other	Total	Number of entities
Bangladesh	1	2	3	1
India	3	11	14	1
Indonesia	0	2	2	1
Maldives	2	0	2	1
Myanmar	1	0	1	1
Nepal	1	0	1	1
Sri Lanka	1	0	1	1
Thailand	2	1	3	1
Total			**27**	**8**

Table 3e Number of participants by country in the South-East Asia Region

Western Pacific Region (WPR)				
Country	Govern-mental	Other	Total	Number of entities
Australia	0	6	6	1
Cambodia	1	1	2	1
China	1	7	8	1
Fiji	0	1	1	1
Japan	0	17	17	1
Korea, Republic of	2	4	6	1
Lao People's Democratic Republic	1	0	1	1
Malaysia	1	1	2	1
Philippines	2	5	7	1
Singapore	1	3	4	1
Viet Nam	0	1	1	1
Total			**55**	**11**

Table 3f Number of participants by country in the Western Pacific Region

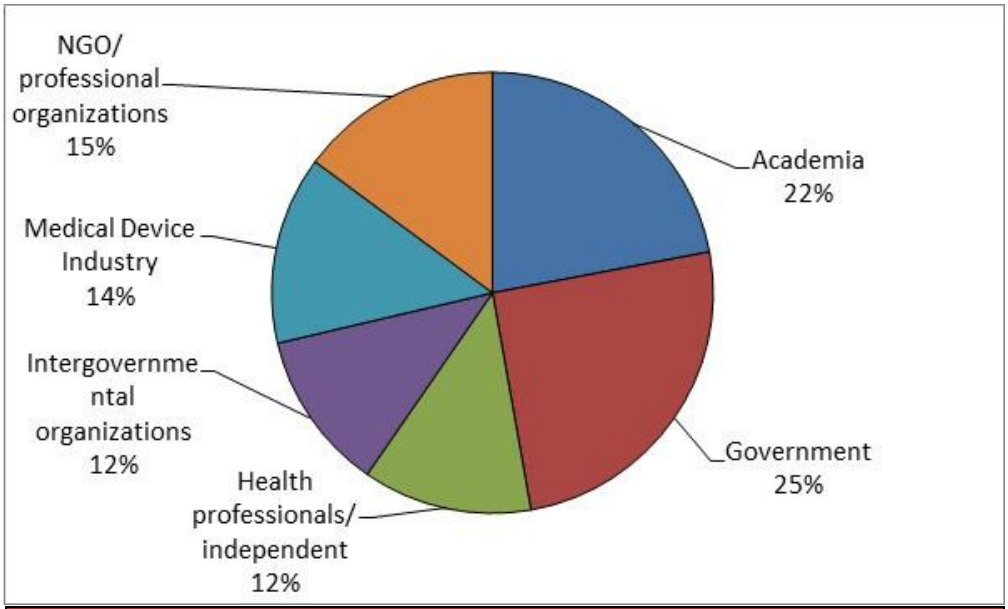
Intergovernmental organization (IGOs)				
Organization	Regional/ Global	Coun-try	Total	Number of entities
European Commission	1	0	1	1
OECD	1	0	1	1
UNESCO Chair of Telemedicine	1	1	2	1
UNICEF	3	0	3	1
UNOPS	0	1	1	1
World Bank	1	0	1	1
African Development Bank	1	0	1	1
WHO AFRO	1	3	4	1
WHO AMRO	2	1	3	1
WHO EMRO	1	3	4	1
WHO EURO	1	0	1	1
WHO SEARO	1	0	1	1
WHO WPRO	0	1	1	1
WHO Headquarters	43	0	43	1
Total			**67**	**14**

Table 3g Number of participants per intergovernmental organization

Statistics of participants

The total number or registered participants was 723, but not all were able to attend: 506 attendees and participants from 103 Member States and 66 from intergovernmental organizations, including the United Nations agencies, attended the Forum.

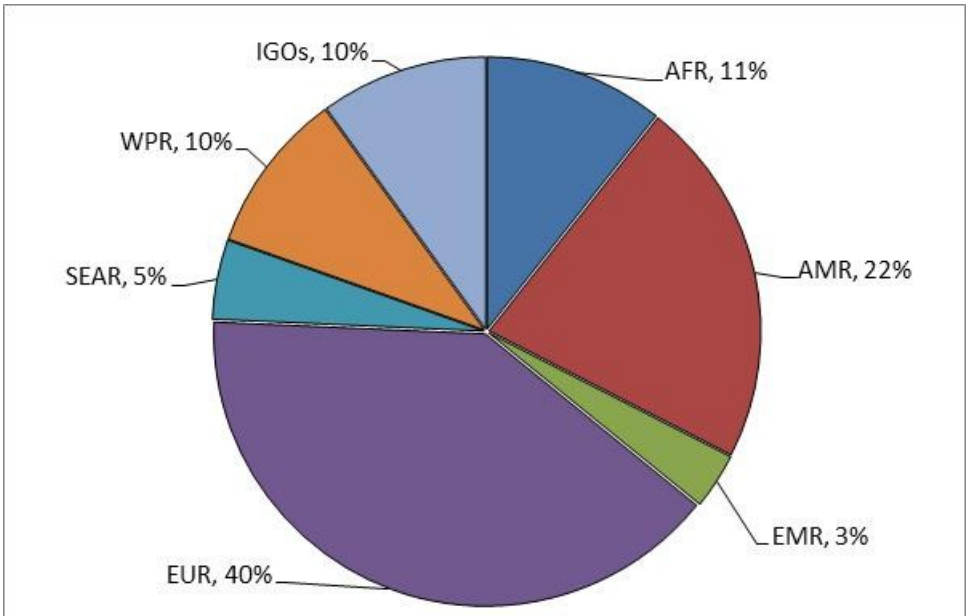
Attendees represented a variety of organizations, with the largest numbers from the government or public agencies (25%) and academic sectors (22%). It is important to note the participation of professional associations and NGOs (15%). The full breakdown by category is shown in Figure 5. Each of the categories included attendees from all six WHO regions (Figure 5).
Appendix 7 contains the full list of participants of the Forum by category and country.



Participants per category	
Academia	126
Government	144
Health professionals/ independent	71
Intergovernmental organizations	67
Medical Device Industry	79
NGO/ professional organizations	85
Total	**572**

Figure 5. Participants per category

Statistics of participants (2)



Individuals participation per region	
African Region (AFR)	61
Region of the Americas (AMR)	125
Eastern Mediterranean Region (EMR)	19
European Region (EUR)	228
South-East Asia Region (SEAR)	27
Western Pacific Region (WPR)	55
Intergovernmental organizations (IGOs)	57
Total Participants	**572**

Figure 6. Individuals participation per region

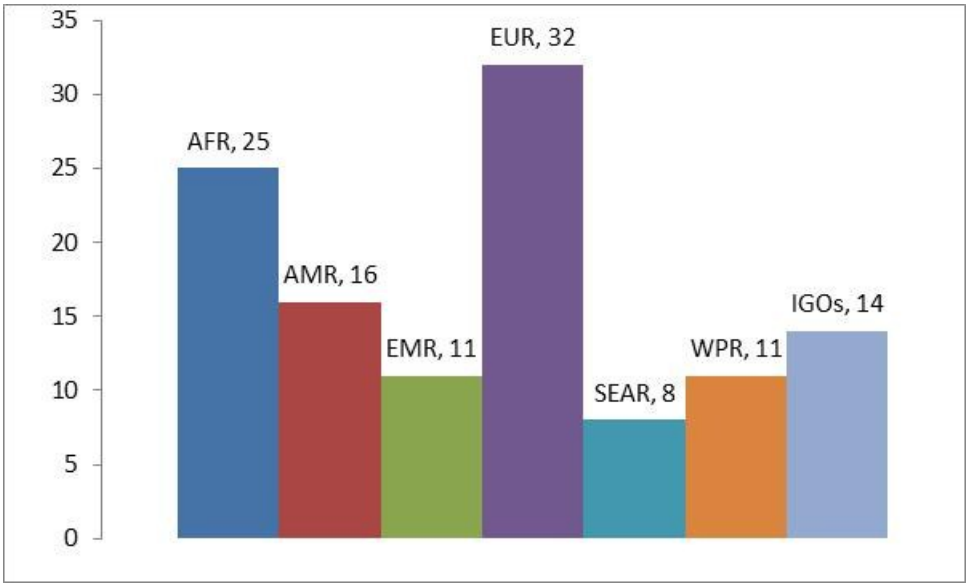


Figure 7. Number of countries per region

Second WHO Global Forum on Medical Devices: outcomes

Process to define future actions

One of the key outcomes of the Global Forum was to consolidate priority actions to be suggested by the Forum participants, as it was done during the First Global Forum.

In order to enable participant agreement, the organizers implemented the following process:

1. The session chair opened each parallel session.
2. The co-chair followed by giving a brief presentation of the work done by WHO in the topic area.
3. Speakers then gave their presentations followed by questions and comments from participants.
4. Participants in each session were invited to submit their statements or actions to follow up, at any time during the session, using an interactive electronic conference device. A total of 263 were proposed (see Appendix 9).
5. The co-chair noted all of the recommendations that came in and selected the top five for voting, thus a total of 114 proposals from all sessions, were presented to the participants.
6. The proposed 5 statements were presented during the session and the participants were invited to vote for what they considered the most important, which rendered a total of 51 proposals (see Appendix 8).

Therefore, a grand total of 263 proposals from all of the sessions were received, 114 were presented for voting, 51 were selected as the most important and finally WHO prioritized 29 of them, for future action (see Table 4).

Outcomes

The programme of the Forum – including the workshops, the plenary and the parallel sessions, films and posters – offered the participants the possibility to share experiences on best practices, to describe challenges and gaps and to network with participants with common problems, and to learn where to find information and resources to address their needs.

The outcomes of the Forum in response to the objectives, are as follows:

- To define methods of increasing access to priority medical devices under the Universal Health Coverage initiative. Each of the tracks of the Forum provided a setting to define actions.
- To share evidence on best practices in health technology assessment, management and regulation of medical devices. It was noted that the regulation of medical devices is still very limited and covers less than half of all countries; and in low-income countries, even those with just a few products, this area needs urgent WHO guidelines and training at local and regional levels. The area of health technology assessment is new to many low– and middle- income countries and they request information on how to proceed with their ministries or organizations to define the role this technology plays in universal health care. In addition, the topics on health technology management, even though information is available from WHO and many advances are now visible even in low-income countries, it is still necessary to increase awareness and provide more support, particularly in low-income countries, to address problems with donations and lack of funds, knowledge and industry support for maintenance throughout the life cycle of the equipment.
- To demonstrate the development and use of appropriate and innovative technologies that respond to global health priorities. This area is now being developed globally in academia and industry and it is expected to have a high impact in the years to come, but still requires a good regulatory knowledge.
- To present the outcomes of the implementation of the World Health Assembly resolution on health technologies (WHA60.29) and the status of actions resulting from the First Global Forum on Medical Devices. These actions are presented in Table 2 and while most of them have been completed or are being addressed, continuous work is needed on health technology assessment, innovations, regulations of medical devices and especially on the free access to a global nomenclature of medical devices. Last but not least, to encourage biomedical engineers to take a leading role in medical devices development, regulations, assessment , management and safe use in order to respond to the populations needs.

From the 263 proposals, 29 actions will be followed up during the next three years.

List of future actions

The Forum generated 263 proposals submitted by the participants. From the ones voted as most important, WHO will encourage the implementation of 29 actions as listed in Table 4.

No.	Recommendation
	Priority Medical Devices
1	WHO to provide a set of tools to adapt an essential / priority medical devices lists to specific countries needs and all to be contained in a database
	Medical Devices policies
2	Medical Devices policies available in each country, should be strongly advocated. This policies to include health technology management, regulations and assessment strategies and plans in place and be implemented.
3	Encourage Ministries to establish a department/directorate in charge of health technology (mainly medical devices) .
	Health Technology Assessment (HTA)
4	HTA networks, agencies and societies to share their strategies, tactics and challenges, to encourage uptake and appropriate use of their work by decision makers.
5	WHO to support the dissemination of HTA practices, to regions with gaps in HTA
6	WHO to encourage a unify HTA database generation efforts for information sharing .
	Health Technology Management (HTM)
7	Identify best practices and share HTM strategies across countries and regions
8	Raise awareness and Inform purchasers and decision makers, that medical device procurement is an investment decision in which price at the time of purchase should reflect both capital cost & operational cost (iceberg concept to encourage to have: funds, human resources, consumables and maintenance throughout the life time of the medical equipment)
9	Accelerate the development and dissemination of WHO database of technical specifications
10	To develop a decision support system for rational selection of high cost medical equipment
11	To have concrete recommendations on the training of maintenance of medical equipment
	Human Resources
12	Foster cross institution collaboration in order to develop innovative biomedical engineering education approaches that will enhance engineering capacity in low-resource settings and reduce brain drain
13	Encourage global efforts to strengthen the role of medical physicists and clinical and biomedical engineers as key health professionals that promote the development, access, quality and safe use of medical devices, particularly in low-income countries
	Innovation and Local Production
14	Encourage close collaboration between technological universities and academia and health care providers in order to address needs of doctors and patients.
15	Support innovation and design "hubs" in low-income countries to encourage technology development .
16	Implement workshops using cross-sector collaborations that teach designers and innovators how best to develop quality, appropriate medical devices for resource limited settings and improve access to these new technologies.
17	Focus on value-based innovation and ensure that newly developed products meet public health needs
18	WHO to support collaborative platforms, possibly online, between interested parties such as NGOs, innovators, manufacturers, and clinicians for the production of medical devices in/ for low-resource settings
	Medical Imaging
19	Health facilities to use comprehensive site analysis and needs assessment to determine when digital radiography systems and ultrasound are of benefit to the target population .
20	Develop digital imaging guidelines and support radiation quality and safety.

Table 4. Priority recommendations

Regulation and Safety	
21	WHO should provide a platform for harmonization of taxonomy and nomenclature of safety reporting and learning systems across different disciplines in health care (e.g. radiation safety, blood safety, techno-vigilance, etc.)
22	WHO to assist low-resource countries to establish effective systems for regulating medical devices and provide guidelines on step approach to start and develop a regulatory unit for medical devices, and provide minimum information requirements for countries with out regulatory process.
23	Build a strong safety culture in health care to prevent adverse events in medical settings and training users in reporting to ensure quality of care and safety of patients
24	Develop a list of international valid minimal standards for medical devices and promote them
25	Encourage that all medical devices and medical software be controlled, whether manufactured locally or imported, and to consider safety and quality in the design and use aspects.
Health care Delivery	
26	Governments in Member states to remember considering the full life cycle cost of medical devices and all health technologies, when selecting and introducing new products
27	IOMP and IFMBE and other professional organizations to work closely with WHO in the field of patient safety and quality of health care.
Health care infrastructure	
28	Energy sources to be considered as part of the product selection criteria, especially for low resource settings where electricity is not stable or not available.
29	WHO to outline the characteristics of hospital infrastructure

Table 4. Priority recommendations (cont'd)

General numeric	
Total countries	103
Total participants	572
Total oral presentations	156
Total posters	116
Total films	11
Total workshops	37

Figure 8 General numeric

Evaluation

Using their electronic device, participants were able to evaluate the workshops, plenaries and parallel sessions. In general, the participants provided positive feedback. They were eager to obtain more information, be engaged in future work and participate in the next forum. For example, of those who completed the evaluations for the workshop sessions, 92% found them engaging and interactive and 86% were interested in attending a follow-up event. 92% of the evaluators said that the plenary sessions were engaging and interactive while 97% said the same of the parallel sessions. Additionally, more than 50% of the evaluators of the parallel sessions said they would be interested in participating in future meetings and supporting future work on the presented topics.

Figures 9 and 10 provides a visual representation of two very important measures of participant satisfaction. Figure 9 shows that over 90% of the participants felt that the conference fulfilled their reasons for attending while Figure 10 shows that 90% would recommend the conference to others.

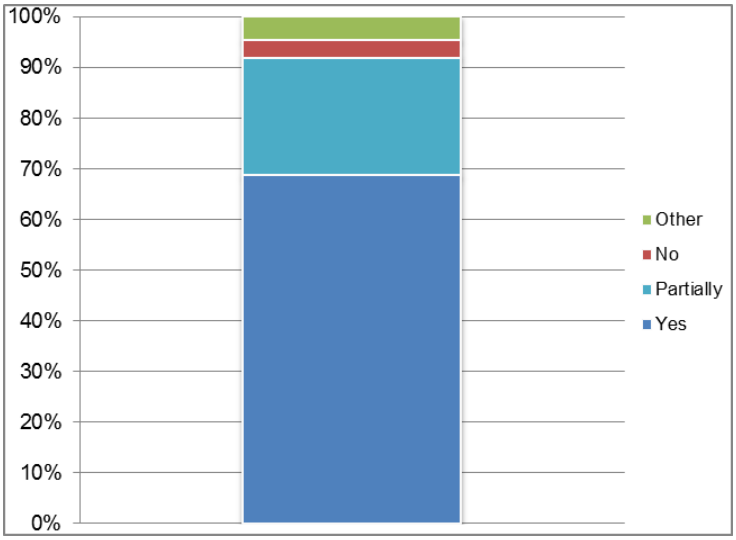


Figure 9. Did the conference fulfill your reason for attending?

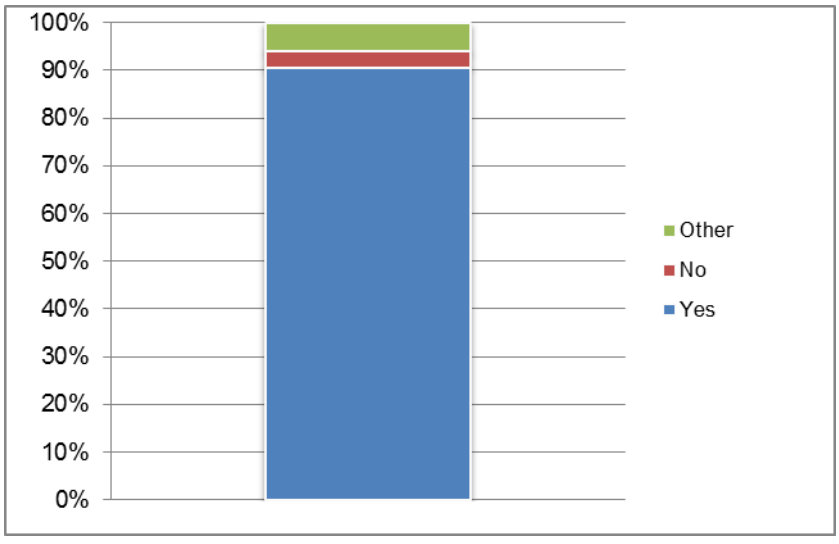


Figure 10. Would you recommend this conference to others?

Appendix 10 provides the results of the evaluation surveys in greater detail and includes the individual evaluations of particular sessions and workshops.

Third WHO Global Forum on Medical Devices

A proposal to host the Third Forum was received during the closing session from Argentina, and another was received by email from Australia. A formal process to request a venue for the Third Global forum will be sent in 2015 to all Member States in order to convene a timely meeting with ample time for organization.

Second WHO Global Forum on Medical Devices: conclusion

The Second WHO Global Forum on Medical Devices was a success as evidenced by the number of attendees, presentations given, and future actions proposed. There was extensive collaboration between experts, professionals, academics, and country representatives. A high commitment of many NGOs, WHO and other UN organizations, academia and general participants was demonstrated at this Forum and is very much acknowledged. Without this shared view and understanding, the Forum would not have been as successful.

The objectives of the Forum were achieved but much work remains to be done in all areas that were discussed. There is a high level of expectation by the participants that WHO will continue providing guidance and collaboration to further advance the innovation, regulations, assessment and management of medical devices, based on public health needs and with the goal to increase access and safe use of quality medical devices in the context of universal health coverage. Hopefully, a Third Global Forum will show the advancements in medical device distribution and innovation, and continue the engagement built in this Forum.

Innovations in medical devices are needed to advance medicine and must become accessible to the global community. As a medical device community, it is our responsibility to make rational decisions, follow ethical behaviour and share our expertise in order to increase the availability of the appropriate medical devices to patients and health workers.

While WHO can leverage the priorities for the global medical device and health care community, it cannot solely accomplish its goals. Thus, we must continue to collaborate with all the medical devices and health technologies developers and users in civil society, governmental organizations, professional associations, health workforce, academia and the medical devices industry to implement the actions proposed in this report as well as WHO resolutions. Through Global Fora we hope to support the improved access to affordable, available, quality and safe medical devices and promote the achievement of universal health coverage in all Member States for the well-being of humankind.

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2. Resolution A/RES/67/81. Global health and foreign policy. In: *United Nations General Assembly, Sixty-seventh session, New York, 12 December 2012. Resolutions and decisions.* New York: United Nations; 2012 (A/RES/67/81; http://daccess-dds-ny.un.org/doc/UNDOC/GEN/N12/483/46/PDF/N1248346.pdf?OpenElement, accessed 8 April 2014).

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5. Resolution WHA61.21. Global strategy and plan of action on public health, innovation and intellectual property. In: *Sixty-first World Health Assembly, Geneva, 19–24 May 2008. Resolutions and decisions, and list of participants.* Geneva: World Health Organization; 2008 (WHA61.21/2008; http://apps.who.int/gb/ebwha/pdf_files/A61/A61_R21-en.pdf, accessed 8 April 2014).

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7. Resolution WHA66.7. Implementation of the recommendations of the United Nations Commission on Life Saving Commodities for Women and Children. In: *Sixty-sixth World Health Assembly, Geneva, 20-27 May 2013. Resolutions and decisions, and list of participants.* Geneva: World Health Organization; 2013 (WHA66.7/2013; http://apps.who.int/gb/ebwha/pdf_files/WHA66/A66_R7-en.pdf, accessed 8 April 2014).

8. Modified from Health systems financing: the path to universal coverage. Executive Summary, World Health Report, WHO/IER//WHR/10.1, 2010.

9. *First WHO Global Forum on Medical Devices: context, outcomes and future actions.* Geneva: World Health Organization; 2010 (http://whqlibdoc.who.int/hq/2011/WHO_HSS_EHT_DIM_11.11_eng.pdf, accessed 8 April 2014).

Appendix 1

Welcome Address and Inauguration by Dr. Margaret Chan, Director-General of WHO

2nd WHO Global Forum on Medical Devices
Welcome Address and Inauguration
Dr. Margaret Chan, Director-General of WHO
Geneva, Switzerland
23 November 2013

I am pleased to welcome you to this Second WHO Global Forum on Medical Devices. On one level the objective of this event is straight-forward; to improve access to high-quality, safe and affordable medical devices that meet priority needs. On another level, improving access is an enormous undertaking with a broad scope and great complexity. The scope of issues that need to be addressed is well reflected in your agenda which covers economic as well as technical challenges and the need for support from national policies and regulatory control, as well as, evidence.

Safety for patients and providers is another critical issue. You will be looking in particular at priority devices that support Universal Health Coverage. You will also consider problems and needs in the context of internationally-agreed health priorities; including meeting the health-related Millennium Development Goals by 2015 and beyond, and coping with the rise in non-communicable diseases and aging populations.

Medical devices are indispensable to healthcare everywhere, every day. But they also contribute disproportionately to soaring healthcare costs. In 2007, the World Health Assembly first adopted its first resolution on health technologies, giving particular emphasis to medical devices. That resolution expresses concern about the contribution of medical devices to rising healthcare costs. These costs have reached crisis proportion in many countries and are coming under close scrutiny from governments, healthcare providers, insurers and consumers. No country, no matter how wealthy, can afford to waste resources on medical devices that have not been clearly shown to provide superior results for patients.

Addressing inequalities in access to essential devices is an especially complex challenge. As it involves intellectual property rights, regulatory control, systems for procurement, reimbursement and maintenance, and above all, technologies that are deliberately designed and priced for use in low-resource settings.

Many of these issues were addressed during the First Global Forum on Medical Devices held in 2010. Since then a number of encouraging trends have emerged. The market is responding to concerns about ever greater costs and complexity. Innovations are making medical devices progressively smaller, less invasive and more cost-effective. The move towards frugal innovation is especially welcome. It reflects a relentless drive, especially by manufacturers in emerging economies, to simplify devices and get the prices down - yet with no compromise of quality, safety or efficacy.

In my view, the poor deserve the very best healthcare because they have been given so little else in life. The solutions you will work out in the coming days will help ensure that poorer populations receive their fair share of the benefits of advances in medical devices.

I wish you a most productive meeting.

Appendix 2

Welcome Message by Dr. Marie-Paule Kieny,

Assistant Director General, Health Systems and Innovation, WHO

2nd WHO Global Forum on Medical Devices
Welcome Message
Dr. Marie-Paul Kieny,
Assistant Director General, Health Systems
and Innovation, WHO
Geneva, Switzerland
23 November 2013

Welcome to this Second Forum and we are really impressed to see how many participants have registered. Indeed as of yesterday we had 677 participants registered. This is really unbelievable and I would like to thank Adriana Velazquez very much, as well as her small team who has put this together.

Prior to this Inauguration of the Forum, yesterday, there have been 28 workshops which were very well attended, held in 7 parallel sessions. This is absolutely not a small achievement to have put all these together.

As you know, WHO and WHO member states are very much these days promoting and pushing towards Universal Health Coverage. What does this mean? It means that everybody, everywhere should get access to the health services that they need of good quality without the risk of financial hardship. This should include services from health promotion, such as cessation of tobacco to palliation - going through prevention, care, therapy, rehabilitation and then to palliation. In the quest to Universal Health Coverage, we need to pay particular interest and importance in the role of medicine and other health technologies, among which is medical devices. Indeed, in low and middle income countries approximately 40% of healthcare expenditures are on medicines, technology or devices and a large part of these expenses are payments that the individual needs to provide from their pocket. It is very important that together we work towards the development of safe, quality and also affordable devices for the whole range of services needed - from promotion to palliation.

WHO member states have recognized for quite a number of years now that medical devices are indispensable for quality healthcare delivery. They acknowledge also the need to prioritize the selection and acquisition of health technologies and to ensure their safe and effective use. Seminal to this work, the World Health Assembly has adopted the first resolution on health technologies, resolution WHA60.29, in May 2007. The First WHO Global Forum on Medical Devices was hosted by Thailand in September 2010, with the aim to advance collaborative efforts to improve access to safe, effective, quality and appropriate medical devices globally.

This forum was attended by participants from 107 Member States. The event raised awareness and served to share ideas on how to increase access to safe and effective medical devices. Since the resolution of the 2007 and the First Global Forum on Medical Devices, WHO has undertaken important work to fulfill the recommendations that we have received. For example, WHO has developed technical documentation on medical equipment for maternal and newborn care for all levels of healthcare facilities in collaboration with UNICEF and UNFPA in order to guide Member States as well as to support the United Nations Commission on Life-Saving Commodities for Women and Children in their efforts to improve maternal and child health.

The *Survey on Medical Devices,* which was launched in 2010 and since updated every year, and which is available on the WHO Global Health Observatory, allows researchers, academia and MOH to analyze the medical devices situation and work towards improving and filling gaps in policy, best practices and capacity building in countries.

The survey has identified that 89 countries do not have a health technology policy and that 57 WHO member states do not have a regulatory agency that has a capacity to evaluate medical devices. Moreover, it has been recognized that health technology assessment is an important tool to achieve rational evidence-based selection of medical devices and to ensure that countries promote the use of safe, effective and affordable devices and that financial resources are used in an efficient way and contribute to achieving Universal Health Coverage. There have been resolutions on health technology assessment in several WHO regions starting by the Americas, and we expect that Member States of WHO will agree on the strong resolution on this topic in May 2014. We look forward to the recommendation to the secretariat of WHO on how we can support Member States to develop and use health technology assessment for medical devices in particular and also for all other health technologies.

Ladies and gentlemen we welcome the numerous initiatives aiming at supporting innovation for improving access to appropriate, safe, affordable and simple-to-use medical devices to target global health priorities.

During the Second Forum, we have ambitious objectives. We would like to define methods for increasing access to priority medical devices under the Universal Health Coverage goal. We would like to share evidence on best practices in health technology assessment, management and regulation of medical devices. We will demonstrate the development and use of appropriate and innovative technologies that respond to global health priorities. Finally, we will also present the outcome of the implementation of the World Health Assembly resolution on health technology from 2007 and the status of actions resulting from the implementation of this resolution, as well as, from the First Global Forum on Medical Devices.

As you will be discussing all these topics in the next two days, it is important to note that to increase access to safe, appropriate technology to all global settings; we need the support from all stakeholders including industry, academia, health workers, donors and professional societies. We in WHO are all very impressed by the number of participants who are attending this Second Global Forum and this makes us even more aware of the importance of securing access to quality-assured and affordable medical devices as part of health service delivery for all.

We very much hope that this Second Global forum will be a good opportunity for you to share experiences and by doing so to contribute to global efforts to achieve better health.

Appendix 3

Conference programme

Main schedule
Day one

Time					
08:00	**Saturday 23 November** Registration				
09:00	**Plenary Session 1 (Salle 1)**				
	FORUM INAUGURATION / OPENING SESSION **"Medical devices for Universal Health Coverage"** *(Panel Discussion 1)*				
10:00	Health break / **Posters / Exhibits**				
10:30	**Parallel sessions**				
	Salle 18	Salle 2	Salle 21/22	Salle 1	Salle 5/6
	Health Technology Assessment: Networks and Societies Around the Globe *Spanish Translation Available *	**Health Technology Management: Country Initiatives**	**Regulation of Medical Devices**	**Innovation in Medical Devices**	**Health Care Delivery** *French Translation Available *
11:15					**Health Care Infrastructure** *French Translation Available *
12:00	Lunch / **Exhibits**				
13:00	**Poster Session 1**				
14:00	**Parallel sessions**				
	Salle 18	Salle 2	Salle 21/22	Salle 1	Salle 5/6
	How to Prioritize Medical Devices	**Health Technology Management: Country Initiatives** *French Translation Available *	**Regulation of Medical Devic-es: Country Ini-tiatives** *Spanish Translation Available *	**Innovation in Medical Devices for Maternal and Child Health**	**Medical Imaging**
15:30	Health break / **Posters / Exhibits**				
16:00	**Plenary Session 2 (Salle 1)**				
	"The unfinished agenda: medical devices are indispensable for reaching the MDG targets" *(Panel discussion 2)*				
17:00	Salle 2 **Film viewing**		**Social networking / Poster viewing** **(until 19:00)**		

Main schedule
Day two

<table>
<tr><td>Time</td><td colspan="5">Sunday 24 November
Registration</td></tr>
<tr><td>08:00</td><td colspan="5"></td></tr>
<tr><td>09:00</td><td colspan="5">Plenary Session 3
(Salle 1)</td></tr>
<tr><td></td><td colspan="5">"Medical devices for the Non-Communicable Disease (NCD) agenda"
(Panel Discussion 3)</td></tr>
<tr><td>10:00</td><td colspan="5">Health break / Posters / Exhibits</td></tr>
<tr><td>10:30</td><td colspan="5">Parallel sessions</td></tr>
<tr><td></td><td>Salle 18</td><td>Salle 2</td><td>Salle 21/22</td><td>Salle 1</td><td>Salle 5/6</td></tr>
<tr><td></td><td rowspan="2">Health Technology Assessment</td><td>Policies for Medical Devices</td><td rowspan="2">Safety of Medical Devices
*Spanish Translation Available *</td><td rowspan="2">Innovative Medical Devices for Low-Resource Settings</td><td rowspan="2">Human Resources in BME
*French Translation Availa-ble *</td></tr>
<tr><td>11:15</td><td>Technical Specifications</td></tr>
<tr><td>12:00</td><td colspan="5">Lunch / Exhibits</td></tr>
<tr><td>13:00</td><td colspan="5">Poster Session 2</td></tr>
<tr><td>14:00</td><td colspan="5">Parallel sessions</td></tr>
<tr><td></td><td>Salle 18</td><td>Salle 2</td><td>Salle 21/22</td><td>Salle 1</td><td>Salle 5/6</td></tr>
<tr><td></td><td rowspan="2">Local Production in Low-Resource Settings</td><td rowspan="2">Procurement of Medical Devices
*French Translation Available *</td><td>Patient Safety</td><td rowspan="2">Innovative Medi-cal Devices for Low-Resource Settings
*Spanish Translation Available *</td><td>Human Resources for Technology Life Cycle Management</td></tr>
<tr><td></td><td>Medical Software</td><td>Human Resources in Medical Physics</td></tr>
<tr><td>15:30</td><td colspan="5">Health break / Posters / Exhibits</td></tr>
<tr><td>16:00</td><td colspan="5">Plenary Session 4 / Closing
(Salle 1)</td></tr>
<tr><td></td><td colspan="5">" Policies, innovation, regulation, assessment, management and safe use of medical devices for increasing access" & Closing
(Panel discussion 4)</td></tr>
<tr><td>17:00</td><td colspan="5">Adjourn</td></tr>
</table>

Plenary Sessions

Time	Plenary session 1 - Saturday 23rd November 2013
Sat. 9:00 - 10:00	**Medical devices for Universal Health Coverage**
	Chair: Dr. Marie-Paule Kieny, Assistant Director General Health Systems and Innovation, WHO
	Welcome Message and Inauguration of the 2nd WHO Global Forum on Medical Devices
	Dr. Margaret Chan, Director General, WHO (video message)
	Challenges in Universal Health Coverage, a Japanese perspective
	Dr. Masato Mugitani, Ex-chair, Global Health Workforce Alliance
	Health Technology Assessment to select priority interventions, HITAP perspective
	Dr. Suwit Wibulpolprasert, Health Intervention and Technology Assessment Program (HITAP), Thailand
	Follow up on the Priority Medical Devices Report: Managing the Mismatch
	Dr. Hugo Hurts, Ministry of Health, Welfare and Sport, Netherlands
	Financing for Universal Health Coverage
	Dr. Andreas Seiter, World Bank
	Medical technology industry to respond to global health needs
	Ms. Gisela Abbam, Global Medical Technology Alliance
	Plenary session 2 - Saturday 23rd November 2013
Sat. 16:00 - 17:00	**The unfinished agenda: medical devices are indispensable for reaching the MDG targets**
	Chair: Dr. Elizabeth Mary Mason, Director Maternal, Newborn, Child and Adolescent Health, WHO
	Supporting infrastructure and health products for maternal and newborn care
	Dr. Feng Zhao, African Development Bank
	Supply of appropriate medical devices for women and children's' health
	Dr. Helen Moller, United Nations Children's Fund (UNICEF)
	Quality assuranced of medical devices in Doctors Without Borders (MSF)
	Ms. Monique Dory, MSF
	Medical technology industry developing affordable new technologies of global health concerns
	Dr. Trevor Gunn, Global Medical Technology Alliance
	Plenary session 3 - Sunday 24th November 2013
Sun. 9:00 - 10:00	**Medical devices for the Non-Communicable Disease (NCD) Agenda**
	Chair: Dr. Shanthi Mendis, WHO
	Scientific and technological advances for health applications
	Dr. Steven Myers, European Organization for Nuclear Research (CERN)
	The advances in medical imaging and the importance of increasing access
	Dr. Ian Labuscagne, President, International Society of Radiology
	Medical devices indispensable for cardiology diagnosis and treatment
	Prof. Alan G. Fraser, European Society of Cardiology
	Inclusion of medical devices in Clinical Practice Guidelines, particularly for NCDs and disabilities
	Dr. Josee Hansen, Ministry of Health, Welfare and Sport, Netherlands
	Medical technology industry to target non communicable diseases
	Ms. Nicole Denjoy, Diagnostic Imaging, Healthcare IT, Radiation Therapy Association (DITTA)
	Plenary session 4 - Sunday 24th November 2013
Sun. 16:00 - 17:00	**Policies, innovation, regulation, assessment, management and safe use of medical devices for increasing access**
	Chair: Mr. Kees de Joncheere, Director, Essential Medicines and Health Products, WHO
	The way forward to optimize medical equipment support projects: a report from Equip'aid 2013
	Dr. Cathy Blanc-Gonnet, Humatem
	A status report on the WHO Global Atlas of Medical Devices
	Dr. Ricardo Martinez Martinez, WHO
	The way forward to improve the regulation of medical devices
	Ms. Jennifer Barragan, WHO
	The way forward to develop improved Health Technology Management practices
	Dr. Nicolas Pallikarakis, International Federation for Medical and Biological Engineering (IFMBE)
	The way forward to educate the next generation of biomedical engineers
	Dr. Ratko Magjarevic, International Federation for Medical and Biological Engineering (IFMBE)
	The way forward to enhance and expand the use of effective Health Technology Assessment
	Dr. Jani Muller, International Network of Agencies for Health Technology Assessment (INAHTA)
	The way forward to ensure the safe use of medical equipment
	Prof. Alan Murray, Newcastle University, United Kingdom
	The way forward to develop innovative technologies to meet global health needs
	Prof. Kathleen Sienko, University of Michigan, United States of America
	The way forward for WHO to facilitate improved access to health technologies that expand health coverage
	Ms. Adriana Velazquez Berumen, WHO
	Closing remarks
	Mr. Kees de Joncheere, Director, Essential Medicines and Health Products, WHO
	ADJOURN

Exhibitors list

2nd Global Forum on Medical Devices Exhibitor list
UN Agencies
PAHO / World Health Organization
United Nations Population Fund
World Health Organization
Civil society/NGO
Africa Health Research Organization
Design that Matters
D-REV
HUMATEM
Jhpiego*
Medical Mission institute - The Advisory Group for International Health
Medisend International
RTI International*
Tropical Health and Education Trust (THET)
Academia
Addis Ababa University, HSC, Tikur Anbesa Specialized Hospital
Ateneo de Manila University
Brigham and Women's Hospital
Center for Preventive Medical Science, Chiba University*
Royal College of Art
Stanford India Biodesign
Swiss Federal Institute of Technology in Lausanne
University Sssociation for Natural and Sport Sciences,Butapest, Hungary
University of Huddserfield
Government
Department of Health Service,Teku, Kathmandu
Ministère de la santé et de la lutte contre le sida,Republique de Côte d'Ivoire*
Ministério da Saúde Brasil
Ministry of Public Health and Population,Yemen*
Professional Associations, Health Facilities and Others
International Organization for Medical Physics
Palm Beach Home Care Nursing Inc
Sohum Innovation Lab
* Brochure only

Films list

Film viewing - Saturday 22nd November 2013 17:00-18:00 Salle 2
eHealth
Le Web VSSM software for vaccine management Ramzi Ouhichi, *World Health Organization, Tunisia*
Transforming the smartphone into an integrated medical device Phillip Olla, *Mobile Diagnostic Services, United States of America*
WHO Compendium of innovative health technologies 2013
A mail-order-pharmacy to improve the access to drugs in developing countries Farell Folly, *Morocco; Thierry Edoh, Germany*
Enabling wider access to accurate hearing screening Michael Melvill, *m2Health, South Africa*
Dry blood spot screening Jordi Martí Gascón, *DBS Screening, Spain*
Low cost, durable sleep apnea treatment which does not require electricity Noel Lindsay, *United States of America*
Bedside newborn phototherapy Timothy Prestero, *Design that Matters, United States of America*
Hollow mattress Iffat Rahman, *Centre for the Rehabilitation of the Paralysed, Bangladesh*
Assistive devices
A low cost mechanical prosthetic hand Khondkar Siddique-e Rabbani, *University of Dhaka, Bangladesh*
Clinical Engineering
Training project for clinical engineers in developing countries Yoichi Sugiura, *Japan Association for Clinical Engineering, Japan*
Infrastracture
Protegemed – An alternative to reduce electric microshock risk during surgery Schardong Spalding Luiz Eduardo, *Universidade de Passo Fundo e Hospital São Vicente de Paulo, Brazil*

Appendix 4

Workshop abstracts and outcomes

Workshop Tracks and Topics
WHO/UN Tools to Improve Healthcare Delivery

Supporting integrated national strategic health planning, costing and health impact analysis: the OneHealth Tool

Ms Karin Stenberg, World Health Organization (WHO)

Service Availability and Readiness Assessment (SARA) tool for health system planning and management

Dr Kavitha Viswanathan, World Health Organization

Crucial role of medical devices in emergency & essential surgical care

Dr Meena Cherian, World Health Organization

Kits for humanitarian health response

Dr Lisa Thomas, World Health Organization

Interagency list of medical devices for reproductive, maternal, newborn and child health

Ms Laura Alejandra Velez Ruiz Gaitan, WHO Medical Devices Unit

WHO medical device information system

Ms Laura Alejandra Velez Ruiz Gaitan, WHO Medical Devices Unit

Health Technology Assessment

Creating synergies between national HTA and regional HTA agencies and hospitals in the assessment of medical devices

Prof Americo Cicchetti, Health Technology Assessment International (Italy)

How to set up an HTA agency

Mr Sumeet Singh, International Network of Agencies for Health Technology Assessment (Canada)

Information retrieval for HTA

Ms Sari Susanna Ormstad, Norwegian Knowledge Centre for the Health Services (Norway)

Nomenclature, Standards and Regulations

GMDN - A Requirement for Unique Device Identification

Mr Mark Wasmuth, Global Medical Device Nomenclature Agency (UK)

Partnership on regulatory harmonization

Dr Li Tao, Asian Harmonization Working Party (China)

International standards – state of play and future trends in the medical domain

Ms Nicole Denjoy, DITTA (Belgium)

Medical software – regulatory and legal trends

Ms Nicole Denjoy, DITTA (Belgium)

National Regulatory Assessment Tool

Dr Yukiko Nakatani, WHO Medical Devices Unit

Digital hospital 21st century: you certainly can't manage it if you don't understand it (YCCMIIYDUI)
Mr Thomas Judd, Center for Healthcare Information Policy and Research (USA)

Health Tech Management / Clinical Engineering

Healthcare Technology Management (HTM): ACCE advanced clinical engineering workshops
Mr Antonio Hernandez, American College of Clinical Engineering(USA)

Improving data quality and technology management with mobile devices
Mr Robert Parsons, Health Partners International (UK)

Computerized Maintenance Management Systems (CMMS): essential features and pitfalls to avoid
Mr William Gentles, American College of Clinical Engineering (Canada)

WHO template for technical specifications of medical equipment
Ms Laura Alejandra Velez Ruiz Gaitan, WHO Medical Devices Unit

A new generation web-based medical technology management system
Dr Kallirroi Stavrianou, INBIT (Greece)

Medical equipment donations: a toolkit for UK – developing country partnerships
Ms Shauna Mullally, Tropical Health and Education Trust – THET (UK)

Medical Imaging and Radiation Safety

Role of medical physics in promoting radiation safety culture in health care
Dr Maria del Rosario Perez, World Health Organization

Medical imaging education in developing countries
Dr Jan Labuscagne, International Society of Radiology

Biomedical Engineering

Human resources for medical devices: the role of the Biomedical Engineer
Ms Adriana Velazquez-Berumen, WHO Medical Devices Unit

How to define the basic academic curriculum to train clinical engineers
Prof Saide Calil, Clinical Engineering Division/ International Federation for Medical and Biological Engineering (Brazil)

Harmonization of biomedical engineering education: status and challenges
Prof Ratko Magjarevic, International Federation for Medical and Biological Engineering, FMBE (Croatia)

Enhancing biomedical engineering education through innovation experiences
Prof James Goh, National University of Singapore (Singapore)

Innovation

Innovation Sandbox Workshop: engaging medtech entrepreneurs to improve health in low- and middle-income countries through the power of co-creation
Ms Aya Caldwell, CAMTech, Massachusetts General Hospital (USA)

Training for local innovation of affordable and appropriate medical devices in developing countries: learning from the Stanford India Biodesign experience
Dr Balram Bhargava, Stanford-India Biodesign, (India)

Local production of medical devices in Africa: characterizing the landscape and assessing feasibility

Mr Mladen Poluta, WHO Medical Devices Unit

Optimizing the WHO Compendium of Innovative Health Technologies for Low-Resource Settings

Ms Jennifer Barragan, WHO Medical Devices Unit

Reproductive, Maternal, Newborn and Child Health

MANDATE: priority setting for medical devices to reduce maternal, fetal and neonatal mortality

Dr Doris Rouse, RTI International (USA)

Medical device introduction: adding the Non-pneumatic Anti Shock Garment (NASG) for obstetric haemorrhage to programs and policies

Ms Elizabeth Andrea Butrick, Safe Motherhood Program, Univ. of California, San Francisco (USA)

Approaches to Improving Healthcare Delivery

Améliorer les pratiques des projets d'appui à l'équipement médical intégrant des dons

(Improving practices in medical equipment support projects which include donations)

Ms Cathy Blanc-Gonnet, Humatem (France)

A tool for prevention and early diagnosis of neuro-degenerative diseases

Mr Ludovico Ciferri, International University of Japan / Istituto Superiore Mario Boella (Japan)

Disaster preparedness for health technology managers

Dr Yadin David, International Union for Physical and Engineering Sciences in Medicine / Health Technology Task Group (HTTG) (USA)

WHO/UN Tools to Improve Healthcare Delivery

Supporting integrated national strategic health planning, costing and health impact analysis: the OneHealth Tool

Time: 09:15-10:00, Friday 22 November 2013

Organizers: UNAIDS, UNDP, WHO, WB, UNFPA, UNICEF, the Futures Institute

Ms Karin Stenberg, WHO (stenbergk@who.int)

Organizer's Report: A presentation was given on the OneHealth Tool, a software developed jointly by a range of international agencies, including WHO. The primary purpose is to provide health planners in low-and middle income countries with an integrated framework for planning, costing, impact analysis, budgeting and financing of strategies for all major diseases and health system components. The OneHealth Tool takes a comprehensive approach to health systems. It incorporates planning and costing of all the health systems building blocks: human resources, facilities, equipment and transportation, medicines and supply chains, health management information systems, monitoring and evaluation, governance activities such as policy and advocacy, and activities related to financing and administration.

The first official version of the OneHealth Tool was released in May 2012. Since then the model has been applied in more than 25 countries to date, most of which in sub-Saharan Africa. While most applications look at resource needs for the entire health sector across programmes and system components, the tool is being used in some countries to look at disease or programme-specific resource requirements. In 2014, the tool will see further development of an NCD (non-communicable diseases) costing and impact module.

The workshop was attended by 30 participants and included a Q&A session.

For more information on the OneHealth Tool see http://www.internationalhealthpartnership.net/en/tools/one-health-tool/

Service Availability and Readiness Assessment (SARA) tool for health system planning and management

Time: 10:00-10:45, Friday 22 November 2013

Organizers: WHO/UN

Dr Kavitha Viswanathan, WHO (viswanathanka@who.int)

Abstract: The Service Availability and Readiness Assessment (SARA) is a health facility assessment tool designed to assess and monitor the service availability and readiness of the health sector and to generate evidence to support the planning and managing of a health system. SARA is designed as a systematic survey to generate a set of tracer indicators of service availability and readiness. This workshop presented the overview of this tool as well as a few country reports.

Crucial role of medical devices in emergency & essential surgical care

Time: 11.10-12.00, Friday 22 November 2013

Organizers: WHO Global Initiative for Emergency and Essential Surgical Care

Dr Meena Cherian, WHO (cherianm@who.int)

Expert members of the WHO Global Initiative for Emergency & Essential Surgical-Care will be part of the workshop.

Abstract: Emergency and Essential Surgical Care (EESC) cuts across several disease-specific programs such as maternal and child health, HIV, and non-communicable disease (e.g. injuries, cancer, diabetes, and neglected tropical disease). Timely access to life-saving medical devices is crucial for delivering surgical services, with the ultimate goals of reaching MDGs and strengthening health systems. This workshop informed participants on the applicability of the WHO Integrated Management for Emergency & Essential Surgical care (IMEESC) toolkit for challenges in access to medical devices, evidence-based planning to address gaps, and guidance on anesthesia infrastructure, supplies, and life-saving basic equipment to deliver the Primary Surgical Care Package in resource-constrained settings.

Organizer's report: There were 60 participants and there were good discussions on Medical Devices in Surgical Services

Kits for humanitarian health response

Time: 13:30-15:20, Friday 22 November 2013

Organizers: WHO/UNFPA/UNICEF

Dr Lisa Thomas, WHO (thomasl@who.int)

Ms Wilma Doedens, UNFPA

Representatives of humanitarian agencies will sit on a panel during the workshop.

Abstract: This workshop aimed to raise awareness and share information on the use of kitted medical commodities to increase access to priority health interventions/services in humanitarian settings. Representatives of humanitarian organizations and UN agencies used recent disasters – such as Typhoon Haiyan in the Philippines – to discuss unique challenges and innovative approaches.

Interagency list of medical devices for reproductive, maternal, newborn and child health

Time: 16.00-16.50, Friday 22 November 2013

Organizers: WHO/UN

Ms Laura Alejandra Velez Ruiz Gaitan, WHO (velezruizgaitanla@who.int)

Abstract: The H4+ Interagency List of Medical Devices for Essential Interventions for RMNCH is a tool to support planning in the health sector for the selection, quality assurance, and procurement of medical devices to implement the Reproductive, Maternal, Newborn and Childhood Health (RMNCH) interventions. The objective of this list is to propose an international consensus on rational selection of essential medical devices for reproductive health according to their public health relevance on the basis of evidence regarding, efficacy, safety and cost effectiveness.

Since June 2012, UNICEF, UNFPA and WHO have been working together on the development of this Interagency list. The objective of this workshop was to share the experience, from an interagency perspective, of having an international consensus on a medical devices list, to discuss the application of the list at country level and to agree on future work needed to complement the work already done.

Organizer's Report: The perceived impact of this project was generally positive. However, the need for instructions to better understand the tables was noted. The end user was an important issue addressed as the audience pointed out that the level of detail in the interventions and in the device descriptions will be of different interest for a doctor, a nurse, an engineer, a planner or an administrator of a hospital. The compilation of evidence based guidelines on RMNCH published by WHO and special notes on medical devices was well appreciated.

WHO Medical Device Information System

Time: 17:00-17:50, Friday 22 November 2013

Organizers: WHO Medical Devices Unit

Ms Laura Alejandra Velez Ruiz Gaitan, WHO (velezruizgaitanla@who.int)

Abstract: The Medical Device Information System (MEDEVIS) is a project directed at addressing the WHA resolution on health technology—specifically paragraph 2.6, which requests the establishment and regular update of an evidence- and web-based health technology database to serve as a clearinghouse which will provide guidance on appropriate medical devices according to level of care, setting, environment, and intended health intervention, tailored to the specific needs of the country or region. The WHO Medical Devices Unit has developed a prototype of a database of medical devices to meet these needs.

Many challenges have appeared as result of this exercise, including questions about a global nomenclature, regulation and evaluation of technologies. WHO is compiling the information and seeking feedback on the structure and logistics of filling and updating the proposed system.

This workshop aimed to discuss the development of MEDEVIS: who are the users, what are the useful and applicable variables, and what would be an efficient process for updating and corroborating information. The opportunity for workshop participants to share examples of using a database on medical devices at the country level was also welcomed.

Organizer's report: Some countries, such as Brazil, can serve as examples of the work done on a database of medical devices. The suggestion of the audience was to strengthen collaboration between Ministries of Health, NGOs, Institutes or other agencies interested in the topic; taking into consideration the need for a multidisciplinary team for creating, supervising and updating it. Nomenclature and information sources endorsed by WHO should also be taken into account when developing the database.

Health Technology Assessment

Creating synergies among national and regional HTA agencies and hospitals in the assessment of medical devices

Time: 09:15-12:00, Friday 22 November 2013

Organizers: Health Technology Assessment international (HTAi)

Prof Americo Cicchetti, Catholic Univ. of Sacred Heart (americo69@me.com)

Dr Iñaki Gutiérrez Ibarluzea, OSTEBA/HTAi, Spain

Dr Carole Longson, NICE/HTAi

Abstract: The level of value produced by the adoption and use of medical devices is strictly dependent on the organizational context where the healthcare process is occurring. Professional competencies, clinical procedures, managerial solutions and other medical technologies interact with medical devices to produce outcomes. Under these conditions, the assessment of medical devices should be completed using evidence collected in the specific hospital context. The decentralization process occurring in the HTA movement is an emerging phenomenon in many countries. Hospitals and other HCOs are facing increasing pressure in relation to financial equilibrium, and they are more and more interested in rational decision-making processes in order to select and adopt new health technologies (HTs). However, local HTA units often coexist with regional and national processes in the same system. In order to avoid duplication of work, as well as to have a comprehensive pipeline of assessed HTs, it is crucial to find avenues for collaboration and to look for a win-win strategy.

How to set up an HTA agency

Time: 13:30-15:20, Friday 22 November 2013

Organizers: INAHTA

Mr. Sumeet Singh, CADTH

Mr. Héctor Eduardo Castro Jaramillo, IETS

Ms. Jani Mueller, CMeRC

Dr Iñaki Gutierrez Ibarluzea, OSTEBA

Abstract: The broad framework of HTA lends itself to wider applications of evidence based decision making resulting in overall system benefits. Using HTA will not only yield important information to address deficiencies in different health systems but will also encompass a wider understanding of the overall impact requiring comprehensive policy considerations and further deliberations and research. However, institutionalization of the HTA programs varies from country to country. For example, a HTA program in a high-income country could provide evidence for appropriateness of expenditures, value for money through improved health outcomes and thereby best return on investment. On the other hand, in low and middle income countries, using HTA could be a possibility to ensure provision of an effective and efficient care in a resource poor setting.

Conducting HTA requires specialized skills which vary from country to country and within a country. It also requires a multi-disciplinary team of experts. A multi-disciplinary HTA agency always provides competitive advantage by creating an environment where experts from various fields can work together. INAHTA has used certain criteria to formally recognize a HTA agency and currently have members across all the continents. This provides some form of a standard for establishment and maintaining a HTA agency.

This workshop will focus on the criteria used by INAHTA for recognition of a HTA agency and take a stepwise approach to guide the participants through a process of establishment of HTA agencies in their own setting.

HTA agencies from 4 different countries and from different backgrounds are going to share their perspectives on setting up an agency. Two of the agencies have in existence for a number of years and are well established while the other two agencies are new. These agencies will share their experiences for establishment of a HTA agency and maintaining their affiliation to INAHTA.

Organizer's Report: The focus of the workshop was to guide the participants through a process of establishing an HTA agency in their own setting and also to point out some of the criteria to consider.

A general presentation on setting up an agency was given followed by country examples from a number of INAHTA member agencies; CADTH (Canada), CENETEC (Mexico), ASERNIP-S (Australia), CGATS (Brazil) and CMeRC (South Africa). These agencies offered the whole spectrum of possible experiences as they not only came from different backgrounds but also have been in existence for different periods: long term, medium term and newly established. The member of these agencies shared their experiences for establishment of a HTA agency.

A short questionnaire was distributed to the participants in order to understand their background, and to establish if they were interested in opening an agency and would like to be contacted by INAHTA. The other questions asked were: existence or non-existence and level of HTA activity in their country, availability of funding and resources, and the type of agency to be established or is in existence. A discussion was held at the end of the session. Those who filled in the questionnaire and wanted INAHTA to contact them came from different backgrounds (local, hospital, regional or national) and represented countries from Asia, Africa and Europe. Additionally, part of the audience expressed active interest in the availability of capacity building measures for HTA. INAHTA is keen to assist with capacity building for HTA and will follow-up with those who seek support in institutionalizing HTA in their respective settings.

Information retrieval for HTA

Time: 16:00-17:50, Friday 22 November 2013

Organizers: Norwegian Knowledge Centre for the Health Services (NOKC)

Ms Sari Susanna Ormstad, NOKC (sor@nokc.no)

Organizer's Report: The aim of the workshop was to alert participants to key issues regarding literature searching for health technology assessments (HTA), as well as to services, resources and competencies that are needed for information retrieval for HTA. The presentation focused on important aspects of information retrieval for HTA, such as scoping and developing the research question, sources to search, how to design search strategies, reference management, and documenting and reporting the search process. An overview of relevant methods handbooks, web resources and training opportunities was presented at the end of the session.

Twenty (20) people attended this workshop. Most of the participants were familiar with HTA and had some understanding for search requirements for HTA. Steps in systematic literature searches were presented with examples, and most of the discussions focused on use and coverage of different databases and sources, as well as on how to develop search strategies for the different sources. Issues such as extensiveness of systematic literature searches, and staff capacity and competences needed for information retrieval for HTA, were also raised and discussed during the workshop.

Nomenclature, Standards and Regulations

GMDN - a requirement for Unique Device Identification

Time: 9:15-10:45, Friday 22 November 2013

Organizers: GMDN Agency

Mr Mark Wasmuth, GMDN Agency (mark.wasmuth@gmdnagency.org)

Abstract: The GMDN Agency is responsible for the Global Medical Device Nomenclature (GMDN), the international standard for medical device naming specified by ISO 15225. This workshop intended to raise awareness of the need for international harmonisation of medical device naming to support the efficient exchange of information between manufacturers, regulators and users of devices. The GMDN is used by over 65 countries to support medical device regulation and is fully endorsed by the International Medical Device Regulator Forum (IMDRF). Following a recommendation by the IMDRF, the GMDN has been nominated as the generic naming descriptor and one of the essential data elements needed to implement Unique Device Identification (UDI). This workshop explained the features and benefits of the GMDN and its relationship to UDI. Examples of the use of UDI were presented. Opportunities were available for the audience to ask questions on access and implementation of the GMDN.

Organizer's Report: The main message from the conference delegates was that the GMDN is a welcome global standard and will be important for the WHO to support the GMDN as the single nomenclature for medical devices in the future. In attendance were many high profile representatives from medical device regulators and healthcare authorities, some familiar with using the GMDN and some not, mainly from developing economies.

Partnership on regulatory harmonization

Time: 11:10-12:00, Friday 22 November 2013

Organizers: APEC, AHWP and Department of Commerce, USA

Dr Li Tao, AHWP (Ltao@its.jnj.com)

Mr Jeff Gren, Department of Commerce, USA

Abstract: For many developing countries, access to safe, affordable, quality medical devices is challenging. However, partnerships with developed regulatory jurisdictions, cooperation with regulator consortia, support from the medical device industry, harmonization of regulatory standards, and approaches with international best practices make it possible for patients to access these products. Recent examples illustrate the value of such partnerships to regulatory harmonization. The Association of Southeast Asian Nations (ASEAN) established ASEAN Economic Community with the target of a single market by 2015. The 10 member states have agreed to and are pursuing harmonization of medical device regulations and a common technical document. The approach is a common Medical Device Directive (AMDD), which is scheduled to take effect in 2015.

The 10 ASEAN Member States are each at different stages in the development of a medical devices regulatory regime. In an effort to help ASEAN Member States benefit from countries with experience in medical device regulation (both pre- and post-market), a US government and industry 2013 pilot program has been launched, in cooperation with the ACCSQ MDPWG, involving U.S. and Australia alumni regulators and industry regulatory experts, providing training focused on helping the 10 ASEAN Member States to prepare for the ASEAN MDD. APEC, AHC and AHW also worked together to organize a series of workshops to sharing experiences of implementation of GHTF guidance in priority areas. For example - clinical evidence, nomenclature and UDI, combination products, etc. are all areas that were considered in the workshops. Regulators and industry experts from US, Japan, Canada, etc. shared their experience with implementing GHTF guidance into their national regulatory system. These activities are part of the strategy and contribute to the goal of regulatory convergence by 2020 set by APEC and AHWP. Most of the work thus far still occurs on an ad hoc basis, and a more systematic approach is needed. More investment and collaboration is required from all stakeholders including WHO, international and regional organizations, government and industry.

International standards – state of play and future trends in the medical domain

Time: 13:30-14:20, Friday 22 November 2013

Organizers: DITTA

Ms Nicole Denjoy (denjoy@cocir.org)

Abstract: International standards are everywhere. They are key in global trade and interoperability of all sorts of products and services, from battery-operated cameras to software systems to air transport. It is for a good reason that the WTO requires its members to base their technical regulation as much as possible on international standards. Standards, however, go well beyond usage in regulatory areas. In the healthcare domain, international standards also provide the best guarantee for equal levels of safety and performance of medical devices. International standards, developed by experts from the key stakeholders and kept up to date by periodic revisions, provide the world with a common set of safety and performance requirements. Uptake and recognition of these standards in national regulations give the best guarantee for availability and access to innovative and safe technology for the best possible health outcome at lowest cost.

The goal was to build awareness by providing an overview of what has been done for the past 10 years and what is in preparation on standards to come in the healthcare domain. It was also a great opportunity to build awareness of all the various international standards that exist (e.g. ISO, IEC, DICOM, HL7), and how these are concretely used in support of regulatory framework but also in the non-regulated domain. This workshop gave an overview of the hot topics in medical standardization, with a view on safety and performance of devices as well as on data exchange, data security and privacy aspects in medical informatics, which are crucial in the emerging field of e-health.

Medical software – regulatory and legal trends

Time: 14:30-15:20, Friday 22 November 2013

Organizers: DITTA

Ms Nicole Denjoy (denjoy@cocir.org)

Abstract: Today's healthcare solutions are increasingly more integrated but become also quite complex, as those systems are combinations of various elements developed by several suppliers. The healthcare domain is highly regulated. However, more and more unregulated elements are being combined with medical technologies. Medical software is regulated differently in various regions of the world, creating unfair competition and uncertainty with regards to roles and responsibilities of key players (doctors, patients, insurers, healthcare providers). Although there are some regulatory obligations in some geographies on Medical Apps, the various organizations bringing integrated care solutions are not necessarily aware of their obligations.

This workshop aimed to provide clarity and build awareness of the regulatory framework for Medical Apps and other stand-alone software and also identified the supporting standards to build an efficient regulatory framework: what regulation is applicable to which software, and how compliance with that regulation can be achieved. It was an opportunity to learn more on the latest updates on current medical software regulations & international comparison, international and EU standards supporting regulations, and practical examples on complying with regulations.

National Regulatory Assessment tool

Time: 16:00-16:50, Friday 22 November 2013

Organizers: WHO Medical Devices Unit

Dr Yukiko Nakatani, WHO (nakataniy@who.int)

Abstract: The National Regulatory Authority (NRA) assessment tool has been developed as a part of WHO's medical product regulatory activities to ensure access to medical products of assured efficacy, safety, and quality for all. The NRA assessment system being used for vaccines and medicines areas (developed in the 1990s) is significantly more advanced than that for medical devices, which was pioneered in 2003. WHO is currently faced with the challenge of revising the NRA assessment tool for medical devices in harmonization with the tool for vaccines and medicines.

This workshop aimed to demonstrate how to use the WHO-supported NRA assessment system and tool for vaccines as an example, and to discuss the specific NRA assessment indicators required for medical devices as well as the feasibility of the tool for medical devices in various countries.

Organizer's report: Yukiko Nakatani introduced the objective of this workshop and the current status of the regulation for medical devices in the world. Alain Prat presented the principle concept of medicines regulation and the design of the assessment tool. He mentioned how important are the regulatory framework and the implementation of guidelines for the regulatory model in order to NRA assessment. Lahouari Belgharbi presented the WHO initiative to strengthen NRAs: 5 steps capacity building for vaccine production. He explained NRA activity process with country experiences of China and Mexico, and he updated the status of the proposed WHO harmonized tool in 2013. Irena Prat presented the medical devices regulations landscape and the NRA assessment tool for IVD and medical devices, she mentioned to integrate the harmonized tool into the NRA assessment database.

Discussions and suggestions could be summarized as follows:

1. WHO should define/guide the minimum model of regulatory framework for medical devices for low-resource countries. IMDRF/GHTF has already provided a lot of documents but the minimum model might be different from IMDRF documents. The minimum model would be more important for low-resource countries.

2. People/jurisdictions are interested in how to build a smart, harmonised regulatory system with limited capacity and competency of the regulator. WHO should support member states in regulatory capacity building.

3. It might be quite important to define the regulatory framework for medical devices as the minimum/harmonized model for low-, middle- income countries. The NRA assessment tool for medical devices should be developed in accordance with such a framework.

Digital hospital 21st century: you certainly can't manage it if you don't understand it (YCCMIIYDUI)

Time: 17:00-17:50, Friday 22 November 2013

Organizers: Centre for Healthcare Information Policy and Research (CHIRP)

Onsite: Mr Tom Judd, MS, CCE, CPHQ, CPHIMS, Kaiser Permanente (USA)

(tom.judd@kp.org)

Contributing remotely:

Elliot Sloane, PhD, CCE, President - Centre for Healthcare Information Policy and Research, USA

Joe Welsh, JD, MPH, CEO - Collegiate Consortium for Workforce and Economic Development, USA

Paul Sherman, President - Sherman Engineering, President Elect - ACCE, USA

Abstract: e-Health is here to stay! EMR/EHR/HIE, mHealth/uHealth/pHealth/BYOD all have a good value proposition --- and ROI -- for healthcare delivery organizations. No technology is risk-free, and these new technologies bring novel safety, security, and reliability issues very much like "classical" medical devices. The Digital hospital of the Future will manage these elements well, presuming “connected patients.”

However, several challenges exist. EMR software/systems and mobile health technologies can harm patients by errors/failures in diagnosis, therapy, or both, and most countries are working on standards, testing, disclosure, and certification approaches to improve product interoperability, regulatory and product certification frameworks viable and suitable for these new modalities, and user and management training and methodologies to support life-cycle ownership issues.

Engineering skill-sets will be critical for success! Health leaders are considering now how clinical engineers (CEs) can help. CEs play important roles in lifecycle management and integration of these new technologies, but most of their training is informal. CEs can do a better job as leaders, policy developers, and managers only if they have more complete training and understanding, which includes current standards-related training, product applications-level training (EMR/EHR/HIE, ICT), contemporary SW/system SDLC competency, as well as project management and System of Systems Engineering training. This workshop demonstrated the CE Role through national and global case studies of the USA (Meaningful Use, IHE, FDA, ONC/TJC), Saudi Arabia, Colombia, and Macedonia.

Organizer’s Report: About 30 to 40 people attended the workshop. Attendees expressed appreciation of the session and that this is where the field of clinical engineering is heading. A next opportunity is a new journal from IFMBE on CE-IT.

Health tech management / clinical engineering

Healthcare Technology Management (HTM): ACCE advanced clinical engineering workshops

Time: 9:15-10:45, Friday 22 November 2013

Organizers: American College of Clinical Engineering (ACCE)
Mr Antonio Hernandez (hernandezantonio@comcast.net)
Mr Thomas Judd, Kaiser Permanente Clinical Technology
Mr Tobey Clark, University of Vermont & Healthcare Technology Foundation
Mr Mario Castaneda, Healthitek, Inc. and Former National Director, Clinical Technology Kaiser Permanente
Also Contributing: Mr Binseng Wang, Dr Elliot Sloane, Dr Fred Hosea

Abstract: Over 50 Advanced Clinical Engineering Workshops (ACEWs) have occurred over the past 20 years in 29 countries with over 4000 attendees. The focus of the ACEWs in primarily low-resource countries has been on building HTM capacity. The 72 American College of Clinical Engineering (ACCE) faculty presenters have interacted with participants during ACEWs, health system stakeholders pre and post, and worked on independent projects to improve HTM worldwide. This pre-conference workshop provided concise background on these ACEWs and focused on the most recent programs. Each of these ACEWs was developed to focus on country needs and requests by partners and stakeholders in government, academic, healthcare system and private sectors. The value of these events is shown by actions taken to improve health based on technological solutions and management of the technology to enhance safety, reduce costs and enrich quality.

Organizer's Report: There were about 100 attendees consisting of Ministry of Health representatives from Africa, Latin America, East Asia, Europe and representatives from a variety of NGOs present. There were a few major themes that resulted from the workshop: 1) planning ACEWs for French-speaking West/Central Africa countries; 2) suggesting that ACCE and others to travel Africa measuring HT improvement and sharing best practices; 3) finding funds for ACEWs in Africa; 4) implementation of remote learning programs for rural areas; and 5) measuring the true impact of ACEWs.

Improving data quality and technology management with mobile devices

Time: 11:10-12:00, Friday 22 November 2013

Organizers: Health Partners International
Mr Robert Parsons (rparsons@healthpartners-int.co.uk)

Abstract: The first part of the presentation is a review of the evolution of inventory and management systems. We review the purpose of inventory management in the context of patient safety, and as a part of the overall system of healthcare involving people, knowledge, equipment and resources. We then review stages in the evolution of inventory input systems, exploring issues of accuracy, comprehensiveness, timeliness, reliability and usability for management and maintenance purposes. Finally we review a typology of input and communication systems, considering tools, format of data, and repository types. In the second part we consider the current situation, where budgets remain tight but connectivity is steadily increasing. This affords opportunities to leverage increased mobility of both platforms and data to improve accuracy, reliability and usability of data. Both software and hardware are evolving towards mobility and reach and towards device simplicity. The movement towards tablet computing has enabled a significant development in human computer interaction (HCI) which makes data collection much more effective. We review mhealth and mhelp data on data collection tools. We then demonstrate in real time a mobile platform configured for use with PLAMAHS, showing how data collection can be immediate, flexible and multi format (using smartphones and both Apple and Android devices). We consider how data can more effectively become knowledge, and how trustworthy data can contribute to patient safety and better outcomes by focusing technicians' work more effectively and releasing clinicians to concentrate on clinical care. Finally we consider issues of management, and how improving inventory data can increase effectiveness of management within the overall health system. [I classified it as an oral presentation, but it could also work nicely as a workshop, with less discussion and more practice with the devices. I'm happy to fall in with however you feel it is best organized. What we can show is using an app on both Android and Apple devices to collect and submit data in real time. We can take and upload photos simultaneously, scan bar codes, and enter text and numeric data. We can then look at and analyse the collected data on a remote server. And we can also, impressively, add geolocations, and map where all the contributions are coming from. (On the day we plan to have some accomplices in Nigeria and in the Philippines uploading during the session.) We can also give participants the opportunity to upload data on any one of my collection of smartphone, android tablet and iPad. It's all very exciting.

Organizer's Report: We looked at inventory taking as part of good HTM practice, which increases patient safety. Without accurate inventory taking all subsequent reporting is compromised. We demonstrated a tablet based form app designed to take data about equipment including make and model, location, condition, with images and documents attached and with a hand written signature identifying the data collector. This allows inventory taking to be handled electronically even in locations with no power or connectivity. The results were displayed in real time on google spreadsheets, and geo-located on a map.

We also demonstrated the possibilities for making and reading QR codes by distributing codes among the audience and inviting them to use freely downloadable apps on their phones to read the codes. Some audience members were delighted to discover that they were sterilizers and others that they were X-ray machines, both apparently in good condition. Overall the lesson is that mobile devices provide now ways of improving reliability and responsiveness of service, which will improve health outcomes by increasing the reliability of medical equipment.

Approximately 60 people attended and the technology worked seamlessly.

Computerized Maintenance Management Systems (CMMS): essential features and pitfalls to avoid

Time: 13:30-14:20, Friday 22 November 2013

Organizers: American College of Clinical Engineering (ACCE)
Mr William Gentles, ACCE (billgentles@sympatico.ca)

Abstract: The management of an inventory of medical devices in a large hospital or healthcare system is a challenging responsibility that can be facilitated by the use of a software program commonly called a Computerized Maintenance Management System or CMMS. The most basic feature of a CMMS is the inventory of medical devices in the organization. Only after the inventory of assets has been captured in an electronic form, is it possible to gain an understanding of the state of the assets, and where the greatest needs for replacement of worn out assets are.

This workshop gave an overview of the essential features of such systems in small and large organizations, with an emphasis on low-resource settings. Some of the many pitfalls and hidden costs that can be encountered when implementing a CMMS were discussed. The session ended with an open discussion of audience experiences with implementing CMMS. Topics covered in the workshop were: why a CMMS is a useful tool, why we cannot just use a paper system to do the same job, a list of the essential (and some optional) features of a CMMS, the importance of backups, how to choose a CMMS that fits your needs, and pitfalls to avoid.

Organizer's Report: The workshop was intended to raise the awareness of some of the issues that will be encountered when trying to implement a Computerized Maintenance Management System in a developing country. There were about 30 people in attendance, and a lively question period followed the initial presentation. The cost of many commercial systems is an obstacle to their implementation, and there was a discussion of the availability of "free" open-source programs that could be downloaded from the internet. Although the WHO document "Computerized Maintenance Management System", a part of the WHO Medical Device Technical Series, contains a list of such free software, the links in the document have all become inactive. One program that is currently available for download at no cost is: Openmedis (Open Source Medical Device Information System). This program is written to run on a web server, not on a standalone computer. In many cases in developing countries, a reliable internet connection is unavailable, so web-based programs such as this one will not be appropriate. A discussion will be initiated on INFRATECH to try to discover other open source CMMS software.

WHO template for technical specifications of medical equipment

Time: 14:30-15:20, Friday 22 November 2013

Organizers: WHO Medical Devices Unit

Ms Laura Alejandra Velez Ruiz Gaitan, WHO (velezruizgaitanla@who.int)

Abstract: In developing countries there is a significant need for counseling regarding minimum specifications and requirements that should be considered before starting a process of purchase or donation of medical devices. Having this type of specification allows for improved access to medical devices of high quality, safety and efficacy, and adequate planning for the financial, human, and legal resources, among others, to be considered in the implementation, functioning and decommissioning of the devices.

Since early 2011, WHO, in collaboration with a working group of experts, has been developing a global template that applies to all types of medical devices. We have started a pilot to develop 70 specifications for different kind of devices. This pilot test involves the participation of WHO collaborating centers and trade associations.

The objective of this workshop was to share and provide feedback regarding the content, process and application of technical specifications at the country level. We also shared the experience of developing technical specifications in the UN.

Organizer's Report: Participants reaffirmed the need for and utility of having global information on technical specifications of medical devices. It was noted though that the user, limitations, and medical devices should be considered and "technical specification" be defined. Comments with regards to the values and ranges of the specifications were received. Some questions about the process and implementation of the specifications were asked. And lastly, some offered to review the pilot technical specifications to give feedback.

A new generation web-based medical technology management system

Time: 16:00-16:50, Friday 22 November 2013

Organizers: Institute of Biomedical Technology – INBIT

Dr Kallirroi Stavrianou, Institute of Biomedical Technology (roy@inbit.gr)

Prof Nicolas Pallikarakis, Institute of Biomedical Technology

Dr Zhivko Bliznakov, University of Patras

Mr Panagiotis Malataras, Institute of Biomedical Technology

Mr Andreas Serafetinidis, Institute of Biomedical Technology

Mr Efmorfia Adamidi, University of Patras

Abstract: Healthcare delivery, today, is entirely technology-oriented and medical equipment plays a major role in improving the quality of patient care. However, the increased number of medical devices (MDs) installed in hospitals leads to a number of problems associated with their proper management. In such an environment, with strong demands for health services of high standards and as low as possible costs, the rational management of medical equipment becomes particularly crucial. The Clinical Engineering Departments (CEDs) need to implement comprehensive Medical Technology Management programs, which should be able to address complex and multidimensional tasks requiring special expertise and dedicated tools in order to achieve the best results. This work presents a new generation of medical technology management software system, developed to assist the CED, with emphasis on safety, efficiency and effectiveness in medical technology in use. It is based on more than 20 years of experience in this field and is a re-engineering result of a previous successful management system in order to meet the new demands in the domain and take advantage of new ICT means. The system provides capabilities to monitor and follow all the procedures related to the medical equipment life-cycle and to collect, store, retrieve and analyse the relevant data. It gives the ability to assess the overall condition of MDs and facilitate the decision-making process towards the improvement of medical equipment management. The system is multilingual, web-based and explores the latest technology in the field of web development and services. It offers a 24/7 access to the MDs data, from any desktop, notebook, tablet PC or even a smart phone, connected to the Internet. It is designed to respond to the new trends and increased demands in the changing healthcare environment worldwide, and assist the CEDs in the broader role they are expected to play.

Organizer's Report: The workshop focused on the mission and needs of Clinical Engineering Departments (CED) within hospitals and on the role of software tools for the management of medical equipment. Emphasis was also given on the characteristics that those systems should have in order to satisfy modern needs.

Prof. Nicolas Pallikarakis (INBIT, Greece) opened the workshop and welcomed the panel of experts. Prof Saide Calil (UNICAMP, Brazil) made an introduction in medical technology management needs stressing the crucial reasons why a Medical Equipment Management System (MEMS) is essential in a hospital's CED. Following that, Mr Panagiotis Malataras & Dr Kallirroi Stavrianou (INBIT, Greece) demonstrated a MEMS developed by INBIT as an example of such a tool. Dr Yadin David (ACCE, USA), Mr Bill Gentles (BTMTC, Canada), and Mr Tom Judd (ACCE, USA) made comments on the features and characteristics that MEMSs should have. They also mentioned some capabilities that could be present to increase effectiveness in terms of user interface (colour coding, online communication/video calls, possibility to function also offline) and interoperability (data exchange with other hospital information systems, medical equipment and testing devices, barcode readers). Finally, the workshop closed with comments and questions from the audience.

During the workshop a questionnaire was distributed to the participants aiming to further investigate needs, trends and attitudes regarding MEMS in terms of adoption and use.

The conclusions drawn from the workshop discussions and from the analysis of replies to the questionnaire could be summarized as follows

- The use of MEMS appeared to be of great importance for the Clinical Engineering Departments.
- Most of the hospitals are using some kind of MEMS and they recognise its great importance and its contribution to the quality and cost management among others.
- Although an in-house MEMS would probably better fit particular needs of a CED, it is not a cost effective solution and it is difficult to keep it updated in long term. Additionally, data collected would not be fully compatible amongst the various systems for further use.
- The users would happily accept the use of a free of charge MEMS. However, the provision of a system without fees for the users should be supported by the developers and a sponsorship would be necessary in order to cover service and maintenance costs.
- Especially for the developing countries there were two additional conclusions:
- The infrastructure appears to be poor as far as computer skills and internet access are concerned.
- However, there is a strong need for a MEMS to be used in order to at least keep track of the medical equipment and spare parts inventories.

The workshop was attended by approximately 50 participants

Medical equipment donations: a toolkit for UK – developing country partnerships

Time: 17:00-17:50, Friday 22 November 2013

Organizers: Tropical Health and Education Trust – THET

Ms Shauna Mullally, THET (shaunamullally@gmail.com)

Mr Andrew Jones, Head of Partnerships, THET

Ms Maggie Collins, Communications Coordinator, THET

Mr Timur Bekir, Communications Officer, THET

Abstract: The Tropical Health and Education Trust (THET) is a UK-based specialist global health organisation that educates, trains and supports health workers in low-resource settings through partnerships. A significant number of the approximately 200 partnerships supported by THET include medical equipment donations from the UK to the developing country partner, in order to support the training or clinical goals of the partnership. To encourage good practice, THET has produced a toolkit for good medical equipment donation practices. Based on the WHO's 'Medical device donations: considerations for solicitation and provision' guidance document, the toolkit provides practical UK-specific guidance to partnerships to assist them in evaluating whether or not to donate, and how to do so effectively if they decide to donate. It also includes case studies from both UK and developing country partner perspectives, and links to other resources. The toolkit's content covers each stage of the equipment donation process, including an initial needs and capacity assessment and project plan. It also covers how to source the equipment, store and pack it, verify its quality and safety, ship and receive it, put it into service, use and maintain it. Finally, it provides guidance on evaluating and learning from the donation. We propose to formally 'launch' the toolkit [Understanding WHO has strict rules about anything construed as endorsement, we are happy to change wording from' launch' if necessary] during a workshop, beginning with a 5-minute video featuring UK and Zambian partners. We will then cover each stage of the donation process, presenting cases studies of both successes and lessons learned. Finally, we will conclude with an examination of how the partnership model itself can foster good donation practices.

Organizer's Report: This workshop introduced a new toolkit for good medical equipment donation practices for UK-developing country health partnerships. The toolkit identifies the 7 stages of the donation process; each section providing step by-step guidance to assist health partnerships in the UK in evaluating whether or not to donate and how to do so effectively. This includes the main activities and tasks; responsibilities of the UK and DC partners; key additional stakeholders; common challenges; practicalities to consider; and signposts to further resources and guidance, such as the WHO's guidance document 'Medical device donations: considerations for solicitation and provision'.

As part of the workshop a short film 'Making It Work: Managing medical equipment in low-resource settings' was screened. This documentary takes a look at the negative impact inappropriate medical equipment donations can have and what THET and others are doing to ensure well thought out, appropriate donations become the norm. The film also highlights the lack of qualified biomedical engineers in Zambia and other African countries and the role health partnership's can play in training engineers, and improving the maintenance and management of medical equipment.

During the last part of the workshop, Nicholas Adjabu (Ghana Health Service), Bill Gentles (Canadian Medical and Biological Engineering Society) and Beverly Bradley (University of Toronto's Centre for Global Engineering) presented a new research project funded by Canada's International Development Research Centre to scope equipment donation practices in Canada and Ghana. The objective of the project is to identify organisations and their practices, and to advocate for knowledge sharing on good practice.

The Tropical Health and Education Trust (THET) is a specialist global health organisation that educates, trains and supports health workers through partnerships; enabling people in low- and middle-income countries to access essential healthcare. THET's toolkit will be available online at www.thet.org in early 2014. For more information contact hps@thet.org

Medical Imaging and Radiation Safety

Role of medical physics in promoting radiation safety culture in health care

Time: 9:15-10:45, Friday 22 November 2013

Organizers: WHO Global Initiative on Radiation Safety in Health Care Settings
International Organization for Medical Physics (IOMP)
Dr Maria del Rosario Perez, WHO (perezm@who.int)
Dr Kin-Yin Cheung, IOMP
Mr Pablo Jimenez, PAHO/WHO
Mr Madan Rehani, IOMP
Dr Slavik Tabakov, IOMP
Mr Fridtjof Nüsslin, IOMP
Prof Habib Zaidi, IOMP

Abstract: Medical physicists (MPs) play a crucial role in promoting and implementing radiation safety culture, as the product of individual and group values, attitudes, perceptions, goals, patterns of behavior and practices that determine the commitment and proficiency of a healthcare institution on radiation safety management. Most medical physicists are skilled in managing safety and appropriate utilization of radiological devices for diagnosis and therapy. Radiation safety culture in health care is embedded in the broader concept of patient safety and is going beyond good medical practice. Establishing a radiation safety culture must start from the top of the organization. However, the dimensions and promotion of the culture will rely on all the relevant stakeholders involved in provision of the service, including directors, administrators, physicians, technical staff, support staff, patients and families. MPs train staff on radiation safety, implement QA and radiation safety programmes, advise medical staff on patient dose reduction through dose optimization in clinical procedures, and ensure all practices and procedures involving radiation comply with national legislative requirements and international guidelines and standards. They should support the framework for organizations to be accountable for continually improving service quality and for ensuring the safeguard of high standards by creating an environment that fosters excellence in clinical care. This includes comparing quality & safety performance to benchmarks and aspiring to move beyond those benchmarks in order to achieve the highest attainable levels. MPs are key players in radiation protection education & training and continuous learning of health professionals which, together with team working and effective communication, are key components of a safety culture programme. MPs provide technical assistance to analyze root causes of radiological incidents, their failure mode and their consequences, to move from “error reports” to “safety learning reporting systems”.

Medical imaging education in developing countries

Time: 11:10-12:00, Friday 22 November 2013

Organizers: International Society of Radiology (ISR)
World Federation for Ultrasound in Medicine and Biology (WFUMB)
International Society of Radiographers & Radiological Technologists (ISRRT)
Dr Jan Labuscagne (ISR) (jlabuscagne@isradiology.org)
Dr Dieter Nuernberg (WFUMB)
Mr Stewart Whitney (ISRRT)

Abstract: Medical Imaging plays a central role in patient care in all parts of the developed world. This is also the case in big cities of the developing world, but not so in the rural areas. There exists a shortage of equipment, as well as technologists to operate the equipment.

Equipment can be readily sourced, provided the budget is available. Technologists then need to be trained to operate the equipment and perform the Imaging studies.

But having the ability to perform Imaging studies is not enough; these studies need to be interpreted to be of benefit. This is traditionally the role of the Radiologist. There is however a great shortage of trained Radiologists in most developing countries, and those that are available, are usually concentrated in the big cities.

It follows that other medical staff also need to be trained to do first line interpretation of basic Imaging studies. These can be doctors, X-ray technologists, or nurses.

Aims

1. To inform participants about the various international organizations' programs and material for training.
2. To gather information by participants about specific needs.
3. To discuss proposals for possible programs to be proposed to the WHO.

Format

1. Three presentations outlined the various international organizations' current programs and material for education.
2. This was followed by opportunity for participants to give information about their situations and needs.
3. Discussion about possible actions.

Biomedical engineering

Human resources for medical devices: the role of the Biomedical Engineer

Time: 13:30-14:20, Friday 22 November 2013

Organizers: WHO Medical Devices Unit

Ms Adriana Velazquez Berumen, WHO (velazquezberumena@who.int)

Abstract: WHO is currently leading a global effort to draft a publication on the role of the biomedical engineer as part of the WHO Medical Device Technical Series. In this workshop, the contents of the book were discussed and debated with the goal of producing an effective and useful publication. The authors of each chapter presented their sections of the book, after which participants discussed and made suggestions for improvement.

How to define the basic academic curriculum to train clinical engineers

Time: 14:30-15:20, Friday 22 November 2013

Organizers: CED/IFMBE

Prof Saide Calil, State University of Campinas (calil@ceb.unicamp.br)

Abstract: Contrary to several other well-established engineering professions (civil engineering, mechanical engineering, etc.), there is no unique model for clinical engineering. Countries adopt different models and, as a consequence, different duties for this profession. Also, teaching units adapt their training courses according to the human resources available for teaching. Therefore, one of the main challenges for teaching units to train Clinical Engineers, according to the needs of their national health system, is the definition of the basic academic curriculum. What is the necessary core of competencies that is expected from a Clinical Engineer to perform his/her basic duties? How to define such core? How to define the disciplines to be offered and encompass the defined core? How to find out the requirements of Hospitals, Industries and Government (National and Regional) and so define the general needs of the health system? How to define the time for each discipline? It was the intention here to describe a method to establish the minimum core of competencies for Clinical Engineering. We then considered the new trends of Clinical Engineering that may be added to the long established Maintenance Management knowledge such as cost control, risk management, training programs and information technology. Finally, it was presented how clinical engineering must adapt to the new trends of the healthcare system regarding system integration, usability and human factor engineering.

Harmonization of biomedical engineering education: status and challenges

Time: 16:00-16:50, Friday 22 November 2013

Organizers: IFMBE

Prof Ratko Magjarevic, IFMBE (ratko.magjarevic@fer.hr)

Prof Herbert Voigt, Boston University

Prof James Goh, National University of Singapore

Mr Mario Fojas Secca, the New University of Lisboa

Ms Martha Zequera, Pontifica Universidad Javeriana, Bogota

Abstract: Biomedical Engineering education programs are present at a large number of universities all over the world. The health care systems around the world need a large number of professionals with engineering education to support medical technology. In a world of growing incidence of chronic disease and ageing population, there is a constant need for innovation in health care technologies and for new solutions which meet the requirements for continuous monitoring, support or care. According to the data from the Labor Organization in the U.S., biomedical engineering jobs have the largest growth at the engineering labor market with 72% of growth rate from 2008-2018. The number of patents in European Union is the highest in biomedical technology. Is that enough to ensure availability of health care for everybody all over the globe? How can biomedical engineering curricula be adopted to the new needs and expectations of the future? Presenters of the workshop addressed these items and proposed solutions for appropriate biomedical engineering education programs of the future.

Enhancing biomedical engineering education through innovation experiences

Time: 17:00-17:50, Friday 22 November 2013

Organizers: Department of Biomedical Engineering, National University of Singapore

Prof James Goh, National University of Singapore (biegohj@nus.edu.sg)

Abstract: The aim of Biomedical Engineering undergraduate degree programs is to produce engineers with a strong foundation in engineering sciences that is relevant to the biomedical field, such that they are able to contribute to the biomedical industry through innovation, enterprise and leadership. The NUS educational program in Biomedical Engineering is characterized by a strong emphasis on scientific and engineering fundamentals and a high degree of flexibility which can provide a wide diversity of educational experiences. We have created opportunities for students to have cross-discipline exchanges with staff and students from Biological Sciences to broaden their understanding and knowledge, consequently stimulating them to think about engineering principles in biological systems. We have also incorporated in our BME Design modules with requirement for innovations; as such, students are encouraged to interact with clinicians to uncover unmet clinical needs. To further enrich our students' "real world" learning experience, we have developed a number of enhancement programs, such as the Industrial Attachment Program, Vacation Internship Program and Technopreneurship & Incubation Program. In the face of globalization, cross-cultural communication is becoming more and more important. Therefore, we have Special Programs like the NUS Overseas Colleges which allows students to work with a company overseas for up to one year. By providing graduates with a combination of broad-based fundamentals and specialized knowledge, our Biomedical Engineering program strives to graduate versatile biomedical engineers who would be best positioned to innovate and lead, and contribute to the delivery of better healthcare technology.

Innovation

Innovation Sandbox Workshop: engaging medtech entrepreneurs to improve health in low- and middle-income countries through the power of co-creation

Time: 9:15-12:00, Friday 22 November 2013

Organizers: CAMTech, Massachusetts General Hospital (MGH)

Ms Aya Caldwell, MGH (acaldwell1@partners.org)

Dr Data Santorino, CAMTech MUST

A panel of experts will lead the workshop.

Abstract: CAMTech brings together interdisciplinary teams to mitigate technology and market risks, and ultimately deliver quality medical technologies to LMICs. CAMTech's approach is co-creation across disciplines (engineering, medicine and business), sectors and geographies, with end-user input continuously influencing medical technology innovation. Few entrepreneurs are prepared to successfully navigate the complex path from new idea to large-scale commercialization of a product in LMICs. Different disciplines and sectors generally work in isolation in the technology development process. This reinforces major barriers to bringing products to market-WorkshopOur workshop will offer a unique opportunity to address these barriers by convening groups from diverse disciplines to provide feedback on technologies, which will then be applicable broadly to other entrepreneurs in the medtech sector. CAMTech will identify three to five entrepreneurs, depending on the length of the session, from its existing network. Each entrepreneur will present their technologies, partnering plans and business plans to the participants. CAMTech will ensure that the entrepreneurs represent a unique perspective of the medtech product development process such as incorporating entrepreneurs from distinct regions (e.g. Southeast Asia, sub-Saharan Africa, OECD) and developing diverse products (e.g. mHealth, devices etc.). The participants will then provide real-time feedback on what is necessary to ensure that the product scales to its intended user to ensure wide-scale public health impact. A similar workshop was held in India at the Federation of Indian Chambers of Commerce and Industry (FICCI) conference in September 2013 with an overwhelmingly positive response. Expected Results Through the workshop, CAMTech will write a white paper after the workshop. The white paper will coalesce the discussions from the workshop to provide a framework for other entrepreneurs in the medtech sector. By providing forums that bring together these experts across disciplines and providing targeted feedback, the end-result can be transformative.

Organizer's Report: Few entrepreneurs are prepared to successfully navigate the complex path from a new idea to large-scale commercialization of an innovation in low- and middle-income countries (LMICs). Different disciplines and sectors generally work in isolation in the technology development process. This reinforces major barriers to bringing products to market. To break down these barriers, CAMTech has created Innovation Sandbox workshops where entrepreneurs have the unique opportunity to brainstorm with a diverse group of experts. CAMTech selects entrepreneurs in various stages of technology development from its existing network and beyond to participate in these workshops. Each entrepreneur presents his/her technology, path to market and business plan to the participants, specifically highlighting the challenges they are facing in moving their technology forward. The participants of the Sandbox then provide real-time feedback on what is necessary to ensure that the product scales to its intended user to have wide-scale public health impact.

CAMTech was invited to host an Innovation Sandbox workshop at the *Second Forum on Medical Devices held by the World Health Organization*. CAMTech selected two entrepreneurs supported by ON, who had received CAMTech's Innovation Award to present at the event. These included the Augmented Infant Resuscitator (AIR) and WiCare's Negative Wound Pressure Therapy device. AIR and WiCare each highlighted three challenges for a total of six for groups to tackle for the remainder of the workshop. Each group was comprised of a mix of engineers, clinicians and business experts through identification (with a coloured sticker) when they joined the workshop. The integration of diverse disciplines ensured cross-disciplinary collaboration to provide real-time solutions. At the end the workshop, groups presented their potential solutions for each challenge. For example, one challenge discussed was how an innovator should decide where to file and how best to protect intellectual property (IP). Suggestions from the group included an online registry that can report counterfeiting as well as ensuring that there is strong branding since, in many of these markets, IP will not be protected, especially if it is a small company. Over 60 participants attended the workshop.

Training for local innovation of affordable and appropriate medical devices in developing countries: learning from the Stanford India Biodesign experience

Time: 13:30-15:20, Friday 22 November 2013

Organizers: Stanford-India Biodesign, All India Institute of Medical Sciences (AIMS)

Dr Balram Bhargava, SIB/AIMS (balrambhargava@yahoo.com)

Dr Avijit Bansal, SIB Alumnus Fellow, Co-founder - Windmill Health Technologies

Dr Aanan Khurma, Consultant - Stanford India Biodesign

Dr Ayesha Chaudhry, SIB Alumnus Fellow, Co-founder - Windmill Health Technologies

Nitin Sisodia (on-site)

Himanshu Gupta (on-site)

Abstract: Developing countries import 80-90% of their medical devices from high-income countries. These devices are often unaffordable and not suited for use in resource-constrained settings. Also, low income settings have specific needs and constraints – with which developed country innovators are not conversant. Dismal health conditions along with rapidly growing healthcare markets, industry and academia therefore present an unprecedented need and opportunity for "Local innovation of appropriate and affordable medical devices in the developing world."

Stanford Biodesign has evolved and pioneered a process for innovation of affordable medical devices and a methodology for training professionals from diverse disciplines in the innovation process. In 2008, All India Institute of Medical Sciences, Indian Institute of Technology and Stanford Biodesign came together under the Stanford India Biodesign (SIB) program with a mandate to enhance the med-tech innovation ecosystem and to train the next generation of med-tech innovators. Since then several doctors, engineers, designers and scientists have trained at the program, inventing 21 devices (1 commercialized) and founding 5 start-up companies. Being the country's flagship program, we have accumulated valuable experience in training as well as ecosystem building activities.

This workshop educated potential innovators about the fundamentals and philosophy of local innovation of affordable medical devices. It also educated policymakers from low-income countries about the working of a successful innovation process and program. The session featured takeaways from the SIB experience, an overview of how to set up a working unit and raise funds as part of the Biodesign process, and hands-on working-learning sessions covering need identification, invention, and implementation.

Organizer's Report: The workshop revolved around the Biodesign process for innovation of medical devices for unmet clinical needs. It focused on the Biodesign process of Identify, Invent and Implement as practiced by AIIMS, New Delhi. It also described the structure of courses offered, fellowships and internships, and the various products that have come out of this programme either as transferred technology or as start ups. The presentation was interspersed with hands on activity for better understanding. The workshop was attended by people from around the world with different backgrounds in academia, medicine, engineering and business. The total number of attendees was close to 45. The workshop helped participants to understand Biodesign's perspective of innovation and that it is open for collaborations to make an impact on society at a global level.

Local production of medical devices in Africa: characterizing the landscape and assessing feasibility

Time: 16:00-16:50, Friday 22 November 2013

Organizers: WHO Medical Devices Unit

Mr Mladen Poluta, WHO, University of Capetown (mladen.poluta@uct.ac.za)

Mr Amir Sabet Sarvestani, WHO, University of Michigan

Mr Peng Si, WHO, Nanyang Technological University

Prof James Abbas, WHO, Arizona State University

Abstract: “Improving access to medical devices through local production and technology transfer" is part of an EU-funded project at WHO now in the second phase of its execution. The project aligns with the mandate given to WHO by the World Health Assembly in 2007 to evaluate and enhance access to appropriate medical devices, especially in low-resource settings. This workshop, hosted by WHO's Medical Devices Unit, included a brief review of Phase II outcomes of the medical devices component of the Local Production and Technology Transfer project, namely findings from a global survey of access to medical devices, and evaluation of a feasibility tool for local production of medical devices that was tested in four sub-Saharan African countries (Ethiopia, Nigeria, South Africa, and Tanzania). In this workshop, participants were engaged in a targeted discussion around barriers to local innovation and production of medical devices, especially in sub-Sahara Africa, thereby contributing to potential solutions and recommendations that will inform the next stages of the project.

Optimizing the WHO Compendium of Innovative Health Technologies for Low-Resource Settings

Time: 17:00-17:50, Friday 22 November 2013

Organizers: WHO Medical Devices Unit

Ms Jennifer Barragan, WHO (barraganj@who.int)

Dr Heike Hufnagel, WHO

Abstract: The goal of the WHO Compendium of Innovative Health Technologies for Low-Resource Settings is to increase awareness of the devices featured but to also ultimately improve access to those devices. This workshop discussed the issues surrounding the annual call for technologies, the method of evaluation of the submissions, and the dissemination of the publication. Furthermore, the workshop addressed how to improve the publication's utility. It was an open discussion moderated by WHO staff.

Organizer's Report: There were approximately 55 participants in this workshop and about half of them had heard about the 2013 Call for Innovative Health Technologies. As such, the first part of the workshop engaged the audience in a discussion on how to improve the visibility of the Call for technologies, particularly in low-resource settings. The audience suggested posting the Call in local newspapers, contacting all Ministries of Health with the request to distribute the information on the Call to stakeholders in the country, creating a global award for the best innovation to make the project known, distributing the Call to societies involved with health technologies, contacting academia that support innovative technologies, and getting into innovator/user networks.

The second part of the workshop engaged the audience in a discussion on improving the impact and use of the publication: Compendium of Innovative Health Technologies for Low-Resource Settings. Participant suggestions for improving use of the Compendium included that the Ministries of Health seek out innovators published in the Compendium to bring the technologies into their country and that the Compendium be distributed to NGOs who buy and install technologies in low-resource regions. Within the actual publication, the participants suggested making the Disclaimer less restrictive and if that is not possible, then perhaps Compendium should be published outside WHO. They also suggested getting public feedback on the use of the technologies from people actually using them to aid procurement officers in decision-making, and include information on the fact sheets as to how many people/institutions are using the technology already.

The participants also provided some general improvement ideas such as making the Compendium into a dynamic online document with regular updates and that technologies in use but without regulatory approval should have a chance of being accepted too. All the ideas presented at the workshop were noted by WHO and will be duly considered prior to executing the next Call.

Reproductive, Maternal, Newborn and Child Health

MANDATE: Priority setting for medical devices to reduce maternal, fetal and neonatal mortality

Time: 9:15-10:45, Friday 22 November 2013

Organizers: RTI International

Dr Doris Rouse, RTI International (rouse@rti.org)

Dr Elizabeth McClure, RTI International

Ms Bonnie Jones, RTI International

Dr Robert Goldenberg, Columbia University Medical Center

Abstract: This workshop provided training on the use of MANDATE, a decision support tool that can assess the comparative impact of various interventions on maternal, fetal or neonatal mortality in low-resource settings. Effective allocation of limited resources to reduce maternal, fetal and newborn mortality requires an informed decision process. Funded by the Bill & Melinda Gates Foundation, MANDATE is a decision support tool for evaluating where and how to allocate resources for technology development options and other interventions to have the greatest impact on pregnancy-related mortality. Specifically, MANDATE enables a user to assess the impact of technology options, interventions or packages to identify technologies (preventatives, diagnostics, therapeutics) with the greatest potential impact for reducing mortality, impact on mother, fetus and newborn mortality, impact in different settings (hospitals, clinics, and homes), and comparative scenarios to determine relative magnitude of impact.

MANDATE is available to the public at: http://mnhtech.org. MANDATE has assisted public and private sector users in answering questions regarding technology development options for reducing maternal, fetal and neonatal mortality. For example: Companies, NGOs and Universities: What new or improved technologies should we develop to have the greatest impact? Foundations, National and Multi-national Funding Agencies: Where should we invest our funds for developing new technologies, buying current technologies or training birth attendants/health personnel to have the greatest impact? Ministries of Health in-country: What are the technologies or training where we should invest our funds to have the greatest impact? In this workshop we provided participants with an overview of the framework for MANDATE and instructed them on its use by running the model with workshop participants to develop case studies. Following the workshop, participants were able to use MANDATE independently to obtain a quantitative assessment of where innovation might have the greatest potential to reduce maternal, fetal and neonatal mortality.

Medical device introduction: adding the Non-pneumatic Anti Shock Garment (NASG) for obstetric haemorrhage to programs and policies

Time: 11:10-12:00, Friday 22 November 2013

Organizers: Safe Motherhood Program, UCSF

Ms Elizabeth Andrea Butrick, Safe Motherhood Program, Univ. of California, San Francisco (UCSF) (ebutrick@globalhealth.ucsf.edu)

Ms Suellen Miller, UCSF

Ms Katie Giessler, UCSF

Ms Keely Bisch, UCSF

Abstract: Obstetric hemorrhage, including postpartum hemorrhage, remains the leading killer of childbearing women. New medical devices, including the Non-pneumatic Anti-Shock Garment (NASG), have recently been added to the WHO guidelines for the management of postpartum hemorrhage and retained placenta. However, policy makers and implementers need guidance to turn recommendations into practice at the country level. The Safe Motherhood Program of the University of California, San Francisco pioneered research in the NASG and has conducted research or provided technical assistance to implementation efforts in over a dozen countries. Drawing on this experience, we led an interactive workshop for Ministers of Health, Maternal Health Directors, Policy Makers and Program Managers on how to incorporate the NASG, into existing care for obstetric hemorrhage. This workshop led participants through an activity to assess whether and where the NASG could be introduced to a maternal health system as a priority, life-saving intervention. We then shared additional insight from our NASG implementation experiences to demonstrate how to integrate the NASG into existing systems and enhance scale-up and dissemination. Finally, we introduced participants to our online NASG Toolkit of resources they can use to support the introduction/implementation process.

Approaches to improving healthcare delivery

Améliorer les pratiques des projets d'appui à l'équipement médical intégrant des dons (Improving practices in medical equipment support projects which include donations)

**In French and English, not translated **

Time: 13:30-15:20, Friday 22 November 2013

Organizers: HUMATEM

Ms Cathy Blanc-Gonnet, HUMATEM (cathy.blancgonnet@humatem.org)

Ms Aurélie Jeandron, HUMATEM, Ms Barbara Comte, HUMATEM, Mr Maurice Page, HUMATEM

Les projets d'appui à l'équipement médical et les dons d'équipements médicaux qui les caractérisent ont encore toute leur place dans un contexte où les structures de santé des pays en développement manquent globalement d'équipements médicaux et de ressources financières à consacrer aux investissements. Cependant, le volume important de dispositifs médicaux non fonctionnels présents dans les structures de santé, dont la majorité provient de dons, appelle à s'interroger sur l'efficacité de l'aide apportée par les acteurs du Nord

Pour améliorer la qualité de ces dons et projets, il semble indispensable d'intervenir sur trois axes principaux:

- **Ajouter de la qualité et de la responsabilité dans les projets** : sensibiliser les donateurs à « mieux donner » (équipements opérationnels, non obsolètes). Les acteurs de coopération internationale devraient, quant à eux, suivre une méthodologie de projet structurée depuis le diagnostic jusqu'à l'évaluation. Quand cela est possible, ils devraient s'approvisionner en matériel sur le marché local (pour favoriser l'économie locale) et/ou privilégier l'acquisition de technologies adaptées (robustes, rentables, faciles à utiliser et à maintenir).

- **Optimiser la qualité « technique » des dons** : Il faudrait inciter les acteurs de coopération internationale à faire appel à des professionnels biomédicaux (internes ou externes) pour valider les capacités locales (compétences médicales et biomédicales, infrastructure, ressources financières…) et pour vérifier la performance des équipements médicaux avant envoi.

- Promouvoir et défendre les intérêts des professions biomédicales dans les pays en développement où elles sont encore sous-représentées et insuffisamment reconnues. Il faudrait notamment aider les personnels biomédicaux à obtenir les moyens nécessaires à l'exercice de leurs fonctions (formation ; équipements de contrôle, mesure et essai ; accès aux TIC ; budget) et à se fédérer au sein d'associations professionnelles.

Depuis 14 ans, la problématique des dons de matériel médical est au cœur des activités d'Humatem qui s'est donné comme objectif d'améliorer les pratiques. Au cours de cet atelier pré-conférence, seront présentés des services ainsi que des outils méthodologiques et de sensibilisation développés par Humatem et par l'OMS, sur le thème des dons de dispositifs médicaux. Puis, il sera proposé aux participants de prendre part à un exercice de brainstorming pour envisager de nouvelles voies à suivre ou à explorer plus largement dans ce domaine. Enfin, ils seront invités à visionner le film documentaire de 35 minutes « Equipés pour soigner – une enquête sur le don de matériel médical » (2012) et à en débattre.

Medical equipment support projects and **donations of medical equipment** have a real role to play since healthcare facilities in developing countries are lacking medical equipment and financial resources to invest. However, the responsibility of northern countries should be questioned regarding the efficacy of the aid they provide in view of the quantities of non-operational devices existing in healthcare facilities, with the majority being donations.

To improve the quality of these donations and projects, three major axes have to be strengthened among northern stakeholders' practices:

- **Add quality and responsibility to the projects**: donors should be sensitized to "better donate" (operational, not obsolete equipment). International cooperation stakeholders should follow a structured project methodology from preliminary assessment to evaluation. Whenever possible, they should consider procuring equipment locally (to support local economy) and/or prioritizing purchase of appropriate technologies (robust, cost-effective, easy-to-use, easy-to-maintain).

- **Optimize the "technical" quality of the donations:** international cooperation stakeholders should be encouraged to call upon biomedical skills (internally, externally) to validate local capacities (medical and biomedical competencies, infrastructure, financial resources...) and check medical equipment performance before sending it.

- Promoting and advocating for biomedical professions in developing countries where they are under-represented and insufficiently acknowledged. In particular, biomedical staff should be supported to obtain appropriate resources to work (training, premises, test and measurement tools, access to ICTs, budget) and to organise themselves in professional associations.

For over 14 years the issue of medical device donations has been at the heart of Humatem's activities which has set a target to improve practices. During this preconference workshop, some available services and methodological or awareness-raising aids developed by Humatem and WHO in the field of medical device donations will be presented. Then, participants will be asked to take part in a brainstorming exercise to imagine new paths which should be followed or wider explored in this area. Finally, they will be invited to watch the 35 minutes documentary film « Equipped for health – an investigation into medical device donation » (2012) and to debate on it.

A tool for prevention and early diagnosis of neuro-degenerative diseases

Time: 16:00-16:50, Friday 22 November 2013

Organizers: International University of Japan/ Instituto Superiore Mario Boella

Mr Ludovico Ciferri, International University of Japan/ISMB (lciferri@iuj.ac.jp)

Dr Emiliano Albanese, Université de Geneve

Dr Paolo Ariano, Istituto italiano di tecnología

Dr Federico Cabitza, Università di Milano--Bicocca

Dr Rainer Wieching, University of Siegen

Mr Masahito Kawamori, NTT Labs–ITU (contributing remotely, TBC)

Prof Ryuta Kawashima, Tohoku University (contributing remotely, TBC)

Abstract: Increases in life expectancy and reduction of communicable diseases is resulting in an unprecedented epidemic of chronic diseases. Amongst these demographic projections show that prevalence of dementia and of its main cause Alzheimer's disease (AD) are expected to steeply increase in the near future. Early diagnosis is key and many factors may be needed to develop prediction platforms. The session introduces some studies presented in a positioning paper awarded the "Best paper award" at the 2013 International Conference on Multimedia, Information Technology and its Applications (MITA) on the requirements of multimedia data monitoring of neural and cognitive anomalies. Aim of the session is to discuss in an interdisciplinary perspective, including social sciences, engineering, medical science and nursing, the feasibility of a predictive platform for neuro-degenerative syndromes like dementia, especially of early signs of the disease with high positive predictive validity. We will illustrate preliminary findings of studies that investigated the characteristics of a multimedia data-monitoring platform, which includes mechanisms for analyzing established symptoms and traits (i.e., gait changes, sleep and speech disorder, etc.) for early detection of dementia and AD. Examples of practical implementation using smart phones and IPTV will be provided, describing how existing e-health devices and systems can be combined to improve early detection and diagnosis, and enhance healthcare of dementia. The rationale is twofold: first to contribute to elaborate on risk profiles and develop risk scores for dementia and AD, enhancing early diagnosis and improving the quality and reducing the costs of health care.; second to flag up those at risk, who may be amenable of specific preventive strategies, encompassing physical (physical functioning and lifestyle) and mental (monitoring, cognitive training) interventions.

Organizer's Report: The workshop took place in Geneva on the eve of the "G8 Dementia Summit", gathered in London, UK, on December 11, 2013, to propose a coordinated global action to tackle dementia. The number of people living with dementia worldwide is estimated at 44.35 million in 2013, reaching 75.62 million in 2030 and 135.46 million in 2050 (numbers are from the latest update of the evidence, reported in the "Policy Brief for Heads of Government The Global Impact of Dementia 2013–2050"). Most people with dementia live in low and middle-income countries, where steepest increases in numbers in the next decades are also expected. Yet the burden and both direct and indirect costs are still highest in most developed countries. This makes it mandatory to take action at a global level.

The aim of this workshop was to review the progress in the design of a platform to improve detection and prevention of dementia. Dementia is a syndrome characterized by progressive decline in cognitive function (including memory, reasoning and language) that interferes with customary activities of daily life and social relationships, causing dependence and alienation. Alzheimer's disease and vascular dementia are the two main causes of dementia, yet mechanisms are not fully understood. Indeed, despite important advances in research in the past years, disease-modifying drugs are not available, and symptomatic drugs can only temporarily keep the progression of the disease at bay, and they may not be efficacious in all patients. Low awareness, stigma and false beliefs about the disease (including that dementia is normal part of aging and that nothing can be done) cause the late recognition of the disease. Under and late diagnoses are the norm rather than the exception in both low and middle as well as in high-income countries. An improved detection of the disease in the general population can positively impact on timely diagnosis, which can have great implications on public health policy, and for patients and their families.

Main components of the multimedia platform current under development to monitor and detect early indicators of cognitive decline pointing to the potential risk of dementia's insurgence are: analysis of gait changes, sleep patterns and speech/language disorder; the evaluation of hearing impairments, cognitive and nutritional deficits. The platform, designed in close coordination with the medical sector, takes in these factors, properly process them, helping to assess the risk of occurrence of dementia and then direct people to the relevant health care service for diagnosis and care.

The rationale is twofold: to contribute to elaborate on risk profiles and develop risk scores for dementia, enhancing early diagnosis and improving the quality and reducing the costs of health care; to flag up those at risk, who may be amenable of specific preventive strategies, encompassing physical (physical functioning and lifestyle) and mental (monitoring, cognitive training) interventions.

Disaster preparedness for health technology managers

Time: 17:00-17:50, Friday 22 November 2013

Organizers: International Union for Physical and Engineering Sciences in Medicine (IUPESM) / Health Technology Task Group (HTTG)

Dr Yadin David, IUPESM/HTTG (David@BiomedEng.com)

Dr Cari Borras, IUPESM/HTTG

Dr Fred Hosea, Kaiser Permenente

Abstract: Jurisdictions of all sizes, from tribal to national governments and global institutions, are concerned about saving life, protecting property, and preserving the economic base of the community and the environment. When disaster strikes, those who have emergency plans and practice them routinely will be in a better position to help the community. The burden is magnified when it comes to protecting the lives of patients and the staff who take care of them due to the critical dependency of the hospital community on its technology and the increased demand for medical services during disasters. The three stages; those of pre-disaster, the disaster response and the disaster recovery must include specific strategies for protecting systems and devices, especially those that are critical to life and those that present unique hazards like radiation devices and radioactive materials. Healthcare professionals need plans, management tools, and training to help them deal with man-made or natural disasters in the most effective and safe way possible. The understanding of system (including IT networks) and device vulnerability is critical, especially in the case where radiation and contamination containment are necessary. Backup support prioritization and strengthening the resilience of the technology prior to and during disasters are all crucial for the hospital mission. The role of the clinical engineering and medical physicist's community is highly important. This workshop provided participants with knowledge on the variety of vulnerabilities faced by hospitals exposed to earthquakes, flooding, and high-winds risks, as well as the best ways to mitigate the risk of damage and disruption of hospital operations caused by these events. The information was presented by experts from the clinical engineering and medical physicist's communities and offered solutions that can improve the safety of hospitals in disaster events.

Appendix 5

Parallel sessions and abstracts

Saturday

Time	Parallel sessions - Saturday 23rd November 2013
Sat. 10:30-12:00	**Health Technology Assessment: Networks and Societies Around the Globe** Session Chair: Dr. H. David Banta *(Spanish translation available)* *Session Co-Chair: Mr. Alexandre Lemgruber*
	Health Technology Assessment International (HTAi)
	Dr. Carole Longson, NICE, United Kingdom
	International Network of Agencies of Health Technology Asssessment (INAHTA)
	Dr. Wendy Babidge, Royal Australasian College of Surgeons, Australia
	European network of Health Technology Assessment (EUnetHTA)
	Dr. Marina Cerbo, National Agency for Regional Healthcare (AGENAS), Italy
	Network of Health Technology Assessment of the Americas (REDETSA)
	Dr. Alexandre Lemgruber, PAHO
	The International Information Network on New and Emerging Health Technologies (EuroScan International Network)
	Dr. Brendon Kearney, HealthPACT, Australia
	HTAsiaLink
	Dr. Sripen Tantivess, HITAP, Thailand
	International Federation of Medical and Biological Engineering, Health Technology Assessment Division, (IFMBE-HTAD)
	Prof. Nicolas Pallikarakis, INBIT, Greece
Sat. 10:30-12:00	**Health Technology Management: Country Initiatives** Session Chair: Mr. Thomas Judd Session Co-Chair: Mr. Jean-Bosco Ndihokubwayo
	Policy and its implementation for medical equipment management in Laos
	Mr. Thanom Insal, Medical Products Supply Center, Ministry of Health of Lao People's Democratic Republic
	Status of medical equipment in Bangladesh
	Dr. Md Aminul Hasan, Ministry of Health & Family Welfare, Dr. SAJ Md. Musa, PHC, DGHS, Bangladesh
	Time to failure of robust equipment for care of sick neonates in Vietnam
	Mr. Gregory Dajer
	Improvement of medical device management in Ugandan maternal and newborn health units through capacity building
	Mr. Robert Ssekitoleko, Louise Ackers, Sarah Hoyle, Uganda Maternal And Newborn Hub, Uganda
	Audit of emergency obstetric and neonatal care (EmONC) equipment in Zambia
	Ms. Shauna Mullally, Canada; Mr Sitwala Machbani, Senanga District Hospital, Zambia; Mr. Emmanuel Musiwa, Lusaka District Health Office, Zambia
	Biomedical equipment management model for rural areas: A public private partnership approach in India
	Ms. Kristy Kainrath, Trimedx Foundation; Jitendar Kumar Sharma, National Health Systems Resource Centre; Mohammed Ameel, Vatsal Chhaya, T Sundararaman , NHSRC, Ministry of Health, India; Michael Zess, Greg Ranger, Subhashree Rajan, John T Surgener, Trimedx Foundation, India
	Planning for essential perinatal equipment: how to deal with hardware, software and people?
	Mr. Claudio Marco Zaugg, Swiss Tropical and Public Health Institute, Switzerland
	Evidence-based decision making for improving access to healthcare technology in low resource settings
	Mr. Dane Emmerling, Chelsea Whittle, Alex Dahinten, Robert Malkin, Duke University, United States of America
	Combining device innovations and strategic technology management for population care in Peru
	Ms. Rossana Rivas Tarazona, Pontificia Universidad Católica del Perú; Fred Hosea, Consultant; Herbert Voigt, Boston University IUPESM; Tobey Clark, University of Vermont/Healthcare Technology Foundation, USA
Sat. 10:30-12:00	**Regulation of Medical Devices** Session Chair: Ms. Kimberly Trautman Session Co-Chair: Ms. Robyn Meurant
	Harmonization and in-country implementation of regulations
	Shelley Tang, Australia

Sat. 10:30-12:00	Developing a competent regulatory workforce for medical devices in the global environment
	Mr. Rainer Voelksen, Regulatory Affairs Professionals Society (RAPS), United States of America; Philippe AuClair, RAPS European Advisory Committee, Belgium; Sherry Keramidas, RAPS, United States of America
	IMDRF medical device single audit program pilot program
	Ms. Kimberly Trautman, US Food and Drug Administration Center for Devices and Radiological Health, United States of America; Ana Paula Teles Ferreira Barreto, ANVISA, Brazil; Mike Ward, Health Canada, Canada; Larry Kelly, TGA, Australia; Hideyuki Kondo, Ministry of Health, Labour and Welfare, Japan
	IMDRF review of the NCAR exchange program: challenges and opportunities
	Dr Isabelle Demade, European Commission, Belgium
	Best international PMS practice and in-country implementation of PMS systems
	Ms. Shelley Tang, Australia
	Harmonizing the regulation of in vitro diagnostic (IVD) medical devices in developing countries
	Dr. Ruth McNerney, London School of Hygiene & Tropical Medicine, United Kingdom
	Single-use medical devices: re-use and re-processing
	Mr. Antonio Jose G. Hernandez, American College of Clinical Engineering, United States of America
	Codification of medical devices in Portugal
	Ms. Emilia Alves Da Silva, INFARMED, National Authority of Medicines and Health Products, IP, Portugal
	Japanese approach of nomenclature system
	Mr. Tomomichi Nakazaki, Tokyo Women's Medical University, Waseda University Joint Institution for Advanced Biomedical Sciences, Japan
	Harmonization of standards and regulations should be addressed through collaboration of government and the private sector
	Mr. Anil Nanubhai Patel, Abel Torres, UL (Underwriters Laboratories), United States of America
Sat. 10:30-12:00	**Innovation in Medical Devices** Session Chair: Dr. Klaus Schonenberger Session Co-Chair: Prof. James Abbas
	Understanding the broader context of design; the use of design ethnography in engineering global health technologies
	Prof. Kathleen Sienko, Mr. Amir Sabet Sarvestani, Mr. Ibrahim Mohedas, University of Michigan, United States of America
	Partnership in medical technology innovation: avoiding the prototype graveyard
	Mr. Timothy Prestero, Design that Matters, United States of America
	Health economics for device developers: a framework for assessing commercial viability
	Dr. Amanda Chapman, Burn Samantha, University of Birmingham, United Kingdom
	Medical devices for non-communicable diseases: opportunities for innovation
	Mr. Amir Sabet Sarvestani, Prof. Kathleen H Sienko, University of Michigan, United States of America
	Medical device innovation – South Africa as a case study
	Mr. Mladen Poluta, University of Cape Town; Tony Bunn, Medical Research Council, South Africa
Sat. 10:30-12:00	**Health Care Delivery** *(French translation available)* Session Chair: Dr. Ricardo Silva Session Co-Chair: Ms. Hanne Bak Pedersen
	Health First Europe model for community care
	Ms. Amanda Bogg, Health First Europe, Belgium
	Accessibility network
	Mr. German Jose Giles, Dr. Alejandro Ferro, Dr. Alejandro Cristaldi, Municipality of General Pueyrredon, Argentina
	Using population health data analytics to optimize medical device investment decisions in the Kingdom of Saudi Arabia
	Dr. Mazen Hassanain, Halah Eldoseri, Ghada Farhat, Dr. Nabeel Abdulaziz, Dr Mohammed F Zamakhshary, Dr Mohammed Yemni, Dr Mohammed Hamzah Khoshim, Ministry of Health of the Kingdom of Saudi Arabia; Mitchell K. Higashi, Denise T Kruzikas, GE Healthcare; Charles Macal, Michael North, Center for Complex Adaptive Agent Systems Simulation, Decision and Information Sciences Division, Argonne National Laboratory, United States of America
	Should we train users in equipment care?
	Mr. Andrew Gammie, Fishtail Consulting Ltd, United Kingdom
Sat. 10:30-12:00	**Health Care Infrastructure** Session Chair: Dr. Ricardo Silva Session Co-Chair: Ms. Hanne Bak Pedersen
	Risks assessment during a construction or remodeling of health care facilities JCI methodology
	Ms. Claudia Cardenas Alanis, Maria Eugenia Moreno Carbajal, Hospital Medica Sur, Mexico

Sat. 10:30-12:00	Energy in healthcare
	Mr. Paul Merlevede, International Federation of Hospital Engineering (IFHE), Belgium
	Réfrigérateur domestique pour le storage des vaccins
	Dr. Ramzi Ouhichi, WHO, Tunisia; John Llyod, Patrick Lydon, Haithem Aouinet
	Eradication of climate-induced neonatal hyperthermia through nursery building design
	Dr. Hippolite Amadi, Imperial College London, United Kingdom; Dr Mohammed B Kawuwa, Obstetrics And Gynaecology Department, Federal Medical Centre Nguru, Nigeria; Dr Lawal I Mohammed, Ms Hajjah Mohammed, Dr Abdulquddus Oyedokun, Paediatrics Department Federal Medical Centre Nguru, Nigeria
	Audit in centre steriles service department of tertiary hospital
	Mr. Jean Marie Vianney Namahoro, Marina Aucamp, Stellenbosch University, South Africa
Sat. 14:00-15:30	**How to Prioritize Medical Devices** Session Chair: Ms. Dessislava Dimitrova Session Co-Chair: Ms. Olumurejiwa Fatunde
	Is the provision of medical equipment enough? Addressing the need for adequate training and support to maximise the effectiveness of introducing modern equipment into the developing world.
	Dr. Maurice Paul David Burke, University College London/University College Hospital London/ Royal Berkshire Hospital, Reading; James Annkah, Ivan Rosenberg, Gary Royle, University College London; Abiodun Adeyemi, Paula Horne, Kate Ricketts, Royal Berkshire Hospital; Shauna Mullally, Tropical Health and Education Trust (THET), United Kingdom; Eric Addison, Komfo Anokye Hospital; Theophilus Sackey, Korle Bu Teaching Hospital, Ghana
	Rational selection and prioritization of medical devices in low- and middle-income countries
	Ms. Karin-Daniela Diaconu, Samantha Burn-Harris, Semira Manaseki-Holland, Carole Cummins, Richard Lilford, University of Birmingham, United Kingdom
	Applying health technology assessment methods for the selection and prioritization of medical devices: a practical example within the Republic of South Sudan
	Prof. Richard Lilford, Samantha Burn-Harris, Karin Diaconu, Semira Manaseki-Holland, Carole Cummins, University of Birmingham, United Kingdom
	Prioritizing criteria for medical equipment assement in a health care facility
	Ms. Maria Moreno Carbajal, Claudia Cardenas Alanis, Hospital Medica Sur, Mexico
	Methodological guidelines for medical equipment assessment studies
	Mr. Eduardo Coura Assis, Ministry of Health of Brazil; Marcus Tolentino Silva, Department of Science and Technology/ Secretariat of Science, Technology and Strategic Inputs/ Ministry of Health; Renato Garcia Ojeda, Institute of Biomedical Engineering/Federal University of Santa Catarina (IEB-UFSC); Saide Jorge Calil, Center for Biomedical Engineering - University of Campinas (CEB-UNICAMP), Brazil
	RENEM – Brazilian national list of equipment and materials
	Mr. Murilo Contó, Clarice Petramale, Vania Canuto, Erlon Cesar Dengo, Marcio Luis Borsio, Darcio Guedes Junior, Ministry of Health, Brazil
	A web tool to support the user need elicitation for the Health technology assessment (HTA) in emerging countries.
	Dr. Leandro Pecchia, University of Warwick, United Kingdom; S Mullally, Canada; F Crispino, Solution Engineering, Italy; S P Morgan, Electrical Systems and Optics Research Division, University of Nottingham, United Kingdom
	Electronic categorization of medical devices in Slovakia
	Dr. Branislav Jadud, Ministry of Health of the Slovak Republic, Slovakia
Sat. 14:00-15:30	**Health Technology Management: Country Initiatives** *(French translation available)* Session Chair: Prof. Saide Calil Session Co-Chair: Ms. Jennifer Barragan
	Health technology management in Uganda
	Mr. Sam Steve Balayo Wanda, Ministry of Health, Uganda
	Healthcare technology management in Kenya
	Mr. Philip Amoko Anyango, Martin Owino, Ministry of Health, Kenya
	Impact of MDGs attainment on medical equipment management in Rwanda
	Mr. Didier Mukama, BMIT, Rwanda
	Immediate impacts of an inventory on the procurement, donations, maintenance and use of medical equipment at Connaught Government Hospital in Freetown, Sierra Leone
	Mr. Alusine Bobson Kabia, Dr. Oliver Johnson, Ministry of Health of Sierra Leone
	Maintenance des dispositifs médicaux et démarche qualité au Senegal
	Dr. Mamadou Sow, Valoris Santé Services/Horizons-Sahel, Senegal
	Example maintenance management of medical devices in Benin: The case of Papané Hospital
	Mr. Charles Pascal Soroheye, Maliki Seidou Adjarath, Aboubakar Moufalilou, Ministry of Health; Virgile Megnigbeto, Papane Hospital, Benin
	The governance problem in medical equipment donation projects: Case of Togo
	Mr. Komi Agbeko Tsolenyanu, NGO ASMENE (Association for Maternal, Neonatal and Child Health), Togo
	Building management capacities for essential equipment and essential medicines supply in Tanzania. A case study.
	Mr. Reinhold Werlein, Swiss Tropical and Public Health Institute, Basel, Switzerland
	Developing HTM capacity for Haiti
	Mr. Thomas Judd, Kaiser Permanente, United States of America

Sat. 14:00-15:30	**Regulation of Medical Devices: Country Initiatives** *(Spanish translation available)* Session Chair: Mr. Rainer Voelksen Session Co-Chair: Ms. Irena Prat
	Medical devices regulations in Cuba. Progress, challenges and opportunities for regulatory strengthening in the region of the Americas
	Ms. Dulce María Martínez Pereira, Lic. Silvia Delgado Ribas, Centro de Control Estatal de Equipos y Dispositivos Médicos (CECMED), Cuba
	Moving towards harmonization of medical devices in Peru
	Ms Lida Esther Hildebrandt Pinedo, Headquarters of Medicines Inputs and Drugs, DIGEMID, Department of Health, Peru
	Post market surveillance in Saudi Arabia
	Dr. Saleh Al Tayyar, Saudi Food and Drug Authority, Abdullah Thabit, Medical Devices Sector of Saudi Food and Drug Authority, Saudi Arabia
	Regulation on changes to registered medical devices and challenges faced in Singapore
	Dr. Huiling Debbie Ko, Health Sciences Authority, Singapore
	Regulation of medical devices in Tanzania
	Ms. Agnes Sitta Kijo, Tanzania Food And Drug Authority, United Republic of Tanzania
	A new horizon for the medical device sector in South Africa
	Ms. Debjani Mueller, CMeRC, University of Witwatersrand, South Africa
	Regulatory affairs of medical devices in Africa; The Nigeria scenario
	Dr. Charity Ilonze, National Agency for Food And Drug Administration and Control, Nigeria
	Towards the implementation of medical devices regulation based on the WHO model in Malaysia and its challenges
	Mr. Zamane Abdul Rahman, Medical Device Authority, Malaysia
Sat. 14:00-15:30	**Innovation in Medical Devices for Maternal and Child Health** Session Chair: Prof. Kathleen Sienko Session Co-Chair: Ms. Laura Alejandra Velez
	The five typical misfits of medical technology in the developing world: Why devices designed for high-income countries don't work and what to do about it
	Mr. Timothy Prestero, Design that Matters, United States of America
	Helping babies breathe: igniting coverage and quality of newborn resuscitation
	Ms. Ingrid Laerdal, Tore Laerdal, Ida Neuman, Laerdal Global Health, Norway, Sweden
	Evaluation and implementation of a bubble continuous positive air pressure system for newborns
	Ms. Kelley Maynard, Z Maria Oden, Jocelyn Brown, Mary Kate Quinn, Rebecca Richards, Rice University, United States of America; Robert Miros, 3rd Stone Design, Heather Machen, Suzanne Iniguez, Alfred Gest, Texas Children's Hospital, United States of America; O'Brian Smith, Baylor College of Medicine, United States of America, Zondiwe Mwanza, Kondwani Kawaza, Elizabeth Molyneux, College of Medicine, Queen Elizabeth Central Hospital, Malawi
	Innovative robust CPAP for respiratory therapy of neonates in low resource settings
	Mr. Grzegorz Dajer, Medical Technology Transfer and Services Ltd., Vietnam
	Ventouse delivery in a low resource setting - A innovative device
	Dr. Tanya Robbins, MCAI (Maternal and Child Health Advocacy International), United Kingdom; Mr. Arfang Faye, Bansang Hospital, Bansang, Gambia
	Efficacy of the embrace infant warmer to treat neonatal hypothermia
	Dr. Sudhir Borgonha, Jane Chen, Embrace Innovations, United States of America
	Diagnostic devices for pneumonia: A new perspective
	Prof. Michael Script, Guardit Technologies, Research & Development, LLC; Dr. Andre Muelenaer, Pediatric Medical Device Institute (PDMI), Section of Pediatric, Pulmonology / Allergy at the Carilion Clinic, Pediatrics at the Carilion School of Medicine, United States of America
	Unexplored success route to Nigeria's MDG4 target on neonatal mortality
	Dr. Hippolite Amadi, Imperial College London, United Kingdom; Prof. Jonathan C Azubuike, Paediatrics Department Enugu State University Teaching Hospital; Prof Gilbert N Adimora, Paediatrics Department, University of Nigeria Teaching Hospital Enugu; Prof. Akin O Osibogun, Public Health Department University of Lagos Teaching Hospital; Dr. Peter Alabi, University of Abuja Teaching Hospital; Dr. Angela C Uwakwem, Federal Medical Centre Owerri, Nigeria
	The potential impact of disruptive technology using a task shifting model in rural Tanzania
	Mr. Denver Phiri, GE Healthcare, United Kingdom; Janeen Uzzell, GE GG&O, Ghana; Seleman Mbuyita, Godfrey Mbaruku, Ifakara Health Institute, Tanzania; Kallol Mukherji, GE Healthcare, India
Sat. 14:00-15:30	**Medical Imaging** Session Chair: Dr. Jan Labuscagne Session Co-Chair: Dr. Miriam Mikhail
	SOMATOINFRA : The use and application of functional anatomic imaging in disaster medicine, war zones, and its great potential in health screening programmes in developing countries
	Mr. Szego John, Ortho-trauma International LLP, United Kingdom; Prof. Mihaly Szacsky, Budapest Technical University, Hungary
	Digital tomosynthesis after detection of suspicious lesions on chest radiography: effect on diagnostic imaging costs
	Prof. Emilio Quaia, Guido Grisi, Elisa Baratella, Roberto Cuttin, Gabriele Poillucci, Sara Kus, Maria Assunta Cova, Department of Radiology, University of Trieste, Italy
	Experience review on digital imaging, PACS and tele-radiology from a middle income country
	Prof. Dorria Salem, Swiss Tropical Institute, Egypt
	Availability of computed tomography and magnetic resonance imaging devices in the WHO European region
	Ms. Alena Usava, Ivo Rakovac, Enrique Loyola, Natela Nadareishvili, Valentina Hafner, Hanne Bak Pedersen, Claudia Stein, WHO Regional Office for Europe, Denmark
	Accessible and affordable point-of-care ultrasound imaging for resource limited settings
	Dr. Sailesh Chutani, Mobisante Inc., United States of America

Sat. 14:00-15:30	Is digital imaging helping to achieve service coverage? Experience review from a middle income country Mr. Martin Raab, Swiss Tropical and Public Health Institute, Basel, Switzerland; Dr. Tarek Badr, Dr. Dorria Salem, Dr. Seham ElSaadany, Directorate General of Radiology of Ministry of Health and Population, Egypt

Sunday

Time	Parallel session - Sunday 24th November 2013
Sun. 10:30-12:00	**Health Technology Assessment** Session Chair: Dr. Hans-Peter Dauben Session Co-Chair: Mr. Alexandre Lemgruber
	EUnetHTA: a network for added value of European collaboration on HTA Dr. Marina Cerbo, Italy
	Common European HTAs of medical devices Dr. Katrine B Fronsdal, Norway
	Health technology assessment for medical devices: Does one size fit all? Dr. Joseph Lazar Mathew, Post Graduate Institute of Medical Education and Research; Thalakkotur Lazar Mathew, Psg Institute Of Advanced Studies, Coimbatore, India
	Hospital-based Health Technology Assessment in France and Europe - A tool for decision making based on evidence Dr. Alexandre Barna, Emmanuel Charpentier, Björn Fahlgren, Marc Vanicatte, CEDIT, Hôpitaux de Paris, France
	A national system for introduction of new health technologies in Norway - formalized coordination of hospital-based and national HTA Dr. Vigdis Lauvrak, Helene Arentz-Hansen, Brynjar Fure, Inger Natvig Norderhaug, Norwegian Knowledge Centre for the Health Services (NOKC), Norway
	Mini-HTA to support evidence-based decisions for new health technologies in Norwegian hospitals Dr. Helene Arentz-Hansen, Vigdis Lauvrak, Brynjar Fure, Norwegian Knowledge Centre for the Health Services (NOKC), Norway
	The value of investing in technology appraisal: Lessons for decision-makers in resource-constrained environments Dr. Vince S. Thomas, V.S. Thomas Global Health Strategy Consulting, Switzerland
Sun. 10:30-12:00	**Policies for Medical Devices** Session Chair: Prof. Nicolas Pallikarakis Session Co-Chair: Dr. Yukiko Nakatani
	Free trade agreements and medical technology: implications for policy makers and others Dr. Trevor Gunn, GMTA, United States of America
	The role of policymakers for health technologies Dr. Masato Mugitani, Ex-chair for Global Health Workforce Alliance, Japan
	Brazilian industrial health complex: Availability of access, industrial development and innovation policy Dr. Paulo Henrique Dantas Antonino, Eduardo Jorge Valadares Oliveira, Leonardo Batista Paiva, Carlos Augusto Grabois Gadelha, Ministry of Health of Brazil
	The role of the general health council of Mexico (CSG) in the national health system of Mexico Mr. Roberto Ayala, Ms. Elsa Arellanes Jarquin, National Center for Health Technology Excellence, Mexico
	Interaction of HTA and regulation in medical devices: A tool for decision-making Dr. Ana Maria Perez Galan, Catherine Ausqui, Health Technology Department, Ministry of Health, Uruguay
	Analysis of therapeutic appliances using the information of health accounts Ms. Xuedan Yuan, David Morgan, OECD, France
Sun. 10:30-12:00	**Technical Specifications** Session Chair: Prof. Nicolas Pallikarakis Session Co-Chair: Dr. Yukiko Nakatani
	WHO collaboration on a national, EU-funded program for medical equipment procurement Ms. Dessislava Dimitrova, Results for Development Institute, Bulgaria; Prof. Nicolas Pallikarakis, Institute of Biomedical Technology (INBIT), Greece
	Medical equipment technical specification chart (CET): A tool for the selection for procurement of medical equipment in Mexico Mr. Roberto Ayala, Ms. Elsa Arellanes Jarquin, National Center for Health Technology Excellence, Mexico
	Specifications for procurement of medical technologies/Especificaciones para contratacion de tecnologias médicas Dr. Mery Wilma Teran Carreon, Unidad de Medicamentos y Tecnologia en Salud, Brazil; Victoria De Urioste, OPS/OMS, Bolivia
	Technical specifications – experience and resources Mr. Andrew Gammie, Fishtail Consulting Ltd, United Kingdom
	Role of technical specifications in reducing cost and improving access to health technologies Dr. Jitendar Sharma, Mohammed Ameel, Vatsal Chhaya, Akanksha Suri, Deepti Bhagia, T. Sundararaman, Ministry of Health & Family Welfare, Government of India

Sun. 10:30-12:00	**Safety of Medical Devices** *(Spanish translation available)* Session Chair: Mr. Alusine Bobson Kabia Session Co-Chair: Dr. Maria del Rosario Perez
	Impact of radiation safety standards on patient safety in the medical Imaging digital era Dr. Caridad Borrás, IUPESM, United States of America
	Engaging with healthcare professionals in India to improve medical device safety: Medical equipment safety workshop series (India 2013) Dr. Niranjan D Khambete, Sree Chitra Tirunal Institute for Medical Sciences and Technology, India; Alan Murray, University of Newcastle, United Kingdom
	Review of 134 reported clinical medical device incidents Prof. Alan Murray, Newcastle University, United Kingdom
	Assessment of adverse events related to the use of the computed tomography equipment Mr. Ricardo Alcoforado Maranhão Sá, Secretaria De Estado Da Saúde De Goiás, Brazil; Walter Vieira Mendes Júnior, Escola Nacional de Saúde Pública Sérgio Arouca, Fundação Oswaldo Cruz, Brazil
	Turkish medical device tracking system (MDTS) Ms. Funda Guler Ozdiler Copur, Ömer Faruk Kuru, Isbara Alp Sezen, Ismet Köksal, Osman Nacar, Ercan Simsek, Turkish Medicine and Medical Devices Agency, Turkey
	Learning from medical devices incidents in the national health service in the United Kingdom Ms. Dagmar Luettel, Dr. David Cousins, Patient Safety for Safe Medication Practice and Medical Devices, NHS England, United Kingdom
	Medical devices vigilance and patient safety: need for global information extraction and dissemination means Dr. Kallirroi Stavrianou, Zhivko Bliznakov, Nicolas Pallikarakis, University of Patras, Greece
Sun. 10:30-12:00	**Innovative Medical Devices for Low-Resource Settings** Session Chair: Mr. Brendon Kearney Session Co-Chair: Prof. James Abbas
	A low-cost, disposable incubator for enabling point-of-care nucleic acid based diagnostics in low resource settings Mr. Jered Singleton, Dylan Guelig, Chris Zentner, Bernhard Weigl, Paul LaBarre, PATH, United States of America; Josh Buser, Paul Yager, University of Washington, United States of America
	Fully-automated point-of-care detection of malaria and other infectious diseases with a disc-shaped diagnostic platform Dr. Konstantinos Mitsakakis, Sebastian Hin, Oliver Strohmeier, Daniel Mark, Felix von Stetten, Roland Zengerle, Laboratory for MEMS Applications, IMTEK - Department of Microsystems Engineering, University of Freiburg, HSG-IMIT, Germany
	A behaviour changing syringe: Making invisible risk, visible to deter the reuse of syringes in a curative context Dr. David Swann, University of Huddersfield, United Kingdom
	A novel device to screen newborns for hearing loss in resource constrained settings to prevent speech loss Mr. Nitin Sisodia, Neeti Kailas, Sohum Innovation lab, Dr. Chandrasekhar, IISc, Dr. Rakesh Lodha, Dr. Ramesh Agarwal, AIIMS, India
	GlobalDiagnostiX: Development of an entirely new, low cost and robust, digital diagnostic imaging system for low-resource contexts Dr. Klaus Schönenberger, Bertrand Klaiber, Beat Stoll, Program EssentialTech, Cooperation and Development Centre, the Swiss Federal Institute of Lausanne and The EssentialMed Foundation, Lausanne, Switzerland; Social And Preventive Medicine Unit, University of Geneva, Switzerland
	Disruptive innovation for sustainable healthcare - Enabling technologies for portable ultrasound devices Prof. Daniel Steenstra, Dr. John Ahmet Erkoyuncu, Cranfield University, United Kingdom
Sun. 10:30-12:00	**Human Resources in BME** *(French translation available)* Session Chair: Prof. Herbert Voigt Session Co-Chair: Mr. Adham Ismail Abdel Moheim
	Academic models for undergraduate biomedical engineering Dr. Shankar Muthu Krishnan, Wentworth Institute of Technology, United States of America
	IFMBE role in the network of training programs in BME on low-resource countries Prof. Mario Forjaz Secca,International Federation on Medical and Biological Engineering (IFMBE), Portugal; Andre Linnenbank, IFMBE, Netherlands; Ratko Magjarevic, IFMBE, United States of America; Herbert Voigt, IUPESM, Croatia
	Undergraduate engineering student clinical immersion experiences: outcomes and management of expectations Prof. Kathleen H. Sienko, University of Michigan, United States of America; Kwabena A. Danso, Henry S. Opare-Addo, Alexander T. Odoi, Komfo Anokye Teaching Hospital, Samuel Obed, Korle Bu Teaching Hospital, Elsie Effah Kaufmann, University of Ghana; Aileen Huang-Saad, Amir Sabet Sarvestani, Frank W. J. Anderson, Timothy R. B. Johnson, University of Michigan, United States of America
	The role of the regulatory professional in shaping good regulatory policy Dr. Philippe Auclair, Sherry Keramidas, Regulatory Affairs Professionals Society (RAPS), United States of America; Rainer Voelksen, RAPS, Switzerland
	Safe care: An initiative for regulations in Kuwait Ms. Hanan Al-awadhi, Kuwait Association for Biomedical Engineers/Kuwait Society of Engineers,Kuwait
	A survey on the training and performance of medical engineering of professionals in Kenya Mr. Peter Matoke, Association of Medical Engineering of Kenya (AMEK), Martin Owino, Mary Ngugi, Medical Engineering Services Division-Ministry of Health; Gordon Agalo, Peter M. Guchu, KMTC-Nairobi Campus; Shadrack Wamwayi, Francis O. Mbanga, Kenyatta National Hospital; George O.Odongo, Isaac Cheptiony, KMTC-Nairobi Campus, Kenya
Sun. 14:00-15:30	**Local Production in Low-Resource Settings** Session Chair: Mr. Amir Sabet Sarvestani Session Co-Chair: Dr. Heike Hufnagel
	Importance of indigenous R&D and manufacture of medical devices in the light of Bangladesh experience Prof. Khondkar Siddique-e Rabbani, University of Dhaka, Bangladesh
	Challenges in local production of medical devices by domestic manufacturers in India Mr. Balram Sankaran, Sree Chitra Tirunal Institute For Medical Sciences And Technology, India
	Facilitating local production for improved access to in-vitro diagnostics Dr. Ruth McNerney, London School of Hygiene & Tropical Medicine, United Kingdom
	Assessing feasibility of local production of medical devices in Sub-Saharan Africa to improve access to quality medical care using the WHO Feasibility Tool Prof. James Abbas, Arizona State University, USA; Amir Sabet Sarvastani, University of Michigan, USA; Mladen Poluta, University of Cape Town & University of Pretoria, South Africa; Peng Si, Nanyang Technological University, Singapore; Adriana Velazquez-Berumen, WHO
	Seating fabrication system for clinical rehabilitation settings in low income countries. The experience of Mexico and Colombia Dr Jorge Letechipia, Abel Arredondo, Aldo Alessi, Luis Hernández, Graciela Fregoso, Andrés Torres, Robinson A. Torres, Yeison J. Montagut, Ibero Ciudad de Mexico, Mexico

Sun. 14:00-15:30	**Procurement of Medical Devices** *(French translation available)* Session Chair: Mr. Andreas Seiter Session Co-Chair: Mr. Prem Prakash Chopra
	Global price system - project to collaboration in economic information about medical devices Mr. Murilo Contó, Eduardo Coura Assis, Clarice Petramale, Vania Canuto, Ministry of Health of Brazil
	Need for care operators to increase efficiency in medical device procurement through volume pooling, resources and expertise Mr. Charles-Edouard Escurat, GIP Resah-Idf, France
	Mechanisms for introducing large medical devices into developing countries. Avoiding the pitfalls of the past and providing possible solutions for the future Dr. Maurice Paul David Burke, Abiodun Adeyemi, Paula Horne, Kate Ricketts, Royal Berkshire Hospital, James Annkah, Ivan Rosenberg, Gary Royle, University College London, Shauna Mullally, Tropical Health and Education Trust (THET), United Kingdom; Eric Addison, Komfo Anokye Hospital, Theophilus Sackey, Korle Bu Teaching Hospital, Ghana
	HIV diagnostics: Procurement, selection and use Dr. Elliot Cowan, Partners in Diagnostics, LLC, United States of America
	Experience of procurement in Myanmar Prof. Tun Tun Lin ,Yangon General Hospital, Ministry of Health of Myanmar
	Challenges facing medical engineering services in Kenya Ms. Salome Wangari Mwaura, Ministry of Health of Kenya
	PROCOT – Cooperation program to capture technical and economics information about medical equipment Mr. Murilo Contó, Erlon Cesar Dengo, Marcio Luis Borsio, Ministry of Health of Brazil
Sun. 14:00-15:30	**Patient Safety** Session Chair: Dr. Edward Kelley Session Co-Chair: Ms. Helena Ardura-Garcia
	The burden of unsafe injections worldwide: highlights on recent improvements and areas requiring urgent attention Prof. Benedetta Allegranzi, WHO, Switzerland
	Lessons learned and challenges in implementation planning for injection safety initiatives Prof. Benedetta Allegranzi, WHO, Switzerland
	Perspectives of a new WHO injection safety initiative focusing on therapeutic services Dr. Edward Kelley, WHO, Switzerland
	Medical Software Session Chair: Dr. Edward Kelley Session Co-Chair: Ms. Helena Ardura-Garcia
	Medical software: are clinical engineers ready to face the challenge? Dr. Ernesto Iadanza, Clinical Engineering Division/ IFMBE, Italy
	When official training in telemedicine will be available for doctors & nurses? Prof. Olga Ferrer-Roca, UNESCO Chair Of Telemedicine, Spain
	Developing interoperability standards for personal health devices Prof. Daidi Zhong, Chongqing University, Xiaolian Duan, Chongqing Academy of Science & Technology, China, Michael Kirwan, Continua Health Alliance, United States of America
Sun. 14:00-15:30	**Innovative Medical Devices for Low-Resource Settings** *(Spanish translation available)* Session Chair: Mr. Martin Raab Session Co-Chair: Ms. Keiko Fukuta
	Assessment of male circumcision devices for HIV prevention in East and Southern Africa Ms. Julia Samuelson, Tim Farley, Gaby Vercauteren, Irena Prat, WHO, Switzerland; Renee Ridzon, United States of America; Tim Hargreave, Scotland; Stephen Watya, Uganda
	Design to improve pressure ulcer care in the community Mr. Gianpaolo Fusari, Jonathan West, Ed Matthews, The Helen Hamlyn Centre for Design, Royal College of Art, United Kingdom
	3D Virtual reality for prosthetic myoelectrical training Ms. Rosa Itzel Flores Luna, Garcia Del Gallego, Mariano, Juarez Mendoza, Ana Marissa, Ayala Ruiz, Alvaro, Dorador González, Jesus Manuel, Universidad Nacional Autónoma De México (Unam), Mexico.
	Increasing accessibility to safe surgical practices by training non-physician clinicians (NPCs) using a battery-powered anesthesia device. Mr. Denver Phiri, Gisela Abbam, GE Healthcare, United Kingdom; Janeen Uzzell, GE Africa, Ghana; Kallol Mukherji, GE Healthcare, India; Karim Asaad, GE Healthcare, Egypt; Thomas Muithya, Kenyatta University, Kenya
	Using mobile technology to collect medical device usage data in real time Ms. Hallie Sue Cho, OttoClave, United States of America
	Phase I results of a simplified negative pressure wound therapy device for use in low resource settings Dr. Gita Mody, Robert Riviello, Brigham and Women's Hospital; Danielle Zurovcik, Massachusetts Institute of Technology, United States of America; Grace Kansayisa, Dominique Mugenzi, Georges Ntakiyiruta, National University of Rwanda and Kigali University Teaching Hospital, Gemimah Uwimana, Rwinkwavu District Hospital, Rwanda
Sun. 14:00-15:30	**Human Resources in Technology Life Cycle Management** Session Chair: Dr. Caridad Borrás Session Co-Chair: Ms. Laura Alejandra Velez
	Improving patient outcome through technology life cycle management: The role of biomedical engineers Prof. Nicolas Pallikarakis, Institute of Biomedical Technology (INBIT), Greece
	Improving patient outcome through technology life cycle management: The role of clinical engineers Dr. Yadin David, IUPESM/Health Technology Task Group (HTTG), United States of America
	Improving patient outcome through technology life cycle management: The role of medical physicists Dr. Caridad Borrás, IUPESM/Health Technology Task Group (HTTG), United States of America

Sun. 14:00-15:30	**Human Resources in Medical Physics** Session Chair: Dr. Kin Yin Cheung Session Co-Chair: Dr. Pablo Jimenez
	A new initiative of IOMP to support professional development of medical physicists in Africa
	Dr. Slavik Tabakov, IOMP, United Kingdom; Kin Yin Cheung, IOMP, Hong-Kong; Fridtjof Nuesslin, IOMP, Germany; Madan Renahy, IOMP, Austria; Raymond Wu, IOMP, United States of America; Joannis Damilakis, IOMP, Greece; Stephen Keevil, IPEM, United Kingdom; Ahmed Ibn Seddick, FAMPO, Morocco; Rebecca Nakatudde, FAMPO, Uganda; Taofeeq Ige, FAMPO, Nigeria
	Pivotal role of the medical physicist in diagnostic imaging: The new challenges of hybrid imaging technology
	Prof. Habib Zaidi, Geneva University Hospital, Switzerland
	Medical imaging training in low-resource countries - a case study in Mozambique
	Prof. Mario Forjaz Secca, International Federation on Medical and Biological Engineering (IFMBE); Clara Ramalhão, Hospital Pedro Hispano, Portugal
	The role of medical physicist on strategic planning and acquisition of appropriate technology in radiation medicine
	Dr. Kin Yin Chueng, IOMP, China
	Professional accreditation of medical physicists, IOMP perspective
	Dr. Kin Yin Chueng, IOMP, China; Raymond Wu, IOMP and Barrow Neurological Institute, United States of America

Health Technology Assessment: Networks and Societies Around the Globe

Session Chair: Dr. H. David Banta *(Spanish translation available)*
Session Co-Chair: Mr. Alexandre Lemgruber

Health Technology Assessment International (HTAi)

Dr. Carole Longson, NICE, United Kingdom

This panel will explore the various HTA networks and societies around the globe. Each of these organizations provide unique benefits to its members, including local and international networks focusing on the development of HTA capacity, supporting enhanced healthcare decision-making and improving health outcomes. These organizations are defined by their membership or geographic area of focus; including a network solely for HTA agencies, a society engaging across the stakeholder spectrum (agencies, academics, industry, patients and clinicians); or by the regions they serve, such as Latin America or Asia. Each organization and the benefits and opportunities of memberships will be explored. The discussion will be moderated, allowing for questions and discussion.

European network of Health Technology Assessment (EUnetHTA)

Dr. Marina Cerbo, National Agency for Regional Healthcare (AGENAS), Italy

The aim of the workshop is to present work on medical devices done within EUnetHTA, the European network for Health Technology Assessment. Since 2006 EUnetHTA's scientific and technical network co-operation has developed a general strategy, principles, and an implementation proposal for a sustainable European HTA collaboration while developing scientific tools and shared standards for collaboration in HTA production. HTA bodies in all EU member states, Norway, Switzerland, and Turkey have participated. Following a brief introduction providing background and terminology for understanding EUnetHTA's collaborative HTA production, the workshop will give an overview of practical tools developed by the network for common production and sharing of so-called "Core" HTA information and related scientific methodology, like methodological guidelines. Special attention will be given to the HTA Core Model® as assessment framework highlighting the results of several pilot applications on devices. Actual experiences of using this framework for assessing the effects of medical devices, including both full- and rapid assessments, and experiences of using the HTA Core Model® Online tool, will be shared. Speakers will focus on lessons learned from these collaborations in terms of barriers and factors for success related to time, resources, efficiency, and communication. In light of these experiences, future improvements proposed during the Joint Action 2 (2012-5) will be discussed, with the objective of identifying opportunities of reducing unnecessary efforts and optimizing use of resources across borders. Following a brief overview of contemporary policy developments according to Cross Border Healthcare Directive, the workshop opens for discussions with the audience.

Network of Health Technology Assessment of the Americas (REDETSA)

Dr. Alexandre Lemgruber, PAHO

PAHO and an HTM team are developing a strategy to address identified medical device and HTM needs, with the Ministry of Health Haiti. Haiti's healthcare system faces many hurdles, particularly since the 2010 earthquake. There has been biomedical equipment technician (BMET) training since 2011 in the private and public sectors (Equipment Support) as well as the multi-region HTM Health Leader trainings in January 2013 (Management Support), and more expected in October, 2013. Recommendations Desired HTM initiatives the next 5 years:
1 Equipment Support: Make best use of existing trained BMETs (Rotary partnership-46, Tripartite partnership-32)
(i). Additional training cohorts to be determined by public/private hospital demand for BMETs
(ii). Technician training only without Management Support component is not sustainable, as found in ACCE HTM training since 1991.
2. Develop a Health Technology (HT) Unit (using best practice HTM) with public-private partnership (PPP) in the capital, with regional satellites.
(i). Paid HT Manager, and volunteer BMETs (5-6) "on-loan" from local hospitals
(ii). Satellite units (3-4) staffed by volunteer BMETs (2-3) locally "on-loan" under HT Manager oversight
(iii). Best practice HTM developed jointly by paid HTM Coordinator (USA-based) and Haiti HT Manager, under PPP Advisory Board (AB) oversight
3. Includes maintenance support of General Medical devices, as well as Medical Imaging and Laboratory. A PAHO equipment focus area Maternal and Child Health.
3. Move this HT Unit toward full self-sustainability over time; activities to be identified with mutual agreement.
4. Management Supporta. Maintain a network of public and private health leaders to guide HT Unit(s) and provide rotating volunteer BMETs, formalized through PPP AB. Also, develop and enable ongoing training for health leaders and BMETs.
5. Project Supporta. Support hospital technology projects as encouraged by PPP AB; e.g. BMET staffing, equipment user training, eHealth – mobile health, donation guidelines, etc.

HTAsiaLink

Dr. Sripen Tantivess, HITAP, Thailand

This panel will explore the various HTA networks and societies around the globe. Each of these organizations provide unique benefits to its members, including local and international networks focusing on the development of HTA capacity, supporting enhanced health care decision-making and improving health outcomes. These organizations are defined by their membership or geographic area of focus; including a network solely for HTA agencies, a society engaging across the stakeholder spectrum (agencies, academics, industry, patients and clinicians); or by the regions they serve, such as Latin America or Asia. Each organization and the benefits and opportunities of memberships will be explored. The discussion will be moderated, allowing for questions and discussion.

International Federation of Medical and Biological Engineering, Health Technology Assessment Division, (IFMBE-HTAD)

Prof. Nicolas Pallikarakis, INBIT, Greece

Healthcare delivery, today, is entirely technology-oriented and medical equipment plays a major role in improving the quality of patient care. However, the increased number of medical devices (MDs) installed in hospitals leads to a number of problems associated with their proper management. In such an environment, with strong demands for health services of high standards and as low as possible costs, the rational management of medical equipment becomes particularly crucial. The Clinical Engineering Departments (CEDs) need to implement comprehensive Medical Technology Management programs, which should be able to address complex and multidimensional tasks requiring special expertise and dedicated tools in order to achieve the best results. This work presents a new generation of medical technology management software system, developed to assist the CED, with emphasis on safety, efficiency and effectiveness in medical technology in use. It is based on more than 20 years of experience in this field and is a re-engineering result of a previous successful management system in order to meet the new demands in the domain and take advantage of new ICT means. The system provides capabilities to monitor and follow all the procedures related to the medical equipment life-cycle and to collect, store, retrieve and analyze the relevant data. It gives the ability to assess the overall condition of MDs and facilitate the decision-making process towards the improvement of medical equipment management. The system is multilingual, web-based and explores the latest technology in the field of web development and services. It offers a 24/7 access to the MDs data, from any desktop, notebook, tablet PC or even a smart phone, connected to the Internet. It is designed to respond to the new trends and increased demands in the changing healthcare environment worldwide, and assist the CEDs in the broader role they are expected to play.

Health Technology Management: Country Initiatives

Session Chair: Mr. Thomas Judd
Session Co-Chair: Mr. Jean-Bosco Ndihokubwayo

Policy and its implementation for medical equipment management in Laos

Mr. Thanom Insal, Medical Products Supply Center, Ministry of Health of Lao People's Democratic Republic

Lao PDR is among the least country with a per capita gross domestic (GDP) of US$630 (2008). Almost 35% of the population lives below the poverty line (2005), 73% of the population resided in rural areas. The health care services are provided through 6 at central, 16 provincial, 129 districts and 837 health centers. Most of medical equipment provided to the health care services in all levels are from the donation and some are from the loan of the bank (WB & ADB). With limited resources and lack of management system, the country is facing low quality of health care services. In 1993, the country had only two biomedical engineers and a few technicians to deal with the maintenance. The manager of the hospitals at all levels did not know how to manage the medical devices. The Policy on Medical Equipment Management (PMEM) is introduced in Lao PDR since 2003. To bring the policy into the practice, a pilot project so called" Medical Equipment Management project" (MEMP) has been established in 2004 with the support of Lux-development. The success of this pilot project later led to the establishment of a number of projects. Through the implementation of this policy the medical equipment management is improved. The numbers of biomedical engineers have increased from 2 to 7; the training has been organized in and outside the country. Two regional workshops were established, the inventory has been done in the whole country. Each provincial hospital has a maintenance team which provides the service to the district hospitals and health centres. A comprehensive policy (the health infrastructure and technology) is developed. A big step has moved forward but the implementation of PMEM still have a big challenge and needs the collaboration from the international.

Status of medical equipment in Bangladesh

Dr. Md Aminul Hasan, Ministry of Health & Family Welfare, Dr. SAJ Md. Musa, PHC, DGHS, Bangladesh

Introduction: Ineffective use and subsequent poor operational performance of medical equipment are the main challenges in developing countries. The chronic lack of functioning medical equipment is generally regarded as an important contributor to the poor quality of health care delivery in Bangladesh like developing country.
Objectives: To explore the main factors contributing to differences in equipment effectiveness in the health sector of Bangladesh.
Realization: The geographical and socio-economic distribution of medical equipment is closely linked to the distribution of health care facilities and services in general. In most developing countries especially in Bangladesh, these patterns of distribution are highly unequal. Whereas more than half of the population in many low- and middle-income economies is rural, health care and other amenities are available mostly in urban areas. In reality, in most developing countries, more than half of the limited public sector financial resources are spent on national-, teaching- or regional tertiary care hospitals, which make a relatively small contribution to the reduction of predominant diseases.
Results:
(i) The direct consequence of the absence of specific policies, with regard to the management of physical assets.
(ii) Ineffective use of the equipment is the important factor (timely equipment maintenance and replacement are regarded as part of this utilization process).
(iii) The fast changing technology in the international equipment market, and the sophistication of modern equipment are regarded as reasons for poor equipment performance in developing countries. The other equipment problem is thought to originate from imperfect selection and purchasing procedures.
Conclusion: Poor performance of the existing equipment is an important contributor to the health crisis in developing countries especially in Bangladesh. Outlook: International medical device companies must look increasingly at developing countries to drive growth.

Time to failure of robust equipment for care of sick neonates in Vietnam

Mr. Gregory Dajer

Background: CPAP is an essential tool in the treatment of RDS in infants, one of the leading causes of newborn mortality. However, CPAP machines are often unsuitable for use in low resource settings as they are insufficiently robust, unnecessarily complex, too expensive to purchase or rely on expensive consumables. MTTS Asia, a Vietnamese biomedical company, has partnered with East Meets West (US based NGO) to design and manufacture a CPAP device suitable to hospitals in low resource countries. Existing technology: MTTS has been manufacturing an appropriate CPAP machine for over 7 years (listed in 2012 WHO Compendium of New and Emerging Health Technologies). Between 2007 and 2012, 491 CPAP machines have been distributed across Asia, of which only 1.6% are known to have been scrapped. It is estimated that as many as 30,000 infants are treated each year with MTTS CPAPs. As the current design demonstrates, it is possible to assemble a functional CPAP device using largely off-the-shelf components and keeping high level integration to a minimum. A reasonable amount of custom electronics and software is necessary, but the majority of sub-systems are manually operated and therefore reliant on user knowledge in order to function correctly. Development: Based on extensive customer feedback and benefiting from the access to the new technologies, MTTS is developing the next generation of CPAP which is scheduled to be launched in early 2014. The aim of the redesign is to create a device that is applicable to a wider variety of contexts (independent of the sources of oxygen, medical air and electrical power) and closely integrated in order to reduce overall clinician effort. The other objectives are to improve device safety, patient comfort, usability and ergonomics as well as lowering lifecycle costs by using high reliability components and materials, thus reducing the likelihood of failure.

Improvement of medical device management in Ugandan maternal and newborn health units through capacity building

Mr. Robert Ssekitoleko, Louise Ackers, Sarah Hoyle, Uganda Maternal And Newborn Hub, Uganda

Lack of technical skills in the biomedical engineering field is one of the leading causes of equipment breakdown in low resource countries. In Uganda the biomedical engineering field is just starting to take shape and as a result, there are many areas that are left without much attention in this field. The technicians, who are mainly electricians, only deal with repairs of such equipment. It is very common for technicians to know about the medical equipment only after it is broken down. Such is common with donated equipment which usually ends up going straight to the end user without the knowledge of hospital management or the technical team. For most of these devices, spare parts, user manuals, and service manuals very difficult for the local health facilities to obtain. The Uganda Maternal and Newborn Hub obtained funding through THET (Tropical Health Education trust) to send out a UK trained biomedical engineer to help in skills building of the local technicians in order to improve the way medical equipment are managed. The project focuses on units related to maternal and newborn health, however, the technicians cover equipment for the entire hospital and the skills gained will benefit whole the equipment. As well as in-house mentorship of the technicians, a two week training program was developed in collaboration with the Amalthea Trust and Kyambogo University to give the technicians an introduction to equipment management. Inventories were developed to capture the equipment and their conditions in the maternal and newborn units in seven health facilities. They also were used to establish what equipment had manuals, and which equipment had been bought or donated. The project ensures sustainability by encouraging the health facilities to consult with local medical equipment suppliers on the equipment being bought or acquired through donation. This way, spares and manuals can easily be obtained.

Audit of emergency obstetric and neonatal care (EmONC) equipment in Zambia

Ms. Shauna Mullally, Canada; Mr Sitwala Machbani, Senanga District Hospital, Zambia; Mr. Emmanuel Musiwa, Lusaka District Health Office, Zambia

The Tropical Health and Education Trust (THET) is a UK-based specialist global health organisation that educates, trains, and supports health workers in low-resource settings through partnerships. A significant number of the approximately 200 partnerships supported by THET include medical equipment donations from the UK to the developing country partner, in order to support the training or clinical goals of the partnership. To encourage good practice, THET has produced a toolkit for good medical equipment donation practices. Based on the WHO's Medical device donations: considerations for solicitation and provision's guidance document, the toolkit provides practical UK-specific guidance to partnerships to assist them in evaluating whether or not to donate, and how to do so effectively if they decide to donate. It also includes case studies from both UK and developing country partner perspectives, and links to other resources. The toolkit's content covers each stage of the equipment donation process, including an initial needs and capacity assessment and project plan. It also covers how to source the equipment, store and pack it, verify its quality and safety, ship and receive it, put it into service, use and maintain it. Finally, it provides guidance on evaluating and learning from the donation. We propose to formally 'launch' the toolkit [Understanding WHO has strict rules about anything construed as endorsement, we are happy to change wording from' launch' if necessary] during a workshop, beginning with a 5-minute video featuring UK and Zambian partners. We will then cover each stage of the donation process, presenting cases studies of both successes and lessons learned. Finally, we will conclude with an examination of how the partnership model can foster good donation practices.

Biomedical equipment management model for rural areas: A public private partnership approach in India

Ms. Kristy Kainrath, Trimedx Foundation; Jitendar Kumar Sharma, National Health Systems Resource Centre; Mohammed Ameel, Vatsal Chhaya, T Sundararaman , NHSRC, Ministry of Health, India; Michael Zess, Greg Ranger, Subhashree Rajan, John T Surgener, Trimedx Foundation, India

To recommend a model plan for various states/provinces for outsourcing "management and maintenance of bio-medical technology" inclusive of operational and financial guidelines, National Health Systems Resource Center has partnered with Trimedx to undertake the following research project. Objectives:

1. To understand the principles of Public private partnership engagement in this domain and to estimate "fiscal space" required for such an undertaking.
2. To develop operational guidelines for best-practices in this regard. Scope: The study would be conducted in 5 states in India – one in each zone (North, South, East, West, and Central) in a select district (Universal Health Coverage pilot district), in all public health facilities in the selected district that would include one district hospital (approx. 100 beds), 15-20 community health centers (30 beds each) and 50-60 primary health centers (10 beds each).

Findings: The data would be collected under the following:

A. Empirical Data (from site) Data 1: Line listing of Medical Devices in District & Sub-District Centers Data 2: Functional Status of each Medical Equipment and identifying non-functional ones

B. Secondary Data (from market research) Data 3: Cost involved (C1) to make the redundant technology functional (obtained from Data 2) Data 4: Cost per annum (C2) in Comprehensive maintenance of all the line listed medical Devices (obtained from Data 1)

Results: The final outcome of evaluation would be to estimate amount of funding required per hundred thousand of investment in medical devices inclusive of all facilities per district in India. The scope of the project includes all laboratories, radiology, surgical and all other diagnostic equipment. The study would not include hospital furniture, surgical instruments and hospital linen. The study could potentially be scaled up in many developing countries to formulate model Public Private partnership guidelines for management and maintenance of medical technology.

Planning for essential perinatal equipment: how to deal with hardware, software and people?

Mr. Claudio Marco Zaugg, Swiss Tropical and Public Health Institute, Switzerland

Mother and Child Health Care is a field with rapidly growing knowledge and a constant increase of newly available medical technologies. In many low- and middle income settings, however, even basic perinatal equipment is often not available or functional when it is needed. Health system planners have been seeking tools and methods to increase the coverage and coordinate investments more efficiently. But two central elements fall short; on one hand structured and complete inventory systems are not in place while on the other hand "essential lists" are missing, too generic, outdated, and do not meet the actual needs of health care providers. The Project "Strengthening Perinatal Health in the Republic of Moldova" funded by the Swiss Agency for Development and Cooperation (SDC) has used a mixed-methods approach for the countrywide procurement of essential equipment in perinatology and neonatology at first, a comprehensive nationwide clinical needs assessment has established the medical priority areas. The medical professional association was adapting the existing "essential list" distinctively per level of care, number of births, and on-going reform plans. "openMEDIS" - an open source inventory and management system was used for the data collection of existing medical equipment. The management of data of the > 5000 devices in 35 hospitals was the responsibility of the facilities' technicians. A gaps-analysis comparing actual vs. target has visualized the shortcomings. Gaps have been prioritized together with all stakeholders considering the available resources until a final list of required equipment was established and procured. This work demonstrates that equipment planning is a multidisciplinary undertaking and requires careful preparation and studying of best practice. Capitalizing and promoting the approach among relevant stakeholder eventually drives capital investments towards a more targeted and cost-efficient allocation of funds.

Evidence-based decision making for improving access to healthcare technology in low resource settings

Mr. Dane Emmerling, Chelsea Whittle, Alex Dahinten, Robert Malkin, Duke University, United States of America

There are significant barriers to keeping donated medical equipment in-service in the developing world. However, there is a lack of evidence to guide the development of interventions to increase access to medical equipment. Our data provides an evidence base for the challenges and opportunities associated with three types of interventions: equipment donations, technician training, and enhancement to the hospital environment. We surveyed 3,283 pieces of equipment from selected departments in 65 public hospitals in Honduras, Rwanda, and Cambodia, along with hospital technicians, directors, and clinicians. Our data showed flaws in the donation process. For example, 14% of donated equipment never arrived at the target hospitals and 10% went out of use within in the first year of donation. Additionally, over time, equipment that was newly donated did not remain in-service more often than other equipment. Technician training increased access to medical equipment. For example, in Rwanda training technicians resulted in 43% less out-of-service equipment (10.2% vs. 17.8%;p=0.002) compared to hospitals without trained technicians. The data also shows that hospital environment also had a substantial effect on access to medical equipment. Factors like availability of spare parts, accessories, and consumables) hamper equipment repairs. Communication with clinicians affects equipment lifespan and repair. Supporting the infrastructure at recipient hospitals can aid trained technicians and increase the likelihood that donations will be kept in use. Factors which inhibit the success of equipment donations need to be more carefully studied before recommendations on equipment donations can be made with confidence. Further research on the ecosystem which surrounds the technician is necessary to understand how to best complement increases in technician capacity. Technician training represents an important and potentially sustainable avenue for increasing access to medical equipment.

Combining device innovations and strategic technology management for population care in Peru

Ms. Rossana Rivas Tarazona, Pontificia Universidad Católica del Perú; Fred Hosea, Consultant; Herbert Voigt, Boston University IUPESM; Tobey Clark, University of Vermont/Healthcare Technology Foundation, USA

The Peruvian health sector has been undergoing decentralization and reform since 2000. The challenges include accessibility to quality health care by the vulnerable population in rural areas, the poor quality of health information, and the limited health workforce capacity. Advanced Clinical Engineering Workshops (ACEWs) have led to awareness of healthcare technology management, the creation of Health Technopole CENGETS at Pontifical Catholic University of Peru (PUCP) and collaboration with the University of Vermont on the development of Healthcare Technology Management (HTM) online courses, internships and multi-disciplinary collaborations. Significant impacts have occurred since the 2012 workshop where ACEW faculty and PUCP met with the National Institute of Health (NIH) to discuss and act on the most pressing health and HTM problems in Peru. 1. Maternal and child health projects have been identified for Cusco related to maternal mortality with the principal focus vertical birth, umbilical cord lead findings, and molar pregnancy disease. The application of technology to improve these areas is part of these projects. 2. Biotechnology unit - Healthcare technology management involves coordinated efforts across national, regional and local organizations. The National Institute of Health in Peru created and funded a Biotechnology Unit to bring increased strategic focus on the evaluation, planning and lifecycle management. 3. Heavy metal pollution – Pollution from mining creates severe health problems. The International Union for Physical & Engineering Sciences in Medicine and PUCP will sponsor a Heavy Metal Detection Workshop in Peru. Ongoing efforts continue with NIH and the Cusco region through the collaboration of Boston University and global partners. Emerging technological and organizational innovations can bring substantial benefits in health status. This presentation summarizes the achievements of a multi-year initiative to align technological and organizational resources across international, national, regional and local levels, demonstrating the need for expertise and organizational capacity to lead effective technological change.

Regulation of Medical Devices

Session Chair: Ms. Kimberly Trautman
Session Co-Chair: Ms. Robyn Meurant

Harmonization and in-country implementation of regulations

Shelley Tang, Australia

While the regulation of medicines is well established, and for the most part, built on a universal framework, the regulation of medical devices, including diagnostics, is relatively new for many jurisdictions and the degree of harmonisation is poor, although improving. In the rapidly evolving world of technology, the rate of change in medical device design and development is high, and this provides a major challenge to regulators in maintaining a balance between timely availability of the latest technology, and the need to ensure safety and performance of a medical device. Another issue in the regulation of medical devices is the number of products available, with the large number of variations within a product range. In order to address the issues of medical device regulation, in 1991 senior regulatory officials and industry representatives from the European Union, the United States of America, Canada, Japan and Australia established the Global Harmonization Task Force (GHTF). The purpose of the GHTF was to encourage convergence in regulatory practices related to ensuring the safety, effectiveness/ performance and quality of medical devices, promoting technological innovation and facilitating international trade. The primary way in which this was accomplished was via the publication and dissemination of harmonized guidance documents on basic regulatory practices. In 2011, representatives from the medical device regulatory authorities of Australia, Brazil, Canada, China, European Union, Japan and United States, as well as the World Health Organization (WHO), met in Ottawa to address the establishment and operation of a new organisation, the International Medical Device Regulators' Forum (IMDRF) to accelerate international medical device regulatory harmonization. This session will provide an update on the accomplishments and on-going harmonization of medical device regulation. In addition, challenges faced and lessons learned during in-country implementation of new regulations will be presented.

Developing a competent regulatory workforce for medical devices in the global environment

Mr. Rainer Voelksen, Regulatory Affairs Professionals Society (RAPS), United States of America; Philippe AuClair, RAPS European Advisory Committee, Belgium; Sherry Keramidas, RAPS, United States of America

The critical need for competent regulatory professional workforce in the medical device sector, working with regulators and industry, is increasing and will be essential for medical device innovation and effective regulation. Findings from studies undertaken by the Regulatory Affairs Professionals Society (RAPS) on the role of the regulatory professional throughout the medical device lifecycle and in development of good regulatory practice and policy provide evidence of the scope of work and career progression of these professionals. Additional information on the knowledge, skills and competencies developed by RAPS provide a strong foundation for developing competency based education and training. This information reinforces the importance of educational approaches that also build analytical and critical thinking skills. Approaches for recruiting, educating and certifying regulatory professionals will be examined. The link between these findings and the 2012 report of the Institute of Medicine on ensuring safe medical products through strengthening regulatory system around the world will be examined. Finally, this presentation will summarize global initiatives to develop a competent regulatory workforce and will invite discussion on the implications for medical device development, access and regulation.

IMDRF medical device single audit program pilot program

Ms. Kimberly Trautman, US Food and Drug Administration Center for Devices and Radiological Health, United States of America; Ana Paula Teles Ferreira Barreto, ANVISA, Brazil; Mike Ward, Health Canada, Canada; Larry Kelly, TGA, Australia; Hideyuki Kondo, Ministry of Health, Labour and Welfare, Japan

The International Medical Device Regulators Forum (IMDRF) recognizes the value in developing a global approach to auditing and monitoring the manufacturing of medical devices to ensure safe medical devices. The IMDRF, at its inaugural meeting in Singapore in 2012, identified a Work Group to develop specific documents for advancing the concept of the Medical Device Single Audit Program (MDSAP). See http://www.imdrf.org/ This global approach open possibilities and pathways to support the development of an international initiative of countries dedicated to pooling technology, resources, and services to improve the safety and oversight of medical devices on an international scale in a Pilot Program starting in January 2014. For many reasons not all IMDRF member countries are able to participate in the pilot at this stage, including changes of medical device legislation, the necessity to have in place country to country confidentiality agreements, etc. This does not diminish the support of all IMDRF member countries in the concept and, most importantly, in the development on the base documents being developed by the IMDRF MDSAP Working Group. The international partners for the MDSAP Pilot Program starting January 2014 are the Therapeutic Goods Administration (TGA) of Australia, Brazil's Agência Nacional de Vigilância Sanitária (ANVISA), Health Canada, and the U.S. Food and Drug Administration; Japan's Ministry of Health, Labour and Welfare (MHLW) and Pharmaceuticals and Medical Devices Agency (PMDA) are official observers and active participants in the Pilot Program's Regulatory Authority Council and subject matter expert groups.

Best international PMS practice and in-country implementation of PMS systems

Ms. Shelley Tang, Australia

The concept of an implemented and maintained post-market surveillance (PMS) system is embraced by several internationally recognized standards, such as ISO Quality Management and Risk Management Standards. These include ISO 9001:2000 (Quality management systems – Requirements), ISO 13485:2003 (Medical devices - Quality management systems - Requirements for regulatory purposes), and ISO 14971:2000 (Medical devices - Application of risk management to medical devices), which include requirements on medical device post-market activities to be performed by manufacturers for certification. PMS provides continuous feedback on the products placed on the market, thereby enabling the manufacturer to maintain a high standard of product quality and customer satisfaction. Helping the manufacturer to obtain an understanding of the performance of the product placed on the market also allows it to minimize exposure arising from incidents or potential incidents through effective alerts and product field safety corrective action processes and procedures. The session will provide an overview of the current best international practice for PMS of medical devices. In addition, challenges faced by Member States introducing a PMS system will be presented and possible solutions discussed.

Harmonizing the regulation of in vitro diagnostic (IVD) medical devices in developing countries

Dr. Ruth McNerney, London School of Hygiene & Tropical Medicine, United Kingdom

Regulation of medical products is intended to ensure safety and quality whilst balancing the need for timely access to new products. Current regulatory oversight of medical devices in developing countries is highly variable. Weak regulation allows poor quality products to enter the market whereas inefficient or overzealous regulation results in unnecessary delays, increases costs and is a disincentive to innovation and market entry. Setting international standards and streamlining the regulatory process could reduce these barriers and improve transparency. The Pan African Harmonization Working Party (PAHWP) on the regulation of medical devices and diagnostics has been established to investigate and recommend harmonization activities with the aim of increasing access to high quality, affordable products in Africa. Priority has been given to in vitro diagnostic medical devices. PAHWP are working in collaboration with other regional harmonization bodies, including the Asian Harmonization Working Party (AHWP) and the Latin American IVD Association (ALADDIV) and other international bodies such as the African Society for Laboratory Medicine and WHO. Results from a survey of regulation of medical devices and diagnostics in partner states of the East African Community shall be presented and five priority areas will be described where convergence of standards and protocols or joint review of data would be advantageous; (i) risk classification rules; (ii) a common registration file for premarket regulation; (iii) auditing quality management systems; (iv) clinical performance studies and; (v) post market surveillance. We shall also describe an on-going pilot study to reduce unnecessary duplication in clinical trials, using as examples tests for use at the point of care for CD4, viral load and early infant diagnosis of HIV. Our intended audience includes regulators, IVD manufacturers, policy makers, end users of IVD medical devices and other stakeholders with an interest in the regulation of in vitro diagnostics.

Codification of medical devices in Portugal

Ms. Emilia Alves Da Silva, INFARMED, National Authority of Medicines and Health Products, IP, Portugal

The Portuguese health system had the need to easily access information that allowed for the identification of all medical devices, with their respective manufacturers and distributors, characteristics, purposes and how to evaluate and compare them. To answer this question, we built a system of means and procedures to collect, store and analyze data of each medical device. This information system lays its foundations in the existence of clear rules to register and update data regarding medical devices and market operators, and the definition that a single medical device should have a unique identification. The system consists of a data base that is a repository, and an application system that stores the information with search functionality and reporting. It comprises a nomenclature to integrate all medical devices, in which the devices are attributed to a unique code. For the registry of information all medical devices should disclose their respective instructions of use, labels and price. We defined the concept of unique medical devices and a process to assign a code to each device, and tested it by collecting data from the hospital acquisitions. A model for communication between the health regulatory agency and market operators was also devised, as well as rules and codes of procedure. The codification of medical devices has been gradually implemented. The sectors of medical devices already codified are: Implantable Prosthetic Devices and Osteosynthesis Devices; Active-Implantable Devices. This information is available online. In the areas subjected to coding, there is now solid information about available medical devices in the market, particularly their respective manufacturer and distributor, as well as the price at which the device was bought by the Portuguese hospitals (National Health Services). The prescription of medical devices is made by code, and the healthcare professionals can access online information about each medical device.

Japanese approach of nomenclature system

Mr. Tomomichi Nakazaki, Tokyo Women's Medical University, Waseda University Joint Institution for Advanced Biomedical Sciences, Japan

Japan was a founding member of GHTF (Global Harmonization Task Force) and introduced a lot of GHTF guidance and GMDN (Global Medical Device Nomenclature) into their regulatory system of medical devices. JMDN (Japanese Medical Device Nomenclature) was established with the combination of both classification system, Nomenclature and 'Risk Classification' for pre-market approval in 2005. The concept of 'Risk classification' needs the hierarchy structure (4 levels), because the Pre- and Post-market regulations of medical devices require best practice of R&D, Clinical Evidence, Evaluation, Manufacturing, Distribution and Vigilance with risk-based concept. Class B (GHTF; Classification) medical devices in Japan are certificated by Notified Body with Japanese Certification Standards. These standards provide the checklist of Essential Principles on each group of medical devices including multiple JMDN. Also they are very valuable in order to identify Basic, Group, Product and Recognized Standards (GHTF; Role of Standards). Notified Bodies can evaluate the application from the applicant with Checklist and compliance with appropriate standards. For example, No 55: Certification Standard of Endoscope Telescopes includes 117 JMDNs from Rigid Anoscope to Flexible Video Nasopharyngoscope. This standard shows EP checklist and JIS (Japanese Industrial Standards) which are translated from international standards under Pharmaceutical Affairs Law. On the other hand, Class A medical devices are notified, and Class C and D medical devices are still pre-market approved with JMDN. During the usage of JMDN, Japan has recognized many issues of Nomenclature system. Pre-market requirements, Post-market requirements, Reimbursement system, QMS audit and Inventory control in the market require each different nomenclature system. Also each country/economy requires their own appropriate system based on culture, history and religion. As a result, it is very important to use nomenclature system globally in each country/economy. The final solution for the harmonization is constantly updating the linkage system.

Harmonization of standards and regulations should be addressed through collaboration of government and the private sector

Mr. Anil Nanubhai Patel, Abel Torres, UL (Underwriters Laboratories), United States of America

UL's experience in this arena has led us to believe that the importance of enhancing and strengthening regulatory systems, harmonizing/converging international requirements, and developing sound, harmonized medical device standards cannot be understated. In an increasingly borderless world, the enhancement of global regulatory systems can be achieved through harmonization of international requirements. Harmonization of standards and regulations should be a collaborative undertaking between government and affected private sector interests with the purpose of addressing the increasingly global trade landscape. Standards define a scope of applicability and specify the requirements and criteria for assessment. Additionally, standards provide structure, set expectations, and ultimately facilitate trade when harmonized through national adoption and recognized by regulators. For example: ISO 13485 Medical devices -- Quality management systems -- Requirements for regulatory purposes, was developed to help foster efforts of international harmonization. ISO 13485 is intended to be complemented by specific requirements of medical regulations around the world, and aims to capture elements of most regulatory programs in a single standard. The standard is a raw framework which specific regulatory requirements are placed. UL helps to facilitate by offering preliminary evaluation, technical documentation review, strategic review, registration assessment, and continuous assessments. By playing an active role in facilitating such standard schemes, UL recognizes that the harmonization of these requirements helps to remove market barriers for various medical products without sacrificing safety or quality; encourages collaboration amongst various economies that help to reduce costs and time for medical device manufacturers; and promotes the consideration of vast structural differences in legislative, legal, and regulatory regimes of countries to achieve a common goal of safe, effective, and innovative medical devices.

Innovation in Medical Devices

Session Chair: Dr. Klaus Schonenberger
Session Co-Chair: Prof. James Abbas

Understanding the broader context of design; the use of design ethnography in engineering global health technologies

Prof. Kathleen Sienko, Mr. Amir Sabet Sarvestani, Mr. Ibrahim Mohedas, University of Michigan, United States of America

To develop technologies that address the complex challenges of global health, we have studied how conventional engineering design processes can be supplemented by methods derived from social science fields such as anthropology. Design ethnography, which encompasses processes for gaining a complete understanding of stakeholders' actions, behaviors, words, and thoughts, provides a framework for acquiring tacit information from stakeholders which would not be obtained through commonly used methodologies in engineering design and market research. This presentation will draw upon medical devices we have recently designed and studied for traditional adult male circumcision (Uganda) and maternal health (Ghana) to illustrate the utility of design ethnography in the field of global health technologies; specifically, the need for engineers to understand the broader context in which a medical device will be used, and the need for design decision making processes to be based on rigorous studies that generate quantitative outcomes rather than anecdotal evidence.

Partnership in medical technology innovation: avoiding the prototype graveyard

Mr. Timothy Prestero, Design that Matters, United States of America

So many technologies are stuck in the prototype phase, how might we create successful public-private partnerships to bring life-saving health care technology all the way to impact? Non-profit Design that Matters, East Meets West Foundation, and for-profit manufacturer MTTS Vietnam created a novel, successful partnership to treat newborn jaundice in rural hospitals while designing Firefly newborn phototherapy. Some highlights of our relationship include:
--Bridging many gaps to have impact: Given so many market failures in the developing world, only a partnership could plug gaps in financing, distribution, marketing, sales, design, manufacture, servicing, and monitoring and evaluation.
--Building shared ownership to overcome obstacles: Designing Firefly together from the very beginning aligned incentives for all three partners to get past inevitable obstacles on the way to implementation.
--An open partnership that mitigates inevitable unknowns: We were able to build on the past experiences of all three organizations by working without confidentiality and being open about intellectual property. MTTS Vietnam is currently completing the production of 200 Firefly devices. Its double-sided lighting, compact size, and high-tech aesthetic make it the most effective phototherapy affordable for low-resource settings. Over the 12 months, East Meets West will distribute the devices to Vietnam, Myanmar, Cambodia, Laos, East Timor, the Philippines, Ghana, and distributors in Thailand and Malaysia. EMW ultimately plans to distribute 1,000 Firefly devices, reaching more than 100,000 newborns. MTTS is now using many of the methods, techniques, and processes gained through the Firefly partnership to design and produce new user-centered products for the poor in the developing world including a bubble CPAP for newborn respiratory distress. Design that Matters, East Meets West, and MTTS continue to collaborate around world class medical devices for the poor using our novel, successful partnership.

Health economics for device developers: a framework for assessing commercial viability

Dr. Amanda Chapman, Burn Samantha, University of Birmingham, United Kingdom

The health economic evaluation of an innovative medical device has an important role to play in the purchasing decisions of healthcare providers. In recognition of this fact, we propose a rational framework for assessing development opportunities entitled the 'Headroom method', which offers medical device developers a simple way to integrate health economics into early development decisions. By estimating the maximum reimbursable price (MRP) for a new device idea, and comparing this reimbursement opportunity with a developer's expected costs, the method helps developers to invest only in those devices that are commercially viable. Moreover, where a positive development opportunity is indicated, this valuation can offer an important input into the design of the new device. By establishing a cap on its value to the purchaser it may, for example, inform the design and technical specifications of the device so that it can be developed/produced at a price which falls within this MRP.The method described has been developed and applied in the context of a high-resource setting (specifically the UK). Its adaption to low-resource settings, whilst viable, introduces difficulties which arise from issues such as uncertainty around reimbursement thresholds for health benefit and the scarcity of unit cost data. In 2012, the WHO produced a compendium of innovative health technologies that have "the potential to improve health outcomes or to offer a solution to an unmet medical need in low-resource settings". We discuss the application of the headroom method to case studies drawn from this compendium of devices under commercial development.

Medical devices for non-communicable diseases: opportunities for innovation

Mr. Amir Sabet Sarvestani, Prof. Kathleen H Sienko, University of Michigan, United States of America

In 2008, 36 million people died (63% of global deaths) from non-communicable diseases (NCDs), 80% of which occurred in low- and middle-income countries (LMICs). Moreover, deaths from NCDs are projected to rise to 52 million by 2030, with NCDs in LMICs responsible for three times as many disability-adjusted life years and nearly five times as many deaths as communicable diseases, maternal, perinatal and nutritional conditions combined. To understand the current landscape of medical devices developed specifically for use in LMICs, we identified and classified devices designed in the last decade to address the top ten causes of death and United Nations Millennium Development Goals (MDGs) 4 (reduce child mortality) and 5 (improve maternal health). Results reveal the mismatch between the number of medical devices commercialized and under development, and the increasing global burden of non-communicable diseases. Of the 361 medical devices identified, 310 (~86%) target infectious diseases and MDGs 4 and 5. Yet, the greatest burden of disease in the near future will be NCDs. Despite the growing burden of NCDs, from the devices identified that address major NCDs, only approximately 6% are in the market and 5% are in the concept stage, whereas 35% and 41% of devices designed for infectious diseases and MDGs 4 and 5 are in the commercialized and concept stages respectively. Given the limited global resources in health, evidence-based approaches are most useful to match health care problems and relevant needs with technological solutions. While infectious diseases, maternal and infant mortality are devastating health challenges primarily affecting LMICs, the magnitude of NCDs should not be overlooked. Hence, medical device industry, academia, and global health organizations need to reconsider their focus and strategies to address the disparities in health technology development.

Medical device innovation – South Africa as a case study

Mr. Mladen Poluta, University of Cape Town; Tony Bunn, Medical Research Council, South Africa

While there have been some notable medical device innovations originating in South Africa a formal structure for supporting innovation has been lacking. A Medical Device Innovation (MDI) Summit supported by the Department of Science and Technology (DST) was held in 2008; factors restraining the emergence of a viable medical device industry were addressed by representatives from industry, government and academia. Summit participants recommended inter alia the creation of an MDI Centre of Excellence to support local innovators in overcoming a number of critical challenges and called for timely, appropriate and adequate funding to bridge the 'Innovation Chasm'. This was followed by a Situational Analysis of the MDI Landscape and a visit by a multi-stakeholder delegation to the UK. An MDI Centre of Excellence branded as MD2M (Medical Devices to Market) was created by the DST in 2009, as was a National Medical Device Innovation Platform by the Medical Research Council to better coordinate MDI-related research at tertiary institutions and to provide additional focus and incentives with the recognition that successful innovation requires strategic, multi-disciplinary and multi-institutional partnerships facilitated by dedicated, milestone-driven funding and focused project management. In its second year of operation MD2M was absorbed into the newly formed Technology Innovation Agency (TIA) of the DST. Recent developments have seen the establishment of (i) a local innovation interest group within the medical device industry and (ii) SHIP (Strategic Health innovation Partnerships), a Product Development Partnership of the MRC co-created and supported by the DST and focusing on innovation of health technologies (drugs, vaccines and medical devices including in-vitro diagnostics). The Department of Trade and Industry, through the Industrial Development Corporation, has also entered the mix by publishing a tender requesting a proposal to conduct research to guide the development of a strategy for the medical devices sector in South Africa.

Health Care Delivery

(French translation available)

Session Chair: Dr. Ricardo Silva
Session Co-Chair: Ms. Hanne Bak Pedersen

Health First Europe model for community care

Ms. Amanda Bogg, Health First Europe, Belgium

Health First Europe is a non-profit, non-commercial alliance of patients, healthcare workers, academics, hospitals, healthcare experts and the medical technology industry. We aim to ensure that equitable access to modern, innovative and reliable medical technology and healthcare is regarded as a vital investment in the future of Europe. We call for truly patient-centred healthcare and believe that every European citizen should benefit from the best medical treatments available. In order to broaden access of innovative technologies for patients, we have developed a model for Community Care which we believe lays out the necessary components for increasing reimbursement and access of medical technologies in the community setting. The model is a road map for high resource settings to organise systems of health to benefit the patient, professional, payer and system. The six areas of needed reform include: 1. Community Care Policy: Establishment of a dedicated community care policy and political leadership to implement the policy 2. Patient-Centric Care: A system designed built in response to citizen health needs 3. Access and Reimbursement: Flexible funding to increase access to innovative community care products, treatments and services 4. Innovation and Value: Incentivising valuable, innovative solutions across the health system 5. Care and Treatment: Creating a mobile and flexible health and social care workforce bound to the citizen, not the system 6. Quality Care and Standards: Generating quality of care assurance in the community

Accessibility network

Mr. German Jose Giles, Dr. Alejandro Ferro, Dr. Alejandro Cristaldi, Municipality of General Pueyrredon, Argentina

The Health Accessibility involves integration concepts from human resources to medical technologies. In the middle, there are critical factors like water, transport, sports and culture necessary to achieve it, in a natural way. The Health System of the Municipality of General Pueyrredon, with a total area of 1453 km^2, has developed programs to work seamlessly with Ministries of Health (National and Province of Buenos Aires) of Argentina, to promote the Health to the community, focusing on prevention and accessibility. In line with this, our main city, Mar del Plata, was elected by the Inter-American Development Bank for the Emerging and Sustainable Cities Initiative, a program that will benefit the population with a better living. From a strategic analysis, the CEMA-Centro de Especialidades Médicas Ambulatorias (Center for Ambulatories Medical Specialties) was opened in November 2012 having in mind all these topics. It creates the Second Level for Patient Diagnosis, joining 33 Primary Care Centers (PCC), with Regional Acute Level Hospitals (RALH). CEMA was projected with a high tech profile, and is evolving by creating networks between stakeholders, with emphasis in patient security, telemedicine and interoperability. Technically speaking, the medical equipment goes from Sphygmomanometers up to MRI, optimizing resources in the region with RALH and PCC. The IT systems and Medical Equipment were selected with the idea of prevention programs, and it is the first time in more than 40 years, that a new Government Health project is consolidated in the region, giving free access to a population of 700,000; whose 39% have no Social Security coverage. Inside its 6,200m^2 building, CEMA has highly motivated personnel to keep the medical systems, working for better results, meanwhile critical factors as explained before, are reaching to the community more often.

Using population health data analytics to optimize medical device investment decisions in the Kingdom of Saudi Arabia

Dr. Mazen Hassanain, Halah Eldoseri, Ghada Farhat, Dr. Nabeel Abdulaziz, Dr Mohammed F Zamakhshary, Dr Mohammed Yemni, Dr Mohammed Hamzah Khoshim, Ministry of Health of the Kingdom of Saudi Arabia; Mitchell K. Higashi, Denise T Kruzikas, GE Healthcare; Charles Macal, Michael North, Center for Complex Adaptive Agent Systems Simulation, Decision and Information Sciences Division, Argonne National Laboratory, United States of America

The General Administration of Research and Studies in the Ministry of Health in the Kingdom of Saudi Arabia works to address health care needs by a newly developing health services and outcomes research (HSOR) Center of Excellence (COE). The primary objective is to optimize utility of medical devices to maximize patient's benefit while minimizing cost. A key focus area for the COE is in analyzing the cost-benefit of medical devices, particularly in the areas of trauma, metabolic disease and oncology. Methods: The COE utilizes a two-fold approach by assessing needs then modeling devices distribution. First, the COE will assimilate information related to health status, quality and cost of care, and patients' satisfaction through surveys and secondary data analysis. Based on this, the COE will evaluate current use of healthcare services within the epidemiologic, demographic, and institutional contexts. Second, the COE will employ agent-based modeling simulation (ABMS) to evaluate the impact of clinical, programmatic and policy changes for optimal investments. In ABMS framework, agents of the healthcare system are visually represented and their multiple interactions are simulated over time. Results: Using the two-fold approach, the COE will generate data to inform the model on resource use and utility today, simulation will then project how and where medical device investments will affect future healthcare services provision and economies. Conclusion: By integrating reliable data sources with powerful simulation tools, the COE will enable MOH to make informed evidence-based decisions on medical devises utility based on changing health needs.

Should we train users in equipment care?

Mr. Andrew Gammie, Fishtail Consulting Ltd, United Kingdom

When a society is industrialised, there is background knowledge that helps citizens care for technology. However, where those citizens are placed in new or challenging environments, or when a society has become industrialised comparatively recently, extra input is required to ensure that human factors are properly considered and technology is used helpfully. In many documented instances, healthcare technology has been poorly used or maintained. Very often the main cause for this is not obvious, but user error is frequently mentioned as a contributing factor. It would therefore be sensible to focus on users as a resource for caring for technology. This could be done through initial medical training, as the learning environment is already established. However, the heart of good equipment care is hands-on skill, which will only be practiced in the clinical environment after formal training is completed. The opposite approach would be to prevent the user from handling technology. Even though this is sometimes the default option for clinical staff afraid of damaging expensive equipment, it would hamper and even prevent effective medical care. For these reasons, healthcare systems promote on-the-job training, with equipment-specific classes for each new device. Where such practice exists, it includes refresher courses every two or three years. This paper describes a new resource for on-the-job training of clinical equipment users in the basics of equipment care. The manual and course developed for it have been trialled in India and are soon to be applied in Nepal. Nineteen types of equipment are covered and a series of simple daily and weekly routines are described. The resources to establish such a programme may seem large, but when compared to the well-known waste of resource in broken or unused equipment, it is not much to pay for improved and more efficient healthcare.

Health Care Delivery

(French translation available)

Session Chair: Dr. Ricardo Silva
Session Co-Chair: Ms. Hanne Bak Pedersen

Energy in healthcare

Mr. Paul Merlevede, International Federation of Hospital Engineering (IFHE), Belgium

IFHE-EU organized a questionnaire about energy consumption versus building constructions and technical infrastructures which included what exists now such as the insulation of building (walls, basements and roof), the kind of energy used, and energy consumption of medical devices. We have to think about: 1. How to reduce energy-invoice: this item concerns energy-efficient installations and medical apparatus, the site-layout (orientation of the building), windows, building materials for walls, basement and roof. 2. Future: One of the big challenges is creating fuel-free consumption by using 'green' principles. The environmental safety is very important: the impact of nuclear and conventional power plants. There are a lot of 'alternative' energy sources like wind, water, sun, technical 'energy-saving' installations (like cold water or ice-water storage for rooms, medical devices, heat pumps, wood-pellets, lightning, etc.). Costs-benefit considerations are discussion points. In healthcare, we always need energy (day and night). Technical aspects, energy consumption behavior and the consumption of medical devices are also very important in reducing energy consumption. We think it is good to create a common factor (figure 1): one of the best factors is the CO_2 /m² (kg CO_2/m²) usable surface heated/cooled. Also the NO_2 level is important (see explained benchmark). This way of working will be easier to make a proposal to the different local governments. The proposal will take care of: building concept, energy management, kind of energy sources versus CO_2 level and versus pay-back period of the investments, controlling energy consumption, defining temperatures in different rooms, environmental considerations according the depletion of earth energy sources and may be financial compensation (compensation for good CO_2 parameter). Our objectives include: reducing CO_2 and energy-checklist (useful for existing buildings who will de-crease energy consumption.

Réfrigérateur domestique pour le storage des vaccins

Dr. Ramzi Ouhichi, WHO, Tunisia; John Llyod, Patrick Lydon, Haithem Aouinet

In Tunisia, the vaccines are stored often in domestic refrigerators. In order to assess the risks of vaccines (freezing and temperature rise): We recorded the temperature every 15 minutes for 12 months (in 2012) within 49 vaccine refrigerators in regional and district warehouse and Health Center (HC). We conducted performance testing in the laboratory on a selection of preferred models of refrigerators available in the Tunisian market. The results were:

-84% of time the temperature was correct (between 2 and 8°)

-1095 frozen alarms and 455 hot alarms were recorded.

-Safety storage decreases the regional level to the HC- Per month, on average of two frozen alarms and one hot alarm were recorded in HC domestic refrigerator. These results are due to the use of refrigerators usually old (average 11 years), using mechanical thermostats which need to be changed at the beginning of each season.

-The regional warehouses are equipped with pharmaceutical refrigerators that have recorded a temperature between 2-8° for 99% of the time without saving any alarms. We tested the stability of the temperature of 4 new refrigerators in a specialized laboratory (according to the stand-ards set for the test E03/RF01.2 E03/RF01-VP.2 and protocols).

The models were selected on the basis of the following criteria:

• Purchase cost between 700 and 1000 dinars

• Capacity usable for vaccines.

• Energy rating (class 1, 2, or 3). Although all four models failed one or more tests at the two test temperatures, the performance of two models in Phase 2 was improved by adding a wall of water-filled packs surrounding the vaccine load.

Conclusion: Domestic refrigerators are not classified or prequalified as medical products in Tunisia and are available at competitive prices. On the other hand, pharmaceutical refrigerator meeting WHO norms are more costly and are not available locally. If these refrigerators cannot be imported for vaccine storage purposes, we recommend that the Tunisian Ministry of Health should:

• Reclassify refrigerators intended for vaccine storage as medical equipment that should meet international or national norms of performance.

• Require that models be prequalified in an independent laboratory according to these norms before countries and partners procure them.

• Require that health workers use a wall of water-filled packs to surround the vaccines within the refrigerators to protect them from temperature fluctuations.

•Require that health workers follow a national standard refrigerator operating procedure.

•Require that health workers use 30-day temperature recorders that meet WHO norms (E006/TR06.3) to monitor the temperatures in all refrig-erators used to store vaccines and that sufficient training is provided for this purpose.

Eradication of climate-induced neonatal hyperthermia through nursery building design

Dr. Hippolite Amadi, Imperial College London, United Kingdom; Dr Mohammed B Kawuwa, Obstetrics And Gynaecology Department, Federal Medical Centre Nguru, Nigeria; Dr Lawal I Mohammed, Ms Hajjah Mohammed, Dr Abdulquddus Oyedokun, Paediatrics Department Federal Medical Centre Nguru, Nigeria

Daytime ambient temperatures of tropical climates can rapidly rise in excess of 43°C, overheating any exposed objects. This leads to the overwarming of neonatal nurseries, occupant baby temperatures soaring up to hyperthermic 40°C during early evenings of sunny days. Unaware of this neonatal 'evening fever syndrome (EFS)', clinicians have responded with doses of antibiotics mistaking this as a sign of infection. Others combined their desperate measures with 'water-sponging' of babies above 37.9°C. Thermoneutral instability increases morbidity and slows down progress. Unnecessary antibiotic treatment complicates situations and could kill such a baby. Climate-induced hyperthermia could be eliminated if nurseries were appropriately sited and designed to guarantee natural coolness. This will allow better neonatal thermoneutral regulation through incubators. Federal Medical Centre Nguru gave Ethical Approval and hosted this research. Two laboratories of building constructs were erected, each double-walled having in-between air space for lagging. Lab-1 was new building with underground floor and heat-exchanger. Lab-2 was an existing room renovated for existing nursery correction. The laboratories were assessed on ability to maintain environmental coolness and incubator/neonatal thermal stability during extreme-hot days as compared to the hospital's main nursery, 'Control-ward'. Data collection continued for 24 months, constructions validated and extreme-hot months of February-May and August-October data extracted and analysed. Average peak-temperature of outside-wind was 43°C (range: 41°C–46°C); Control-ward was 39°C, Lab-2 (36°C) and Lab-1 (33°C). All incubators in Control overheated during the temperature-high periods of the day but there was no incubator overheating in Lab-1. There were 131 water-sponging events for fever-quenching on Forty-four (86%) of sampled babies in the Control-ward. Only one baby was water-sponged twice in Lab-1.Labs-1&2 demonstrated the capacity of relative coolness for the neonates' comfort unlike Control-ward. Preterm neonates easily assume a body temperature similar to their immediate environment. We recommend nurseries be purpose-designed, integrating EFS-minimization as a design constraint.

Audit in the Central Seterilisation Services Department of tertiary hospital

Mr. Jean Marie Vianney Namahoro, Marina Aucamp, Stellenbosch University, South Africa

The Central Sterilisation Services Department (CSSD) has the full responsibility for reprocessing of the reusable contaminated items in Tygerberg Academic Hospital. The process for sterilizing any instruments started from transportation to the CSSD, sorting, disassembling, cleaning, inspection disinfection (inside the decontamination area), packaging, sterilization (inside the clean processing area), and storing then distribution to the end users. An observational audit was performed in CSSD of Tygerberg Academic Hospital on 24 June 2013 to measure the compliance level with decontamination standards. The audit result shows the compliance level of 85.71% of decontamination standards. The improvement should be made on hand-hygiene (hand-hygiene facilities and practice), awareness on Personnel Protective Equipment in the CSSD storage rotation and effective cleaning of medical devices.

How to Prioritize Medical Devices

Session Chair: Ms. Dessislava Dimitrova
Session Co-Chair: Ms. Olumurejiwa Fatunde

Is the provision of medical equipment enough? Addressing the need for adequate training and support to maximise the effectiveness of introducing modern equipment into the developing world.

Dr. Maurice Paul David Burke, University College London/University College Hospital London/ Royal Berkshire Hospital, Reading; James Annkah, Ivan Rosenberg, Gary Royle, University College London; Abiodun Adeyemi, Paula Horne, Kate Ricketts, Royal Berkshire Hospital; Shauna Mullally, Tropical Health and Education Trust (THET), United Kingdom; Eric Addison, Komfo Anokye Hospital; Theophilus Sackey, Korle Bu Teaching Hospital, Ghana

The World Health Organization predicted that by 2017 the death toll due to cancer in developing countries will be greater than 10 million per year accounting for more than two thirds of the world cancer deaths, exceeding those caused by HIV/AIDS, tuberculosis and malaria combined. However, the developing world has very limited provision for cancer diagnosis and treatment. While radiotherapy continues to play a major role in the global fight against the disease, in developing countries this life saving procedure remains extremely inadequate. A large proportion of all cancer patients will require radiation treatment during the course of their disease. However, in these regions radiotherapy services are very limited and not available to many cancer patients. In a number of regions this issue is starting to be addressed but resources are limited and very few of the staff have had the opportunity to be trained in modern radiotherapy techniques. Consequently they face a difficult challenge to implement new technologies and get quickly up to speed on clinical protocols, equipment maintenance and operation, at the same time as running a busy cancer service. It would therefore seem that the application of resources and expertise that exists in the UK, to assist the healthcare professionals who are providing cancer treatment in the developing countries, would be of enormous benefit. The sole provision of modern medical equipment is not enough to rectify the considerable difference between the levels of healthcare available. Once the equipment is in place, there have to be enough trained personnel to deliver the required level of care. Therefore, the aim of the paRTner project is to instigate and develop a continuing voluntary partnership infrastructure of high quality training and support for radiotherapy professionals within these developing countries, while providing an essential supply chain of donated modern medical equipment.

Rational selection and prioritization of medical devices in low- and middle-income countries

Ms. Karin-Daniela Diaconu, Samantha Burn-Harris, Semira Manaseki-Holland, Carole Cummins, Richard Lilford, University of Birmingham, United Kingdom

Medical devices form an integral part of health service provision and carry substantial budgetary expenditure implications. Policy makers, health service managers and providers balance competing issues: medical device purchasing decisions against diverse disease burdens and limited budgets. In low- and middle-income countries national clinical cost-effectiveness review and commissioning bodies are usually absent. Major international organizations and consultancies recommend what medical devices health service institutions should invest in. However, there is as of yet no international consensus around what devices should be essentials or priorities for procurement. This talk first offers the conclusions of a systematic review of relevant academic and grey literature which investigated the medical device selection and prioritization methods employed in low- and middle-income country procurement. This review includes relevant literature and guidelines issued by international donor agencies as well as international health advisory bodies such as the WHO and its aim is to ascertain and explicate the various issues and factors affecting national procurement processes. Second, two contrasting case-studies undertaken in Gambia and Romania will be presented to illustrate in greater depth the elements affecting procurement as well as medical device management more generally. A discussion around the different international and national contexts and their relevance to rational selection and prioritization methods that are and could be employed within the settings follows. Drawing on the above as well as consultations at a medical device prioritisation workshop with world-leading experts undertaken at the University of Birmingham (October 2013), relevant rational device selection and prioritization methods and heuristics will be explored throughout the talk and final pragmatic recommendations will be discussed.

Applying health technology assessment methods for the selection and prioritization of medical devices: a practical example within the Republic of South Sudan

Prof. Richard Lilford, Samantha Burn-Harris, Karin Diaconu, Semira Manaseki-Holland, Carole Cummins, University of Birmingham, United Kingdom

There is a growing literature on prioritisation of medical devices in low and middle-income countries, including the WHO Priority Medical Devices project which outlines both gaps in device availability as well as prioritisation of issues around device innovation, manufacturing and assessment. There is also a large and growing compendium of the health technology assessment and cost-effectiveness of health interventions in different regions, spearheaded by the WHO through its WHO-CHOICE programme. However, while these efforts are welcome, they are not equipped to fully address the questions posed by policy-makers in low- and middle-income countries (LMICs). Specifically, policy-makers are interested to know what devices they should purchase for each level of healthcare facility, a problem not easily solved either by reference to available lists of “essential devices” or to a compendium on intervention cost-effectiveness. The presentation describes a medical device selection exercise undertaken within the Republic of South Sudan. Here, the author was commissioned to develop a quick and pragmatic solution to a resource allocation problem within a low-resource setting. A ‘mixed method’ approach was taken, incorporating issues such as infrastructure and human resource constraints into the medical device selection method alongside traditional cost-effectiveness analysis. The talk uses the example of assessing cost-effectiveness of pulse oximetry for intra-operative monitoring to illustrate the challenges of applying standard health technology assessment tools to low-resource settings. To conclude, the talk will draw on extensive discussions with world leading experts and decision makers (University of Birmingham, Expert Research Workshop 2013) to issue pragmatic recommendations around topics such as parameter estimation, transferability of methods/models between settings as well as the use of multicriteria decision analysis for priority setting and decision making within LMICs.

Prioritizing criteria for medical equipment assessment in a health care facility

Ms. Maria Moreno Carbajal, Claudia Cardenas Alanis, Hospital Medica Sur, Mexico

Health technologies are constantly improving and new technologies emerging. Inside the healthcare facility, physicians are our main clients and constantly they require the use of these technologies that facilitate the clinical procedures and improve time and costs. However, workers inside a health care facility, specifically members of the acquisition of health technologies committee have the need to prioritize medical requests and identify primordial necessities in order to attend all medical requirements and identified necessities. Therefore, a quantitative methodology was developed in the Operations Department at Medica Sur Hospital, with the intention to prioritize medical equipment assessment. This methodology consists in four criteria that include different parameters with their corresponding numerical value. At the end the final sum given to the specific medical device represents the order of priority that must be given during the HTA procedure. The four criteria are: Necessity of the medical device acquisition, Advantage of the medical device acquisition, approximate time for the delivery of the device in-site the health care facility, benefit for the health care facility. The purpose of the implementation of this methodology allows the acquisition committee to prioritize medical devices requests while being able to attend physicians and necessities to ensure the operation of the hospital.

Methodological guidelines for medical equipment assessment studies

Mr. Eduardo Coura Assis, Ministry of Health of Brazil; Marcus Tolentino Silva, Department of Science and Technology/ Secretariat of Science, Technology and Strategic Inputs/ Ministry of Health; Renato Garcia Ojeda, Institute of Biomedical Engineering/Federal University of Santa Catarina (IEB-UFSC); Saide Jorge Calil, Center for Biomedical Engineering - University of Campinas (CEB-UNICAMP), Brazil

Introduction/Background: Although many methods currently established about HTA for drugs can be adapted for medical equipment, there are specific methodological issues that require more attention when equipment is assessed. Furthermore Medical Care Equipment (MCE) management in Brazil faces a lack of methodologies and Health Technology Assessment (HTA) studies and the management faces situations such as uncritical incorporation, unsatisfactory performance, high maintenance costs, elevated repair rates, inadequate use and technological obsolescence. Objectives: This publication is intended to guide the analysis of technicians and managers interested in assessing MCE, whether for inclusion, exclusion or modification of these technologies at various levels of management of the Brazilian Health System (SUS). Methods: Developed by the Institute of Biomedical Engineering (IEB-UFSC), of the Federal University of Santa Catarina (UFSC) member of the Brazilian Network for Health Technology Assessment (Rebrats) and Collaborating Center of Pan American Health Organization (PAHO), and revised by Center for Biomedical Engineering University of Campinas (CEB-UNICAMP) the methodological guideline was an initiative of the Ministry of Health, through the Department of Science and Technology (DECIT).
Conclusions: The guideline is an internationally unprecedented methodology in the field of HTA, and this work sought to address the various types of analysis that are specific for this group of health technologies. This project contributes for the rational use of health technologies, seeking to support health managers in decision making on incorporation and withdrawal of MCE from standardization of HTA studies and the definition of clear criteria for issuing opinions and analysis of studies in the public health area.
Discussions: The purpose is that this tool in conjunction with other already existing ones, can integrate important contexts not yet seen in other guidelines. Hopefully, this guideline will be useful in the professional practice of the MCE assessment process in Health Care Establishments.

RENEM – Brazilian national list of equipment and materials

Mr. Murilo Contó, Clarice Petramale, Vania Canuto, Erlon Cesar Dengo, Marcio Luis Borsio, Darcio Guedes Junior, Ministry of Health, Brazil

To ensure the actions of the Brazilian Unified Health System (SUS) can be achieved with universality, integrity and gratuitous, the Ministry of Health (MH) provides investment programs for institutions to acquire equipment and materials for the operation of its services. As the budget is always limited, the MH implemented a methodology to make improvements in their processes of adoption and investment, divided into four fronts: (1)-Adoption of a National List of Equipment and Materials (RENEM); (2)-Regulatory processes for incorporation and management of RENEM; (3)-Creation of a bench of prices; and, (4)-Automation of investment analysis. RENEM was adopted after systematic standardization of nomenclatures culminating in the preparation of equipment combos distributed according to the complexity of healthcare environments, eliminating issues of requests not according to their profile service. A computerized system was developed to manage the structure of RENEM and the entire process of investment analysis, streamlining routines and paper elimination. Regulating incorporation of RENEM items established the minimum requirements of scientific evidence and deadlines for decision making. A cooperation program was created to capture economic and technical information and a function was introduced into the system that provides the technical features of the equipment in multiple choices. Each technical feature has a monetary value associated that represents the impact on the final price. Thus, the system performs a dynamic price setting which automatically adjusts to the selected specification. A tool that performs the historical search of the quantity and value of equipment financed by state, city and institution allowed the creation of ABC curves and Pareto analysis, identifying the key items of RENEM that require further attention. As a main result, the number of investments approved in 2012 was almost four times higher than the previous year with significant improvement in projects quality.

A web tool to support the user need elicitation for the Health Technology Assessment (HTA) in emerging countries.

Dr. Leandro Pecchia, University of Warwick, United Kingdom; S Mullally, Canada; F Crispino, Solution Engineering, Italy; S P Morgan, Electrical Systems and Optics Research Division, University of Nottingham, United Kingdom

Understanding user needs is essential for Health Technologies Assessment (HTA) of medical devices. Few studies propose analytic and quantitative methods to elicit user needs, and among those a method that seems to be particularly effective to elicit user need was the Analytic Hierarchy Process (AHP)[1]. The assessment of user need, especially for HTA processes, is even more important in emerging countries given the heterogeneity of health organizations and different skills and knowledge among healthcare operators. Web tools may represent one of the possible contributions to the diffusion and the standardization of HTA methods in emerging countries. This paper describes a free web tool [2, 3] for the use of the AHP for the user need elicitation and the HTA. METHOD: The Analytic Hierarchy Process (AHP) is a multifactorial decision-making method based on the idea that it is possible to prioritize elements by: grouping them into meaningful categories and sub-categories; performing pairwise comparisons; defining a coherent framework of quantitative and qualitative knowledge; measuring intangible domains. RESULTS: The AHP has been proved to be effective in user need elicitation and in HTA, although not easily used by lay users. The tool developed gave interesting result in terms of its usability by people not strongly experienced in AHP. Further details can be found in the references [1, 2].REFERENCES1.Pecchia L, Martin J, Ragozzino A, Vanzanella C, Scognamiglio A, Mirarchi L, Morgan S (2013) “User needs elicitation via analytic hierarchy process (AHP). A case study on a CT scanner”, BMC Medical Informatics and Decision Making, 5 January 2013, 3(1):2, DOI:10.1186/1472-6947-13-22.Pecchia L, Crispino F, Morgan SP (2013) A software tool to support the Health Technology Assessment (HTA) and the user need elicitation of medical devices via the Analytic Hierarchy Process (AHP). CHI2013, Vilamore, Portugal, 7-9 November 20133. Web site: http://www.ahpapp.net/

Electronic categorization of medical devices in Slovakia

Dr. Branislav Jadud, Ministry of Health of the Slovak Republic, Slovakia

The presentation will introduce electronic categorization of Medical Devices and it will demonstrate benefits from this new model of reimbursement recently implemented in Slovakia. We will emphasize the importance of data quality and data analysis as well as the importance of surgeon expert groups and their recommendations to the reimbursement. The electronic categorization is a publicly available online process, which contains all relevant data from applications of registered producers placed on electronic portal for the most effective reimbursement. The list of Medical Devices reimbursed upon public health insurance funds is updated quarterly and also comprises of a 'limits' part that indicates the monetary restrictions for selected groups. The process of electronic categorization is giving to the health insurers, government institutions, industry representatives and public valuable outcomes from the database of reimbursed Medical Devices via National Health Information Centre. The electronic categorization is very much adaptable to the dynamically changing market environment of Medical Devices and is contributing significantly to fulfil needs of patients as well as health care professionals while reflecting sustainability, possibilities and stability of health care systems in Slovakia.

Health Care Infrastructure

Session Chair: Dr. Ricardo Silva
Session Co-Chair: Ms. Hanne Bak Pedersen

Risks assessment during a construction or remodeling of health care facilities JCI methodology

Ms. Claudia Cardenas Alanis, Maria Eugenia Moreno Carbajal, Hospital Medica Sur, Mexico

Hospitals continuously perform improvements in their facilities by remodelling, construction, or demolition. However the main aim of these activities is to ensure minimal effects over daily operations activities through the implementation of different policies or procedures that guarantee the safety to patients, family, visitors and users. The Risk Assessment tool was developed at Medica Sur Hospital according to the JCI best practices and recommendations for two main purposes: the first main purpose is quantify the level of risk associated with a construction or remodelling in a health care facility, and the second purpose is to define the preventive measurements that must be followed to minimize or eliminate the negative effects of the construction or remodelling within a Hospital. This tool measures the level of risk through the implementation of quantitative indicators for 5 risk categories: Patient Safety, Type of construction or remodelling, Nosocomial Infections, Impact on adjacent areas inside the hospital and level of compliance with official standards or regulations. For each risk category, a series of indicators are defined with a corresponding numerical value, where higher values imply higher risks. In order to obtain the level of risk of the construction or remodelling, the final score of each of the five categories must be summed. According to the final value obtained, the risk levels are classified in three main categories: low, medium or high level of risk, based on the level of risk obtained, a list of preventive measurements are defined and must be implemented during the remodelling or construction in a HealthCare Facility.

Health Technology Management: Country Initiatives *(French translation available)*

Session Chair: Prof. Saide Calil
Session Co-Chair: Ms. Jennifer Barragan

Health technology management in Uganda

Mr. Sam Steve Balayo Wanda, Ministry of Health, Uganda

MEDICAL EQUIPMENT MAINTENANCE STRATEGIES IN UGANDA'S RESOURCE CONSTRAINED ECONOMY
Background: Uganda's Health System consists of Central and Local Government Health Systems. The Ministry of Health is responsible for Policy, Strategic Planning, Resource Mobilisation, Sector Standards & Quality Assurance, Provision of centrally coordinated services, and M&E of sector performance. In the last twenty years, Uganda has invested in rebuilding and expanding the country's infrastructure which broke down in the 1970's to meet the increased demands. One of the major health programmes was the construction and equipping of Facilities with the number rising from 1073 in in 1988 to 5229 in 2012 to cater for increased population from 15.784m to 34.133m. Prior to 1992, medical equipment maintenance was carried out across the country by maintenance technicians travelling from the Ministry headquarters in Entebbe. Regional Medical Equipment Maintenance Workshops (RWs) were conceived in 1992 with the aim of decentralising medical equipment maintenance services to regional level. There are nine RWs located at Arua, Hoima, Lira, Gulu, Soroti, Mbale, Fort Portal, Kabale RRHs; and in Wabigalo, Kampala. Objective of the Programme The establishment of RWs is intended to reduce travel time and subsistence allowances for technicians to keep equipment in good working condition. Further, it facilitates accurate diagnosis and/or operation of patients nearer to the population. The resource constrained economy with poor road infrastructure has rendered close proximity of services the most feasible option to save lives. Challenges The country suffers from insufficient funding for equipment maintenance, old mobile workshops to repairs sites, inappropriate procurement procedures for spare parts, limited updated inventory and BME knowledge and skills. Results Establishment of the RWs has contributed significantly to availability of equipment in good working condition and reduction in maintenance costs. Conclusion Despite the great challenge of insufficient funding, the country has registered benefits from the programme.

Healthcare technology management in Kenya

Mr. Philip Amoko Anyango, Martin Owino, Ministry of Health, Kenya

A number of WHO sponsored studies conducted on the state of medical equipment and devices in developing countries in the early eighties revealed that more than fifty percent of the inventory was not in use. The challenge was not lack of equipment, but non-functioning equipment. Some of the underlined reasons were lack of skilled and knowledgeable man power on maintenance and repair of medical equipment, lack of spare parts and awareness among others. To address these challenges, Kenya with the help of development partners like GTZ, now GiZ Austrian development agency, embarked on the program of training Medical engineering Technologists and Technicians at Mombasa Polytechnic and Medical Engineering Technicians Training Schools. To complement the training, GTZ set up three workshops in three hospitals complete with experienced instructors and equipment for hands on training. The presentation will discuss the impact of this intervention thirteen years after the project ended in 2009. It highlights the role of the Professional Association of Medical Engineering in Kenya in collaboration with the WHO, IFHE, IFMBE, ACCE and GAME played in creating awareness on the importance of proper healthcare technology management and putting in place national equipment policy. It will also discuss the reforms that are being put in place to ensure there is effective maintenance of the equipment. The paper concludes by identifying major challenges in the lack of HTM policy and need for specialized skills training.

Impact of MDGs Attainment on Medical Equipment Management in Rwanda

Mr. Didier Mukama, BMIT, Rwanda

MDGs have been hailed to spur on development in the developing world. They have clearly defined indicators and objectives, but unfortunately with regards to some technical skills and certain topics, those goals are not yet defined. However, there has been tremendous development in the area of HTM and biomedical engineering in the past years in Rwanda. These are mainly due to the fact that the pursuit of reaching MDG targets provided a platform for the development of Health Technology Management in general and in Biomedical Engineering in particular. This presentation attempts to demonstrate how the implementation of MDGs in Rwanda contributed to a rapid growth of awareness, implementation and improvement of medical equipment maintenance management in public hospitals. The presentation tracks records of strategies adopted by the Ministry of Health of Rwanda in order to attain MDGs and tries to investigate how they directly or indirectly benefited HTM of Medical Equipment Management. It shows the situation of medical equipment management at public hospitals and how it has been gradually improving. Though HTM and medical equipment management are not directly measured goals of the MDGs, the latter provided space for awareness and implementation of medical equipment management plans at the Central Level and in the hospitals. It resulted in better understanding from the political, academic as well as technical authorities from different implementation levels.

Immediate impacts of an inventory on the procurement, donations, maintenance and use of medical equipment at Connaught Government Hospital in Freetown, Sierra Leone

Mr. Alusine Bobson Kabia, Dr. Oliver Johnson, Ministry of Health of Sierra Leone

Connaught Hospital is a 300-bed tertiary government hospital in Freetown, Sierra Leone. It was renovated in 2005 after the civil war, and since then has been the site of numerous programmes to donate medical equipment and improve services. Despite these efforts, the quality of care has remained substandard. A Taskforce set up by the Health Minister in April 2013 to overhaul the hospital identified the shortage, inappropriate procurement, poor maintenance and misuse of medical equipment as a significant cause of this poor care. A Hospital Improvement Committee was tasked with overhauling clinical engineering as a priority. This included developing a system for tracking and maintaining equipment and ensuring that all existing items of equipment were functioning and appropriately located, with staff trained in their use and supplies of necessary consumables. In July 2013, the hospital worked in collaboration with colleagues from King's Health Partners in the UK, which has a strategic partnership with Connaught, to set up an electronic physical asset management system. This system logged the location, asset number, technical specifications, condition, maintenance provisions, users, frequency of use and ownership of all hospital equipment for the first time in a government hospital in Sierra Leone. The inventory demonstrated the enormous scale of the problem, with most equipment being non-functional or unused and with critical equipment gaps. The inventory was implemented rapidly by staff with only basic training and no additional funding. It has immediately enabled significant quantities of hospital equipment to be relocated or repaired and for the hospital to restructure proposals for several major grants and donations (valued at millions of US dollars), which had originally selected inappropriate items of equipment while omitting critical ones. This poster summarises and quantifies the methodology, findings and immediate impacts of the new electronic physical asset management system at Connaught Hospital.

Maintenance des dispositifs médicaux et démarche qualité au Senegal

Dr. Mamadou Sow, Valoris Santé Services/Horizons-Sahel, Senegal

Maintenance of medical devices and hospital's quality procedures in developing countries. The introduction of new medical technologies in the hospitals of developing countries and the way to handle them, which is more and more complicated, makes it necessary to reorganize the job in the maintenance sector by introducing the quality management approach. This condition must be fulfilled to allow, firstly, an optimal use of equipment, the enhancement of the agents' qualifications, the improvement of the working conditions, but also to improve welcoming conditions for patients. The point is, today, particularly in Senegalese hospitals, that Technical Maintenance Services (TMS) are heavily inefficient because of: bad organization of the service; excessive length of the reaction time; inadequate training of maintenance staff; - non-involvement of maintenance personnel in the supplying process for medical devices. The use of the quality management procedure called 5s/Kaisen/TQM, well known in Japan, can help improve this situation. It has been introduced in this way in Senegalese hospitals for three years and the results are encouraging for the control of the working environment. It induces the following consequences: an improvement of the functionalities and the cleanliness of the offices, workshops and stores; a reduction of the waiting time for a document, a working tool; and therefore a faster and more appropriated response to the requests for medical interventions. The methodology can be summed up by a proper implementation of the following five steps: sort, set, shine, standardize, and sustain. Regarding the standard quality management, it should permit: the proper monitoring of existing facilities with a permanent inventory of the equipment following a specific codification with technical characteristics; the development of a preventive maintenance plan including; the warranty of the availability of the spare parts; the establishment of traceability forms for the interventions on the equipments; the effective involvement of the maintenance service under the following conditions: during the acquisitions, when drawing up specifications, the TMS must ensure, in accordance with the administrative services and the medical officers, the selection of the equipment on the basis of strong criteria, which should be easy to use and maintain and the existence of a customer service. Generally speaking, the TMS should: develop the estimate budget and systematically draw the review of the maintenance costs; supervise the activities of external service providers; proceed to a prioritization of interventions according to the degree of emergency; provide regular reports with the identification of operating losses due to non-service; train maintenance personnel as well as operating personnel; participate to all the activities involving medico- technical areas; attend meetings of the committee in charge of receiving donations and make sure that only functional materials are accepted. Taking a long term view with this approach can significantly improve the response to the need for good quality health care. Mamadou SOW Expert Consultant in Hospital Management.

Example maintenance management of medical devices in Benin: The case of Papané Hospital

Mr. Charles Pascal Soroheye, Maliki Seidou Adjarath, Aboubakar Moufalilou, Ministry of Health; Virgile Megnigbeto, Papane Hospital, Benin

Introduction: In order to contribute to improving management of biomedical equipment, UNICREDIT Organization built and equipped with the Software Maintenance Management Computer Aided (CMMS) "LOGEMA" Papané hospital in February 2012. This service is managed by a technician. Since the installation of these tools which are the improvements achieved?
Objective: evaluate the maintenance politic of equipment within Papané hospital.
Achievements: We collected information on the period before and after the use of CMMS software for its scaling. Fifty eight biomedical equipment were recorded in 2011 and 65 in 2012, a growth rate of 10.8%.
Results: The failure rate in 2011 is 43.1% while in 2012 it was 30.8%; availability Registry Safety Quality and Maintenance in 2011 is 40% and 98% in 2012, the rate of availability of biomedical equipment is not known in 2011 while in 2012 it was 96%. In 2012, 20 devices are determined as critics of the risks associated with medical interventions; the rate of preventive maintenance of critical equipment is 89% in 2012 and not traced in 2011. In 2011, the repair cost of medical devices is 2.6 million and 2.5 million CFA in 2012; please note, that the number assigned to outsourced service maintenance in 2011 was 04 while in 2012 it was 01.
Conclusion: The digitization of maintenance service provides good traceability activities, reducing outages and a mastery of the repair cost. It reduces the constraints of data records. But it requires training of maintenance actors.
Outlook: Provide maintenance services of computer tools - Strengthening the capacity of biomedical technician of maintenance.- Aid all the hospital in Benin to have CMMS software.

The governance problem in medical equipment donation projects: Case of Togo

Mr. Komi Agbeko Tsolenyanu, NGO ASMENE (Association for Maternal, Neonatal and Child Health), Togo
The quantity of medical equipment donation to NGO delivering health care services is increasing in Togo. But some governance difficulties appear in the management of these equipment.
Objectives: Evaluate governance problems in medical equipment donation between North partners and healthcare services organizations of Togo; Make recommendations to improve the practices. Methodology of Literature review, key stakeholders consultation, questionnaire administration, interviews, experience sharing. Results: Donation projects are suffering of coordination mechanism, strategic plan and monitoring/evaluation plan, framework of the cooperation of actors, and experience sharing. Furthermore, the alignment and harmonization by North partners are not respected. The planning of the use of donations does not exist at the level of lot of projects. A national data reporting system on the donations is weak. These practices affect the transparency and the visibility in the management of the projects and create governance problems and decrease the help efficiency. The lack of donations management mechanisms presents governance problems. In order to improve the donations impact on the beneficiaries, a better coordination becomes urgent. Perspectives increase advocacy for a better coordination of management of the donations. Create an observatory of bad practices to improve the governance in the project of medical equipment donation: strategic plan, coordination mechanism, monitoring and evaluation plan, creation of observatory of bad practices. We can add the absence of the following tools: code of good practices, environmental and social management plan, waste management plan, technical assistance support plan, and sustainability plan for civil society organization's beneficiaries of medical equipment donation.

Building management capacities for essential equipment and essential medicines supply in Tanzania. A case study.

Mr. Reinhold Werlein, Swiss Tropical and Public Health Institute, Basel, Switzerland

The importance of medical equipment has been underlined in the World Health Report 2000 (WHO) and urged to all member states in the Sixtieth World Health Assembly (WHO, 2007) to introduce adequate policies and effective technology management systems. The reality shows, however, that by and large improvements are elusive. Absence of adequate policies, ineffective procurement procedures, very limited numbers of qualified technical personnel and very limited financial resources are some of the problems leading to a high percentage of non-functional equipment and hence to a substantial impairment of medical services delivery in many countries. Estimates indicate that 60-80% of medical equipment available is "out of order" and cannot be used. Due to a lack of documentation and studies in this field, precise figures do not mostly exist. Facility based health services depend increasingly on supportive facility infrastructure and appropriate medical equipment which will quickly erode in the absence of technology management capacities. Isolated approaches to improve technology management have largely failed to produce the desired results. Health Technology Management is still not in the spotlight of an indispensable part of health systems strengthening. In Tanzania, the SwissTPH support a large scale "Health Promotion and System Strengthening Project, HPSS". Although the emphasis of the HPSS project focuses on the aspects of health promotion and health financing, "health system strengthening" is not complete without strengthening the management and use of essential medicines and health technologies. In an integrated approach, HPSS supports all aspects of technology management including up to date inventory and gap analysis, training of technicians, workshops and tools, maintenance procedures and documentation. A vital element of lasting technology support is to integrate technical staff into the District Health Management teams. The presentation will review success factors and challenges with regards to health technology management in Tanzania.

Developing HTM capacity for Haiti

Mr. Thomas Judd, Kaiser Permanente, United States of America

PAHO and an HTM team are developing a strategy to address identified medical device and HTM needs, with the Ministry of Health of Haiti. Haiti's healthcare system faces many hurdles, particularly since the 2010 earthquake. There has been biomedical equipment technician (BMET) training since 2011 in the private and public sectors (Equipment Support) as well as the multi-region HTM Health Leader trainings in January 2013 (Management Support), and more expected in October, 2013. Recommendations desired for HTM initiatives for the next five years:

1. Equipment Support: make best use of existing trained BMETs (Rotary partnership-46, Tripartite partnership-32)
   i. Additional training cohorts to be determined by public/private hospital demand for BMETs
   ii. Technician training only without Management Support component is not sustainable, as found in ACCE HTM training since 1991
2. Develop a Health Technology (HT) Unit (using best practice HTM) with public-private partnership (PPP) in the capital, with regional satellites
   i. Paid HT Manager, and volunteer BMETs (5-6) "on-loan" from local hospitals
   ii. Satellite units (3-4) staffed by volunteer BMETs (2-3) locally "on-loan" under HT Manager oversight
   iii. Best practice HTM developed jointly by paid HTM Coordinator (USA-based) and Haiti HT Manager, under PPP Advisory Board (AB) oversight
3. Include maintenance support of General Medical devices, as well as Medical Imaging and Laboratory. A PAHO equipment focus area for Maternal and Child Health
4. Move this HT Unit toward full self-sustainability over time; activities to be identified with mutual agreement.
5. Management Support. Maintain a network of public and private health leaders to guide HT Unit(s) and provide rotating volunteer BMETs, formalized through PPP AB.
6. Develop and enable ongoing training for health leaders and BMETs.
7. Project Support. Support hospital technology projects as encouraged by PPP AB; eg, BMET staffing, equipment user training, eHealth – mobile health, donation guidelines, etc.

Regulation of Medical Devices: Country Initiatives

(Spanish translation available)

Session Chair: Mr. Rainer Voelksen
Session Co-Chair: Ms. Irena Prat

Medical devices regulations in Cuba. Progress, challenges and opportunities for regulatory strengthening in the region of the Americas

Ms. Dulce María Martínez Pereira, Lic. Silvia Delgado Ribas, Centro de Control Estatal de Equipos y Dispositivos Médicos (CECMED), Cuba

The Cuban Regulatory Program for medical devices responds to a centralized model, has a scientific and collaborative methodologies, perfects the conformity assessment emphasizing the aspects of risk management, provides a level of inspection systems for medical devices during their life cycle, in the manufacturer's inscription, management quality systems and surveillance as part of the sanitary regulations, also increase professionals competitions for specialists who develop regulatory activity. As part of these results we have maintained a consistent level of publication referred to the technical activity and regulations. The establishment of the Medical Devices Regulatory Program in Cuba and the constant improvement of its legal technical base are an essential part of the regulatory development, which facilitates discussions at the international level and ensures patient safety. Recently we have worked with the application of impact assessment methods to determine improvement opportunities, using a set of indicators for evaluation. As experience in the Region of America highlight the actions directed to the analysis of likeness and differences starting from the systematic celebration of exchange activities among the regulatory authorities, and the development of the cooperation in common, that they propitiate reduce inequalities in the development of regulatory programs and help improve the convergence of these. The challenges and opportunities have been identified from the need to constantly update the regulations, based on technological development, implementation of international standards and practices, to guarantee the safety of medical device, both in patients and users with a minimum risk for medical practice; being recommended to keep global spaces to discuss regulatory issues of medical devices with the highest level of commitment.

Moving towards harmonization of medical devices in Peru

Ms Lida Esther Hildebrandt Pinedo, Headquarters of Medicines Inputs and Drugs, DIGEMID, Department of Health, Peru

The Headquarter of Medicines Inputs and Drugs - DIGEMID is a technical-normative department of Peru's Department of Health, which exercises parsonage, regulative and normative national functions for medical devices. As an importing country that facilitates the revenue of medical device insurances, Peru has managed to introduce inside the Law N°29459, Law of the Pharmaceutical Products, Medical Devices and Sanitary Products and Regulation approved by means of Supreme Decrees D.S N°016-2011-SA.The universal concept of medical devices classifies four levels of risk: low, moderate, and high. Currently, the Modification of Regulation, manages only the approval of the Modification of the Only Text of Administrative Procedures TUPA (Document of management that contains the administrative procedures (Sanitary Authorizations on the basis of the levels of risk), that for legal exigency, must initiate the administered ones before DIGEMID) D.S. N° 013-2009-SA., and it must contain indexes like the Law N°29459 and its regulations. Modifications are not possible simply on the basis of the levels of risk. Thus, we wait that the norm is approved before finishing the present year.

Post market surveillance in Saudi Arabia

Dr. Saleh Al Tayyar, Saudi Food and Drug Authority, Abdullah Thabit, Medical Devices Sector of Saudi Food and Drug Authority, Saudi Arabia

The Medical Devices Sector at the Saudi Food and Drug Authority (SFDA) specifies the overall framework of regulatory approach for post-marketing surveillance of medical devices in Saudi Arabia. The Medical Devices Interim Regulation (MDIR) was issued on Dec. 27, 2008. Followed by a set of Implementing Rules (IRs) as administrative methods used as a part of medical device regulation force the law to ensure medical devices placed on the market and/or put into service within the KSA comply with all relevant provisions of the IRs to ensure that they achieve an appropriate level of safety and performance with regard to the manufacture, supply and use of medical devices. Also a set of Guidance Documents intended to assist organizations operating in the field of Medical Devices to understand their obligations under the SFDA-MDIR and its IR's were issued on Jan. 20, 2011. SFDA regulates medical devices throughout their life span from conception to disposal to assure that risks associated with medical devices are minimized. Post market surveillance is a set of processes and activities the SFDA uses to monitor the safety and effectiveness of medical devices once they are on the market. These activities are designed to generate information to quickly identify poorly performing devices, other safety problems, and rapidly reacting to crisis via taking all necessary actions as well as Protecting whom ever in contact from unsafe medical devices. On the other hand, SFDA has established the National Center for Medical Devices Reporting (NCMDR) with databases involving different stakeholders (consumers, industry professionals, and governmental agencies and international organizations), which is devoted to receive adverse events reports and feedback information about any medical devices malfunction from hospitals and healthcare facilities all around KSA; as well as, receiving product recalls from manufacturers and suppliers to assure that proper action has been conducted.

Regulation on changes to registered medical devices and challenges faced in Singapore

Dr. Huiling Debbie Ko, Health Sciences Authority, Singapore

There are different stages in the product development of a medical device that make up the product life cycle. Two distinct stages include pre-market activities (product design, manufacture and regulatory approval) and post-market surveillance (product maintenance and disposal). The Health Sciences Authority (HSA) in Singapore, Medical Device Branch, is the Authority responsible for regulating medical device products placed on the Singapore market. Implementation of changes to registered devices is dependent on the impact of the change in terms of the safety, quality and efficacy (SQE) of the changed device and has to be titrated against the risk classification assigned to device categories (ie: Class A - lowest risk and Class D - highest risk). In that regard, Singapore has categorised the changes to be notified to the authority, broadly, into minor administrative, administrative or technical change, of which the former can be implemented immediately and the latter requires more extensive review prior to the supply of the changed device. With rapidly surfacing technology coupled with ongoing improvements to devices, changes to existing devices on the market are inevitable. The challenge in adopting a streamlined, risk-based approach at the pre-market level to keep astride with new technology encountered for changes to approved devices include software upgrades, changes to indications and changes to manufacturing processes. In addition, approximately 20% of changes are due to a field safety corrective action (FSCA) that is required as a corrective and preventive action (CAPA). Such changes will require extensive review and approval before the device can be supplied in Singapore. In Singapore, with a life expectancy of 82 years, accompanied with an aging population, regulation of medical devices and enhancements to Singapore's medical device regulation framework have been made to ensure and safe guard public health while ensuring timely market access.

Regulation of medical devices in Tanzania

Ms. Agnes Sitta Kijo, Tanzania Food And Drug Authority, United Republic of Tanzania

Tanzania Food and Drugs Authority (TFDA) is mandated under Section 5(1)(a) of the Act, to regulate all matters relating to quality, safety and performance of medical devices including importation, manufacturing, labelling, storage, promotion, selling and distribution of medical devices in the country. Methodology Regulation of medical devices at TFDA involves registration, importation and exportation, inspection at the port of entry, issuance of business permits, post marketing surveillance and vigilance for medical devices. Evaluation, inspection, licensing and sample collection of medical devices is done according to the guidelines and working tools developed. Results: A total of 300 applications for registration of medical devices were received since 2010 and 99 (33%) applications were registered and posted to TFDA website www.tfda.or.tz 6,768 applications for importation and 53 for exportation of medical devices were received and 6,018 (88%) import permits and 53 (100%) export permits were granted. Post marketing surveillance conducted annually: 600 samples of AD syringes and 120 samples of surgical gloves were collected and sent to laboratory for evaluation. Three adverse event reporting forms for users, health providers, suppliers and manufacturers for medical devices were developed though implementation not yet started. Conclusions: Regulation of medical devices in low and middle income countries is possible when systems are put in place to regulate their quality, safety and performance. A major milestone has been achieved in Tanzania through the setting up of regulatory system for regulation of devices. Nevertheless, a lot still needs to be done.

A new horizon for the medical device sector in South Africa

Ms. Debjani Mueller, CMeRC, University of Witwatersrand, South Africa

Access to high-quality, safe, and appropriate priority medical devices is becoming bedrock of delivery of effective and efficient health care. The decision making process related to commissioning, maintenance and decommissioning of medical devices often taken without evidence, results in poor service delivery particularly in developing countries. The WHO baseline country survey provides a global reference on health technologies, particularly on the availability of specific medical devices, policies, guidelines, standards and services. Developing country specific case studies and sharing road maps on progress would be beneficial. Objective: To describe the current processes being undertaken in South Africa. Method: The study is a qualitative analysis of the various processes currently undertaken in South Africa. Result: In South Africa, medical devices and medical diagnostic sector is estimated at US $2.5/3 billion. Although the South African pharmaceutical sector is subject to comprehensive regulation, it is found that the current knowledge of the medical device sector is insufficient. The absence of a regulatory system combined with a 'multi-channel' system of procurement of medical devices (between public and private as well as within public system across different provinces) contributes to this problem. Lack of skilled manpower, integrated approach to management of medical devices and absence of a regulatory environment were identified as major challenges. South African Health Product Regulatory Authority is currently being established to address the gap. A detailed study is being planned to document the current regulation and legislation; market funding and financing. Additionally, another project is exploring the possibility of setting up a South African Health Regulatory Training Institute to address the shortage of skill in regulation. Conclusion: South Africa is currently in the process of introducing National Health Insurance. Effective and efficient use of medical devices would assist in provision of Universal Health Coverage in this country.

Regulatory affairs of medical devices in Africa; The Nigeria scenario

Dr. Charity Ilonze, National Agency for Food And Drug Administration and Control, Nigeria

In recent times, there has been an upsurge in the demand and need to use various types of medical devices for efficient health care delivery. This has in turn exposed the regulatory gaps and the need for National Regulatory Authorities (NRA) to take charge of the regulatory aspect of these devices to avoid chaotic circulation of substandard or fake medical devices within their jurisdiction. The National Regulatory Authorities in developing countries have been considered non stringent and requires further strengthening in various aspects of their regulatory functions (Milstien and Belgharbi, 2004). Therefore medical devices as an emerging component in healthcare delivery and majority of which are formulated with advanced technology pose a regulatory challenge to most developing countries in Africa. Meanwhile, the entire process between discovery of medical products and the accessibility (Plotkin, 2005) takes a long duration of time. Increased regulatory activities of various National Regulatory Authorities (NRA) have further elongated the time. These activities, though place hurdles for manufacturers (Milstien and Belgharbi, 2004) have led to ensuring to a large extent that only quality, safe and efficacious products are permitted for use within their jurisdiction. This, however, implies that priority medical devices developed and targeted for diseases in developing countries may encounter difficulties with regulatory approval process as the regulators may not have adequate capacity to evaluate these products. This results in delayed access and coverage for the intended population. Efficient harmonized regulatory approval process which can produce timely delivery of quality medical devices to the African populace is therefore an urgent need. The Nigeria NRA, National Agency for Food and Drug Administration and Control (NAFDAC) was established by decree 1993 (as amended) to control and regulate medicines, food, medical devices and other regulated products. The agency therefore has an established regulatory framework for medical devices which continually improves in line with global best practices. This paper outlines the regulatory approval processes of medical devices in Nigeria to elicit comparison with other NRA's licensing processes and consequently further action in the regulation of medical devices.

Towards the implementation of medical devices regulation based on the WHO model in Malaysia and its challenges

Mr. Zamane Abdul Rahman, Medical Device Authority, Malaysia

This article gives an overview of the regulatory framework of the medical devices regulation and the regulatory control of activities based on the WHO regulatory model in Malaysia. The objectives of this medical devices regulation are to ensure patients safety and to invigorate the medical device industry in Malaysia. The Malaysian medical devices regulatory framework is based on the global harmonization trend as promoted by the Global Harmonization Task Force (GHTF), Asian Harmonization Working Party (AHWP) and Medical Device Product Working Group (MDPWG) of the ASEAN Consultative Committee for Standards and Quality (ACCSQ) and supported by the World Health Organization (WHO). The scope of the regulatory control covers the entire life-cycle of the medical device with reference to the WHO model which covers from pre market, placement-on the market and post market. In each phase, the safety and performance of the medical device is assessed, evaluated, approved and regulated based on evidence in accordance with systems bench marked to international requirements. The article also highlights the stage-by-stage regulatory controls of medical devices activities in each phase. Finally the article introduces the challenges of implementation of medical device regulation based on WHO model during the transitional plan before the implementation of the mandatory phase in 2015.

Innovation in Medical Devices for Maternal and Child Health

Session Chair: Prof. Kathleen Sienko
Session Co-Chair: Ms. Laura Alejandra Velez

The five typical misfits of medical technology in the developing world: Why devices designed for high-income countries don't work and what to do about it

Mr. Timothy Prestero, Design that Matters, United States of America

Why are beaded necklaces and abacuses the current state of the art in the developing world for diagnosing pneumonia, the leading cause of childhood mortality? Why are national-level ICUs in low-resource settings overwhelmed with cases of severe newborn jaundice, when treatment only requires shining a blue light on the skin? In 2012, 6.5 million children died before the age of five (UNICEF, 2013). Well-designed medical technology for prevention, diagnosis, and treatment, has the potential for major impact on child mortality in the developing world. However, according to a Duke University study, 98% of donated medical equipment from the western world is broken within five years (Malkin, 2007). The social sector is currently flooded with cost-reduced technologies for the developing world that do not provide many other benefits and are not trusted or well-adopted by users. Design that Matters (DtM) finds the best applications for design and technology to create massive impact in serving the poor in the developing world. We have uncovered five typical misfits of medical technologies: -- untrustworthy-- hard to use correctly -- expensive to own and operate-- hard to maintain -- context incompatible. To design high-impact medical devices for low-resource settings, DtM uses a variety of techniques to get iterative feedback early and often in the design process. Tools like rapid prototypes, flash cards, and sketching engage not just the end user, but the entire ecosystem of people who must choose, use and pay the dues for a medical technology to reach impact. With our partners East Meets West Foundation and manufacturer MTTS, DtM recently launched Firefly phototherapy to treat more than 100,000 newborns with jaundice in rural hospitals in Southeast Asia and beyond. We are now embarking on two technology development programs to tackle pneumonia, the leading cause of child mortality worldwide.

Helping babies breathe: igniting coverage and quality of newborn resuscitation

Ms. Ingrid Laerdal, Tore Laerdal, Ida Neuman, Laerdal Global Health, Norway, Sweden

In just over 3 years, the Helping Babies Breathe (HBB) program has increased the global coverage and quality of newborn resuscitation and newborn resuscitation medical devices. One million babies die on the first day of life. The majority of these could be prevented with basic interventions like newborn resuscitation. However, the UN Commission on Life-Saving Commodities stated that there is limited access to newborn resuscitation commodities and too few staff trained on newborn resuscitation in low-resource countries. To ensure that birth attendants have the essential skills and equipment to save new-borns in low- resource countries, American Academy of Paediatrics with partners developed HBB. It is a 1-day training in newborn resuscitation, based on the latest evidence. By following a simple algorithm and hands-on simulation training using a newborn simulator, students learn lifesaving skills. The newborn simulator, bag-mask, suction and action poster is left at the facility to ensure retention of skills after training. The HBB roll-out is supported by a Global Public-Private Development Alliance, in collaboration with Ministries of Health. So far, HBB has been introduced in 60 countries with 130,000 birth attendants trained and equipped. HBB has increased the demand and coverage of medical devices. Since the launch in mid-2010, a total of 120,000 bag-masks, 150,000 penguin suction devices, and 50,000 NeoNatalie Newborn Simulators have been supplied. These products are available for low-resource countries on a not-for-profit basis. Research has proven that HBB has lifesaving impact. Implementation of HBB in Tanzania was associated with a 47% reduction in early newborn mortality and 25% reduction in rates of fresh stillbirths. The UN General Assembly recently highlighted HBB as a breakthrough innovation that can save children now http://www.path.org/innovations2015/. The HBB program has also spurred new innovations to improve quality of newborn resuscitation, such as the Upright Newborn Bag-Mask. Reference: http://www.laerdalglobalhealth.com/doc/2503/Helping-Babies-Breathe-Global-Development-Alliance

Evaluation and implementation of a bubble continuous positive air pressure system for newborns

Ms. Kelley Maynard, Z Maria Oden, Jocelyn Brown, Mary Kate Quinn, Rebecca Richards, Rice University, United States of America; Robert Miros, 3rd Stone Design, Heather Machen, Suzanne Iniguez, Alfred Gest, Texas Children's Hospital, United States of America; O'Brian Smith, Baylor College of Medicine, United States of America, Zondiwe Mwanza, Kondwani Kawaza, Elizabeth Molyneux, College of Medicine, Queen Elizabeth Central Hospital, Malawi

Problem: Over 1 million neonatal deaths occur annually due to respiratory issues, 99% of which occur in the developing world. In the developed world, respiratory distress syndrome (RDS) is often treated with a bubble Continuous Positive Airway Pressure (bCPAP), but these systems are not yet widely available in the developing world. Commercial bCPAPs cost up to $6,000 USD and are often too costly or complex for developing world hospitals. Indigenous bCPAP setups can be effective, but often require wall air and may not be suitable for long-term use. There is a need for a durable, low-cost bCPAP system for the treatment of RDS in new-borns in the developing world. Solution: A team at Rice University developed a $400 bCPAP that delivers the same therapeutic pressure and flow as commercial devices. The device was evaluated in a pilot clinical trial with 87 neonates at Queen Elizabeth Central Hospital in Blantyre, Malawi. For babies with RDS, treatment with bCPAP over the standard-of-care of nasal oxygen increased survival rates from 24% to 65% (p=0.006). Current Status: With support from a Saving Lives at Birth transition-to-scale grant and in partnership with the Malawi MOH, the Rice team is implementing bCPAP in all 4 central and 27 district hospitals in Malawi. The implementation includes clinical training, community education, tracking of usage and survival 6 months before and 9 months after bCPAP introduction, and an economic evaluation to assess whether using bCPAP to treat neonatal RDS is an effective use of resources. It is estimated that this 3-year program will prevent ~1,400 deaths in Malawi. Future Work: It is estimated that bCPAP could reduce neonatal mortality by >17% in Africa, saving the lives of 178,000 babies each year. Sustainable partnerships and implementation strategies are needed to deploy bCPAP on a large scale throughout Africa and beyond.

Innovative robust CPAP for respiratory therapy of neonates in low resource settings

Mr. Grzegorz Dajer, Medical Technology Transfer and Services Ltd., Vietnam

Background: CPAP is an essential tool in the treatment of RDS in infants, one of the leading causes of newborn mortality. However, CPAP machines are often unsuitable for use in low resource settings as they are insufficiently robust, unnecessarily complex, too expensive to purchase or rely on expensive consumables. MTTS Asia, a Vietnamese biomedical company, has partnered with East Meets West (US based NGO) to design and manufacture a CPAP device suitable to hospitals in low resource countries. Existing technology: MTTS has been manufacturing an appropriate CPAP machine for over 7 years (listed in 2012 WHO Compendium of New and Emerging Health Technologies). Between 2007 and 2012, 491 CPAP machines have been distributed across Asia, of which only 1.6% are known to have been scrapped. It is estimated that as many as 30,000 infants are treated each year with MTTS CPAPs. As the current design demonstrates, it is possible to assemble a functional CPAP device using largely off-the-shelf components and keeping high level integration to a minimum. A reasonable amount of custom electronics and software is necessary, but the majority of sub-systems are manually operated and therefore reliant on user knowledge in order to function correctly. Development: Based on extensive customer feedback and benefiting from the access to the new technologies, MTTS is developing the next generation of CPAP which is scheduled to be launched in early 2014. The aim of the redesign is to create a device that is applicable to a wider variety of contexts (independent of the sources of oxygen, medical air and electrical power) and closely integrated in order to reduce overall clinician effort. The other objectives are to improve device safety, patient comfort, usability and ergonomics as well as lowering lifecycle costs by using high reliability components and materials, thus reducing the likelihood of failure.

Ventouse delivery in a low resource setting - A innovative device

Dr. Tanya Robbins, MCAI (Maternal and Child Health Advocacy International), United Kingdom; Mr. Arfang Faye, Bansang Hospital, Bansang, Gambia

The EgAr Device was developed for ventouse delivery in 2012 by Mr. Arfang D Faye, a registered midwife working in Bansang Hospital, which is the main referral hospital in rural Gambia. The major components of the device are one 60 ml or 100 ml plastic syringe, two valves removed from broken aneroid blood pressure machine inflators, a stethoscope tube and two outflow control units from urine bags. The device works as a two way pump, able to create both negative and positive pressure alternately. The standard metal or plastic cup is used for vacuum delivery and only 2-3 pulls from the syringe create enough negative pressure to create a vacuum suitable for delivery of the baby without the need for continuous pumping. Following approval by the authorities of Bansang Hospital, the EgAr Device was tested from July to November 2012 as a possible replacement for the standard vacuum delivery set which had been damaged and could not be repaired or replaced. The obstetrician and a few registered midwives performed all the vacuum deliveries using the EgAr Device. Data was collected prospectively on 24 women of different ages and parities who met the criteria for vacuum delivery; 22 women had successful vacuum delivery. No short term or long term complication in either mother or baby resulting specifically from use of the EgAr Device was observed or reported. Although not used during the test period, a gauge is now available to determine the pressure generated by the EgAr Device during vacuum delivery showing that 2-3 pulls achieves 0.8 kg/ cm^2.The EgAr Device alone has been used for all vacuum deliveries in Bansang Hospital from July 2012 without any repair or need for replacement. It is inexpensive, light and portable, easy to use, easy to clean and sterilize, and thus has the potential to be extremely useful in low resource settings like Bansang Hospital.

Efficacy of the embrace infant warmer to treat neonatal hypothermia

Dr. Sudhir Borgonha, Jane Chen, Embrace Innovations, United States of America

The Embrace Infant Warmer has helped over 21,000 infants in 11 countries overcome hypothermia. The infant warmer is available for use with or without electricity, the latter used with heated water and more impactful in the community and low resource settings. The WHO recommends thermoregulation to address hypothermia as a critical component of neonatal care. The consequences of hypothermia are more significant in resource-limited settings and impact the progression of achieving the UN Millennium Development Goal 4 (Between 1990-2015, reduce the under-five mortality rate by two thirds). There are a number of approaches to treat hypothermia in the neonate and include incubators, warmers, exothermic mattresses and light bulbs. These technologies have failed to significantly impact neonatal hypothermia in the community setting due to cost, availability and lack of dependable electricity. These approaches also have the disadvantage of physically 'distancing' the baby from the mother, a process that detracts from the other significant benefits of the infant being in close physical contact with the mother. The Embrace Infant Warmer (EIW) is a bed of biocompatible materials into which the infant is placed. A heating pouch consisting of a proprietary Phase Change Material (PCM) is independently heated using an electrical heater or heated water. Once the PCM pouch is warmed to 37°C, it is placed in the pocket of the baby bed. Therefore, the heated pouch is not in direct contact with the skin of the infant but continues to provide heat through indirect transmission. Once the heated pouch is placed in the baby bed, it maintains a temperature of 37°C for 4-6 hours and the infant can be carried, fed or transported. A number of clinical studies have been conducted to demonstrate safety and efficacy of the Embrace Infant Warmer.

Unexplored success route to Nigeria's MDG4 target on neonatal mortality

Dr. Hippolite Amadi, Imperial College London, United Kingdom; Prof. Jonathan C Azubuike, Paediatrics Department Enugu State University Teaching Hospital; Prof Gilbert N Adimora, Paediatrics Department, University of Nigeria Teaching Hospital Enugu; Prof. Akin O Osibogun, Public Health Department University of Lagos Teaching Hospital; Dr. Peter Alabi, University of Abuja Teaching Hospital; Dr. Angela C Uwakwem, Federal Medical Centre Owerri, Nigeria

MDG4 targets two-third reduction in under-5-mortality rate (U5MR) by 2015. Since neonatal mortality accounts 40% of U5MR in Nigeria, any measure undertaken to improve newborn care contributes towards MDG4 target. Many years into MDG4 pursuit, Nigeria could not demonstrate significant progress in newborn survival, from Ibe's (1993) 'increasing-admission-delivery' report to Ogunlesi et al's (2008) 'worsening-hypothermia-risks'. Inadequate neonatal transport to care-centres made premature babies arrive hypothermic. Extreme-low-birth-weight (<1500g) and extremely-preterm (<31weeks-GA) neonates would die without incubator care. A typical Nigerian newborn-centre could have 45 neonates on admission, of which 30 could be preterm. Such situation requires over 20 units functional incubators if the babies must survive. However, no Nigerian centre could demonstrate consistent availability of 4 functional incubators over a period of two years. Incubators were unaffordable and sophisticated, hence low-cost culturally-compliant models must be developed to tackle this fundamental deficiency for MDG4 to succeed. Outreach was initiated (2003) to: (i) devise the Recycled-Incubator-Technique (RIT), which applies generic components to convert carcasses into low-cost incubators, capable of 10 years of life. A cumulative 20 hospital newborn-centres were recruited and progressively expanded in incubator capacity using RIT-systems. (ii) Create centre-based research groups. (iii) Develop elective training courses that instruct clinicians/nurses. (iv) Train independent local artisans to use local materials to produce spare parts. (v) Install power-banking and apnoea-monitoring systems. (vi) Institute biyearly failure-preventive and auditing services. Based on Amadi et al (2010) study, outreach reduced average neonatal mortality by 25% (from 254/1000 to 192/1000); boosted morale/confidence of nurses/clinicians by 79%; accelerated discharge by 19%; boosted patient influx by 27%. These figures have since appreciated, doubling in some hospitals, as centres expand beyond 15-units incubator-capacity and, in fact, up to 38-units in a single centre. RIT and associated techniques have demonstrated the vital signs of efficiency that would have guaranteed MDG4 target in Nigeria.

The potential impact of disruptive technology using a task shifting model in rural Tanzania

Mr. Denver Phiri, GE Healthcare, United Kingdom; Janeen Uzzell, GE GG&O, Ghana; Seleman Mbuyita, Godfrey Mbaruku, Ifakara Health Institute, Tanzania; Kallol Mukherji, GE Healthcare, India

The Bellagio Study group on child survival calculated that full implementation of 16 new-born health interventions could reduce neonatal deaths by 75%. Two such interventions, skilled birth attendants (SBAs) and access to emergency obstetric care (EmONC) are closely linked to the use of ultrasound (U/S). Lack of appropriate technology and skilled manpower are among the reasons why U/S is not deployed. Healthcare staff trained in the use of U/S to identify high risk pregnancies can increase access to this equipment. This would then be used to develop a healthcare model that uses technology to encourage the use of skilled birth attendants (SBAs) and channel at risk pregnancies to EmONC.Healthcare workers in Tanzania who are trained on the use of portable U/S to diagnose conditions related to pregnancy complications that result in maternal and infant death. Training was divided into lectures and practical sessions at a local hospital. A total of 16 U/S topics were covered. Practical sessions emphasised fluid, placenta location, biparietal diameter, crown rump length, foetal position, length and heart-beat. Pre- and post-training assessments were carried out and analysed. After 98 hours of training, participants were oriented to key elements of image formation including colour-Doppler. In addition to performing independent scanning, participants used anatomical and sonographic terminology confidently to describe processes and pregnancy outcomes such as foetal position including breech position. Pre-training assessment scores averaged 5, (95% CI: 3; 6) and in contrast, post-training the average was 14 (95% CI: 12; 15) p-value < 0.0001. Lower-mid tier healthcare providers can learn to perform sonographic procedures following a short training period. The ability of paraprofessionals to reach more pregnant women in rural parts of the country means there is a greater likelihood that more mothers can be referred to EmONC centres where SBAs can attend and facilitate safer delivery.

Medical Imaging

Session Chair: Dr. Jan Labuscagne
Session Co-Chair: Dr. Miriam Mikhail

SOMATOINFRA : The use and application of functional anatomic imaging in disaster medicine, war zones, and its great potential in health screening programmes in developing countries

Mr. Szego John, Ortho-trauma International LLP, United Kingdom; Prof. Mihaly Szacsky, Budapest Technical University, Hungary

The use and application of Functional Anatomic Imaging in disaster medicine, war zones, and its great potential in health screening programmes in developing countries. SOMATOINFRA is a unique technology which allows high-speed, dynamic, real-time imaging of functional life processes. It is the only currently available real-time, functional anatomical imaging technology. It makes possible the creation of real-time images reflecting the high-speed human metabolic life processes through capturing the electromagnetic radiation (human radiation) emanating from the human body. These real-time images are suitable for comprehensive analysis. This method is totally non-invasive; there is no contact whatsoever with the subject being examined. This technology is based on the "Triple Theory" and it may be used to monitor the whole body with no time limit. SOMATOINFRA may be used for a virtually unlimited number of human diagnostic examinations. It is worthwhile to emphasise its usefulness in disaster and war medicine, in early diagnosis of fractures and trauma, in assessing blood circulation, changing metabolic processes, and the detection of infection. It is an excellent and efficient tool to assist triage in the case of mass injuries. In the early diagnostic stages it has the ability to precisely assess sepsis of soft tissues and to uncover infections as well as to measure pain objectively. In disaster and war medicine SOMATOINFRA provides excellent early diagnostic assessment of sepsis providing great benefit to patients. SOMATOINFRA can also provide assessment of developing osteomyelitis in the early stages, ganglion nerve involvement and its remote pain manifestation. We believe that SOMATOINFRA will increasingly become an indispensable tool in the diagnosis and treatment of orthopaedic trauma and rehabilitation. In developing countries, extensive screening and preventative medicine is an almost unachievable dream with traditional diagnostic tools and traditional medical equipment. On the other hand, using SOMATOINFRA technology makes possible the low cost assessment and diagnosis of changed or changing life processes and pathologies and their precise localisation in the patient, following a simple but at the same time complex scan. SOMATOINFRA is an inexpensive yet highly efficient method of screening for pandemics, screening of large populations, it can objectively assess metabolic changes and it can also access and localise oncology processes.

Digital tomosynthesis after detection of suspicious lesions on chest radiography: effect on diagnostic imaging costs

Prof. Emilio Quaia, Guido Grisi, Elisa Baratella, Roberto Cuttin, Gabriele Poillucci, Sara Kus, Maria Assunta Cova, Department of Radiology, University of Trieste, Italy

Digital tomosynthesis (DTS) is a new, minimal-dose x-ray imaging technique that provides tomographic images with the same workflow as a standard x-ray exam. DTS has been demonstrated to enable improved detection and diagnosis for many indications. This paper evaluates diagnostic imaging costs before and after the implementation of digital tomosynthesis for patients with suspected thoracic lesions detected on conventional chest radiography (CXR). Methods: Four-hundred-and-sixty-five patients (263 male, 202 female; age, 72.47±11.33 years) with suspected thoracic lesion(s) after CXR underwent DTS. When a pulmonary non-calcified lesion was identified by DTS, the patient underwent a diagnostic CT exam. If a benign pulmonary or extrapulmonary lesion or pseudolesion was identified on DTS, the patient did not undergo any additional imaging. Diagnostic imaging costs were evaluated before and after DTS implementation. The average imaging cost per patient was calculated by normalizing the costs before and after DTS implementation. Results: In 229/465 patients who underwent DTS after suspicious CXR, DTS showed 193 thoracic lesions and 36 pleural lesions. The lesions in the remaining 236/465 patients were ruled-out as pseudolesions or false positive findings of CXR. Chest CT examination was performed in 127/465 (27%) patients while in the remaining 338/465 patients (73%) CXR doubtful findings were resolved by DTS. The average per-patient costs of CXR, DTS and CT were €15.15, 41.55, and 113.66 respectively. The per-patient saving in diagnostic imaging costs after DTS implementation was € 24.79.Conclusion: When used as a problem solving tool for suspicious findings resulting from CXR, the increased diagnostic accuracy of DTS enables reduction in the use of CT and a reduction in the total cost of diagnostic imaging follow-up of lesions detected on chest radiographs. Consequently, per-patient diagnostic imaging costs decreased after DTS implementation in patients with suspected thoracic lesions.

Experience review on digital imaging, PACS and tele-radiology from a middle income country

Prof. Dorria Salem, Swiss Tropical Institute, Egypt

In the past decade attempts were made to introduce digital radiology in lower income settings. Beside cost-effectiveness issues, digital radiology, PACS [PACS the abbreviation stands for picture archiving and computed system] as well as Tele-radiology encapsulates the potential advantages of improved storage and retrieval of cases and the ability to connect to other information networks, such as health information systems. Tele-radiology is growing globally about 15% per year against the low increasing of professional radiologist that only grows about 2% per year. The concept of the technology might be simple, but the benefit is so huge. [http://info.radiologyservicesonline.com/blog-0/bid/133095/Benefits-of-Hosted-PACS-Systems-for-Teleradiology] Tele-radiology allows the radiologists to make analysis without having to be in the same location as the patients using the common network technologies like telephone lines, internet, LAN and it can be operated using the latest technology, such as computer clouds. So if we can summarize some of the Tele- radiology benefits:

•Images can be accessed anywhere which compensates for radiologists number shortness
•Indiscriminate diagnostic services to all citizens in terms of equity, accessibility and quality irrespective of their sites
•Ability to archive unlimited numbers and types of examinations which helps in patients follow ups
•Elevating the professional level of all the radiologists through having a second opinion from more experienced consultants who could be at any remote place
•Allows users to view images in different locations simultaneously for the purpose of discussions and sharing experiences
•Film-less service that will reduce the costs of the developing process, the doses of exposures to patients from the exams repetitions and consequently the number of films used leading to a cleaner environment
•More convenient working environment as a result of easier workflow that would motivate workers to be more productive

Availability of computed tomography and magnetic resonance imaging devices in the WHO European region

Ms. Alena Usava, Ivo Rakovac, Enrique Loyola, Natela Nadareishvili, Valentina Hafner, Hanne Bak Pedersen, Claudia Stein, WHO Regional Office for Europe, Denmark

The availability of modern medical equipment is an important measure of structure quality of healthcare services. The objective of this abstract is to report on the availability of two commonly used diagnostic devices, namely Computed Tomography Scanners (CT) and Magnetic Resonance Imaging units (MRI) in the Member States of the WHO European Region.
Methods: Data on availability of medical equipment is collected through the Joint EUROSAT / OECD /WHO Regional Office for Europe data collection on nonmonetary health care resources and is disseminated through the European database on human and technical resources for health. The database is freely available from http://data.euro.who.int/HlthResDB.
Results and discussion: On average, 1.49 CT scanners were available in the year 2011 in the WHO European Region, an increase of 32% compared to 2005. Large variation in the availability of CT devices was observed, with country specific density ranging from a low of 0.02 to high of 7.94 devices per 100 000 inhabitants. Fifteen out of 53 Member States did not provide data on the number of CT devices. In the year 2011, 0.93 MRI scanners per 100 000 inhabitants were available in the WHO European Region, an increase of 45% since 2005. Sixteen countries did not provide data on the number of MRI scanners. The availability of CT and MRI devices increased considerably over the last few years in the WHO European Region, but substantial inequalities in availability exist between countries. More than 25% of countries have not yet submitted the data on the availability of MRI and CT devices to the WHO Regional Office for Europe. Therefore, the results should be viewed with caution. Future annual updates of the database will allow situation monitoring and provide countries with possibilities to improve data availability and quality. Acknowledgements: We gratefully acknowledge the contribution from Gaëlle Balestat and Gaetan Lafortune from OECD and Elodie Cayotte, Margarida Domingues-De-Carvalhoand and Hartmut Buchow from Eurostat.

Accessible and affordable point-of-care ultrasound imaging for resource limited settings

Dr. Sailesh Chutani, Mobisante Inc., United States of America

Putting ultrasound imaging devices in the hand of every healthcare provider at the point-of-care (POC) can dramatically increase access to health care while reducing costs. It can enable a higher level of care to be provided in less expensive settings such as clinics, rural and under-resourced healthcare facilities, elder care facilities, and mobile and emergency response situations. It also enables hospitals to improve their efficiency through quicker triage and by reducing the need for moving patients for imaging. Furthermore, ultrasound guidance for procedures such as central and peripheral line placements, and steroid injections can reduce the rate of infections and complications. Ultrasound is a safe non-invasive versatile diagnostic modality that can help in low-cost detection and monitoring of heart disease, vascular disease, fetal health, cancers of the thyroid, lung, breast, and wound management; and is substituting CT imaging in detection of conditions such as appendicitis in kids under 12 due to radiation risks.
Ultrasound-imaging systems that are based on smart phones, tablets, and Internet cloud services can be more accessible and affordable by leveraging the economies of scale and rapid performance improvements of consumer electronics. These systems can leverage built-in network connectivity for seamless access to image management in the cloud and to diagnostician networks for remote diagnosis. We show how such devices are being used successfully in varied settings such as the Everest base camp, rural clinics in Sierra Leone, Nepal, Haiti, and India, as well as community clinics, urgent care centers, and hospitals. They have the potential to bring imaging to 70% of the world's population that lacks access today, and to achieve one of the MDG by improving maternal and fetal health.

Health Technology Assessment

Session Chair: Dr. Hans-Peter Dauben
Session Co-Chair: Mr. Alexandre Lemgruber

EUnetHTA: a network for added value of European collaboration on HTA

Dr. Marina Cerbo, Italy

The National Agency for Regional Healthcare (AGENAS) is a non-economic and non-regulatory public institution in charge of: supporting national and regional health planning, comparing costs and efficiency of healthcare services, detecting malfunctions in managing health resources (human resources, materials and provision), spreading health innovation and experimentation.
It is a technical-scientific Agency of the Italian National Health Service. It promotes collaboration at the different levels of the NHS and is involved in monitoring, conducting studies and elaborating proposals to share with the Ministry of Health and the Italian Regions.
The main areas of activities are:

- Promoting quality, efficiency and equity of healthcare provided by the Italian National Health Service;
- Performing analysis of health expenditure;
- Supporting Regions with financial troubles complying with plans for solvency and requalification;
- Supporting Regions in health planning and evaluation and managing health innovation
- Health Technology Assessment of medical devices and clinical procedures;
- Horizon scanning on emerging health technologies; and
- Managing continuing medical education.

The National Agency coordinates the Italian Network of HTA among HTA technical units of Regions.
AGENAS has been designed by the Ministry of Health as partner of EUnetHTA Joint Actions 1 and 2. In EUnetHTA Joint Action 2 AGENAS is leading the work package 4 on Core HTA collaborative production. AGENAS is member of INAHTA, EUROSCAN and HTAi.

Common European HTAs of Medical Devices

Dr. Katrine B Fronsdal, Norway

The aim of the workshop is to present work on medical devices done within EUnetHTA, the European network for Health Technology Assessment. Since 2006 EUnetHTA's scientific and technical network co-operation has developed a general strategy, principles and an implementation proposal for a sustainable European HTA collaboration while developing scientific tools and shared standards for collaboration in HTA production. HTA bodies in all EU member states, Norway, Switzerland, and Turkey participate. Following a brief introduction providing background and terminology for understanding EUnetHTA's collaborative HTA production, the workshop will give an overview of practical tools developed by the network for common production and sharing of so-called "Core" HTA information and related scientific methodology, like methodological guidelines. Special attention will be given to the HTA Core Model® as assessment framework highlighting the results of several pilot applications on devices. Actual experiences of using this framework for assessing the effects of medical devices, including both full- and rapid assessments, and experiences of using the HTA Core Model® Online tool, will be shared. Speakers will focus on lessons learned from these collaborations in terms of barriers and factors for success related to time, resources, efficiency, and communication. In light of these experiences, future improvements proposed during the Joint Action 2 (2012-5) will be discussed, with the objective of identifying opportunities of reducing unnecessary efforts and optimizing use of resources across borders. Following a brief overview of contemporary policy developments according to Cross Border Healthcare Directive, the workshop opens for discussions with the audience.

Health technology assessment for medical devices: Does one size fit all?

Dr. Joseph Lazar Mathew, Post Graduate Institute of Medical Education and Research; Thalakkotur Lazar Mathew, Psg Institute Of Advanced Studies, Coimbatore, India

Health technology assessment (HTA) has rapidly emerged as the best tool to support evidence-based decisions on all forms of health technology. The various components of HTA can be readily adopted or adapted in different settings for technologies such as pharmaceuticals, vaccines, and other health-care products. However, there are unique challenges and limitations for medical devices. Objectives: This session focuses on (i) the basic principles and procedures involved in HTA of medical devices and (ii) the challenges in transferability and applicability of HTA to a different setting. Topics:
1. HTA for medical devices: this presentation will present the principle and components of health technology assessment using examples of medical devices.
2. Does one size fit all? This presentation will describe issues related to transferability and applicability of HTA for medical devices, from one setting to another with a focus on baseline population, health-professional skill, learning curves, the supporting health-care system and regulatory framework.
3. The way forward: this presentation will describe the options available including adapting HTA for contextual relevance, adopting without modification, and mini-HTA for rapid, context specific decisions.
4. Discussion: This interactive discussion will allow all participants to share their experience, perceptions and solutions.
Intended audience: HTA professionals, clinicians, policy-makers/planners, research scholars, and medical device industry representatives, from developed and developing countries.

Hospital-based Health Technology Assessment in France and Europe - A tool for decision making based on evidence

Dr. Alexandre Barna, Emmanuel Charpentier, Björn Fahlgren, Marc Vanicatte, CEDIT, Hôpitaux de Paris, France
Hospital-based Health Technology Assessment in France and EuropeA tool for decision making based on evidenceComité d'Evaluation et de Diffusion des Innovations Technologiques (CEDIT) Assistance Publique-Hôpitaux de Paris (AP-HP) A decision in medicine should be based on up-to-date scientific results. Because this is difficult to achieve for the individual health care professional or decision maker, the scientific community has developed tools enabling the integration of research results into health care and decision making processes. HTA systems have emerged at the national level, and more recently at the hospital level because:
•Some technologies are not evaluated at the national level (ex: medical devices)
•Even if evaluated, national assessment reports do not address the local and precise questions of interest to a hospital.
•New technologies arrive mainly at university hospitals, which are often subject to pressure from manufacturers, physicians and patients to adopt them. The CEDIT is the hospital based HTA agency of the University Hospitals in the Paris region (AP-HP). Its two main missions with respect to procedures and medical devices are:
•Providing HTA as a tool for decision making
•Ensuring early alert and awareness activities (EAA)
As main activity, each HTA is performed according to four axes of analysis:technical, medical and economic aspects, and finally the social acceptability of the technology. The work is undertaken according to an established procedure that will be described.
Innovative technologies have to be recognized and adequately funded, to be sustainable. The CEDIT is also engaged in identification and evaluation of procedures in view of their reimbursement by the national system. Current developments include national and European cooperation seeking to harmonize methods and reports and to avoid duplication of effort. Research programmes aiming to provide tomorrow's best practice in hospital based HTA are under way.

A national system for introduction of new health technologies in Norway - formalized coordination of hospital-based and national HTA

Dr. Vigdis Lauvrak, Helene Arentz-Hansen, Brynjar Fure, Inger Natvig Norderhaug, Norwegian Knowledge Centre for the Health Services (NOKC), Norway
To strengthen patient safety in Norwegian hospitals a national system for the introduction of new health technologies is in the process of being implemented. The system aims to support equal access to new and innovative technologies. Prevention of harmful, non-evidence-based technologies from being introduced, prioritization, disinvestment of obsolete technologies, and rational use of limited resources are also within the aims of the system. The system has been developed based on an extensive national consensus process involving the Norwegian Directorate of Health, the four health regions in Norway, the Norwegian Knowledge Centre for the Health Services (NOKC), and the Norwegian Medicines Agency. The new system comprises:
•A horizon scanning function for identification of new technologies
•Directions for Health technology assessments (HTA) including hospital based HTA (mini-HTA) for technologies that are non-pharmaceuticals, rapid technology assessments and full HTA for any prioritized technology performed at the national level
•A prioritizing and decision making process
Within this system, NOCK is responsible for the administration of horizon scanning activities, hosting the national mini-HTA-database, developing the mini-HTA system in cooperation with the Regional Health Authorities, production of prioritized single technology assessments on non-pharmaceutical technologies as well as performing full HTAs on prioritized technologies of any kind. In our talk, we will present the structure of the system, how we at NOKC as the national HTA center will support the system and our experience with the system so far. To our knowledge this is one of the few systems were the use of HTA in hospital settings and on the national level is coordinated in a formalized manner. We believe that our experience may be valuable to any setting were national HTAs have to be strictly prioritized, and were hospital HTA may contribute to improved local decision making.

Mini-HTA to support evidence-based decisions for new health technologies in Norwegian hospitals

Dr. Helene Arentz-Hansen, Vigdis Lauvrak, Brynjar Fure, Norwegian Knowledge Centre for the Health Services (NOKC), Norway

It is important to ensure that new health technologies are properly evaluated before they are introduced into clinical practice. Mini-HTA is a tool designed to support evidence-based decisions before uptake of new technologies at the hospital level, and is primarily used to assess medical devices, procedures and diagnostic and organisational technologies. A mini-HTA evaluates the effect, safety, and costs as well as ethical and organisational consequences of a new technology. We have, in cooperation with the Western Norway Regional Health Authority, developed a Norwegian procedure for mini-HTA. In the national system for introduction of new technologies (see abstract from Lauvrak et al), mini-HTA represents the basis for decision-making at the hospital level. Mini-HTA uses the same methodology as HTA, but is a simplified version. The Norwegian mini-HTA is a form that consists of three parts, of which part one regarding effect, safety, costs, organizational and ethical considerations, is the largest. This part is usually prepared by the clinician who wants to introduce a new technology, preferably in cooperation with the hospital's librarians and economists, and can normally be completed within a week. The evaluation of effect and safety is based on a literature search with critical appraisal of relevant research documentation. The clinician's evaluation should be reviewed in part two of the mini-HTA-form, by a non-biased colleague with sufficient competence within the relevant field. Part three of the mini-HTA is a summary of part one and is completed by the decision maker who concludes whether the new technology should be introduced in the hospital or not. In a mini-HTA, the contextualisation of HTA to a specific hospital brings into the assessment process the consideration of its unique characteristics, such as the choice of an available comparator, budgetary consequences for the hospital and the specific organisational patterns of the hospital.

The value of investing in technology appraisal: Lessons for decision-makers in resource-constrained environments

Dr. Vince S. Thomas, V.S. Thomas Global Health Strategy Consulting, Switzerland

Although HTA has emerged as a crucial tool for rational decision-making on competing health resource needs in most developed economies, its use as a tool for effective health system development in developing economies lags far behind. It can be argued, however, that the use of HTA might be more critical in the latter environments where resources are particularly scarce, population demand for health services is overwhelming and the threat of poor decision-making that might result in wastage and unmet need is simply untenable. There is often little familiarity of HTA or its constituent disciplines amongst health care decision-makers in such environments though, as well as a lack of appreciation of the value to be derived from even a rudimentary but comprehensive technical appraisal of the available health technologies for a specific application. This presentation uses a case study of an urgent request for an assessment of RT technologies in a resource-constrained public health environment to describe the development of a Guidance Report and Appraisal Template as basic tools to orient decision-makers in such settings to the value of technology appraisals.

Policies for Medical Devices

Session Chair: Prof. Nicolas Pallikarakis
Session Co-Chair: Dr. Yukiko Nakatani

Free trade agreements and medical technology: implications for policy makers and others

Dr. Trevor Gunn, GMTA, United States of America

At present, more regional and sector-specific free trade agreements, involving more nations than at any time in recent memory, are in the process of being negotiated. These agreements have garnered much interest by Governments, multilateral organizations, NGO's, the private sector and a diverse group of stakeholders. The TransPacific Partnership, the Transatlantic Trade & Investment Partnership and the WTO's sectoral negotiation termed "the Information Technology Agreement" are amongst the most important agreements now being negotiated. These discussions have very specific implications for the medical technology sector—and governments, manufacturers and a wide swathe of important actors. Increasingly, governments and all actors directly involved in negotiating such agreements (whether they are directly connected with health or not) need to have a working understanding of these agreements, their constituent parts, as well as potential ramifications. This session will touch on the important following elements:

-What are free trade agreements?
-Which free trade agreements are currently being negotiated?
-What are the key components and issues being discussed in each of the major, multilateral and sector-specific trade agreements?
- How have Governments, NGO's and the private sector engaged with these various Agreements to-date?
-What are the major debates occurring in the context of the raft of presently–discussed trade agreements?
-What are the anticipated outcomes of the respective agreements, if they are passed, ratified and put into practice?
-What are the broader implications for medical technology regulators, payers and the private sector of one or more of these agreements?

Trevor Gunn, Managing Director of International Relations, Medtronic (representing GMTA), is Vice Chair of the formal Trade Advisory Committee at USTR, which provides advice and direction to the US Government on these agreements. He is Adjunct Professor, School of Foreign Service (CERES), Georgetown University. Full bio: http://explore.georgetown.edu/people/gunnt/

The role of policymakers for health technologies

Dr. Masato Mugitani, Ex-chair for Global Health Workforce Alliance, Japan

Universal Health Coverage (UHC) does not simply refer to the provision of health and medical services to people nationwide, it also encompasses various other facets that are all interlinked. Firstly, as a means of providing health and medical services under UHC, a choice must be made to rely on taxation or insurance for funding, or a mixture of both. Even if a national health insurance scheme is created, unless there is universal access to medical services including medical devices it cannot be termed as UHC. Also, even if there is universal access, if the services that are accessible do not offer a sufficiently high standard of medical care the populace paying for the service will not accept it. Health insurance premiums must be set at a level that if affordable for all people and unless health-related costs are controlled and overseen nationwide will bring a country's finances to the brink of bankruptcy. In this connotation, criteria for medical devices in terms of UHC are Effectiveness, Safety, Availability, Accessibility and Affordability. I have experienced and overcome all these various challenges relating to UHC and half a century has now passed since a Japanese national health insurance scheme was introduced in the 1960s. I seek to leverage the knowledge and experience of Japan to spread and promote UHC in the world.

Brazilian industrial health complex: Availability of access, industrial development and innovation policy

Dr. Paulo Henrique Dantas Antonino, Eduardo Jorge Valadares Oliveira, Leonardo Batista Paiva, Carlos Augusto Grabois Gadelha, Ministry of Health of Brazil

According to the World Health Organization (WHO), there are currently over 10.000 types and around 1,5 million models of medical devices. This wide range reveals the sector complexity and the multiplicity of regulations adopted by members of WHO. It is common sense, however, that ensuring the availability of such devices is crucial to the successful development of strategies and actions in their health systems.This work aims at presenting the recent efforts Brazil has been developing in the medical devices sector in order to strengthen the Industrial Complex of Science, Technology and Innovation in Health as a structural foundation to the sustainable economic and social development, reducing access to health vulnerability in the Brazilian Unified Health System (UHS) context.To achieve that goal, several plans, programs and actions related to the Health Industry and Innovation Complex that Brazil has been enforcing were analyzed. In this context, it is possible to highlight the Program for the Development of the Health Industrial Complex (PDHIC); the Partnerships for Productive Development (PPD); the Plan for Expansion of Radiotherapy Within UHS, the Innovate Health Program (IHP); and National Program for Qualification, Production and Innovation in Equipment and Materials Used in Health, including Government Purchases, internalization of ISO norms, attraction of investments, and promotion and support to research, development and innovation projects. Data shows the Brazilian Policy for Medical Devices and the WHO principles are convergent, especially regarding the goal of ensuring the improvement of access, quality and use medical products and sanitary technologies

The role of the general health council of Mexico (CSG) in the national health system of Mexico

Mr. Roberto Ayala, Ms. Elsa Arellanes Jarquin, National Center for Health Technology Excellence, Mexico

The assessment for the incorporation or modification of health technologies or medical devices in public Institutions is performed by the General Health Council of Mexico (CSG), which is a sanitary authority that depends on the President of Mexico, it is composed by representatives of public health institutions and government offices. The main objective is to provide a coordination mechanism for all institutions and entities comprised in the National Health System. One of the agreements is that Health Institutions should use the terms and codes indicated in a document named Basic Chart for the first level of attention and the Catalog of medical supplies for the second and third level of attention. The main purpose of these documents is to optimize the public resources that are used for medical attention in Mexico; medical devices indicated in these documents have proven their safety, therapeutic efficacy and efficiency, through a methodological process supported by criteria of transparency, efficiency and evidence according to the advances in science and technology, to promote quality and rational use of them. All medicines, healing material, instrumentation, medical equipment and diagnostic aides used by public institutions are grouped, characterized and encoded in basic charts and catalogues, they are a useful reference tool to update and inform health professionals, in case that they require to procure medical supplies or devices. Every medical device is described in a technical specification, in the case of medical equipment we can see Mexican terms and codes, specialties, services, description, indispensable or optional accessories for the function of the device, consumables, spare parts, installation requirements and maintenance. Nowadays, the National Center for Health Technology Excellence (CENETEC) participates in the Instrumental and Medical Equipment Committee as a permanent guest in the CSG, advising and providing information based on the best available evidence for better decision making.

Interaction of HTA and regulation in medical devices: A tool for decision-making

Dr. Ana Maria Perez Galan, Rafael Alonso, Catherine Ausqui, Health Technology Department, Ministry of Health, Uruguay

Integrated National Health System of Uruguay (SNIS) created in 2007 introduced new policies to promote the rational use of health resources. Any new incorporation of technology must be approved by the Ministry of Health taking into account, not only the license, but evidence regarding its usefulness; demographic and epidemiological data; health services indicators and the rationale for its geographical location. In this context, MoH starts in 2009 a comprehensive analysis of all requests for incorporation of new technologies is being carried out by a multidisciplinary team. Healthcare providers or institutions required to ask for authorization in any case of new incorporation of Equipment and Health Services of medium and high complexity. A descriptive study of characterization of and geo referencing of CT and MRI was developed in 2011-2012 and a web census of equipment is being implemented nowadays. A questionnaire was developed for evaluation of applications presented for the technical analysis conducted by the MoH. Reports may arise to: no recommendation of the incorporation requested, recommendation after incorporation of amendments and suggestions, or recommendation for inclusion under the terms established in the request. Up to now, 112 applications have been analyzed, 82 related to the incorporation of medical equipment and 30 for health services incorporation. The procedure to incorporate new technology has been an innovative experience for the MoH since each analysis requires, not only the expedition of the free sale certificate of the new equipment or services, but to make a review of epidemiological situation regarding needs of each technology, service use and the potentiality of share use with other providers. This innovative methodology tends to avoid duplication of services and promotes complementarity among healthcare providers and services in a context of budgetary restrictions and contributes to build a unique system: the SNIS.

Analysis of therapeutic appliances using the information of health accounts

Ms. Xuedan Yuan, David Morgan, OECD, France

Information in health accounts can be utilized to analyze financing schemes and providers of expenditure on therapeutic appliances. After the economic crisis in 2008, the expenditure on therapeutic appliances in a couple of OECD countries dropped sharply, mainly caused by the decrease in the out-of-pocket expenditure or social security funds. In addition, OECD is conducting a pilot project of collecting data of health accounts based on diseases, age and gender. Trends of spending in several OECD countries on the therapeutic appliances by different diseases, different genders (men or women), and different age groups are addressed. For instance, men between 60 and 70 years old in Czech Republic spend more on purchasing therapeutic appliances for treating neoplasm than women at the same age.

Technical Specifications

Session Chair: Prof. Nicolas Pallikarakis
Session Co-Chair: Dr. Yukiko Nakatani

WHO collaboration on a national, EU-funded program for medical equipment procurement

Ms. Dessislava Dimitrova, Results for Development Institute, Bulgaria; Prof. Nicolas Pallikarakis, Institute of Biomedical Technology (INBIT), Greece

Modern medical technology presents an essential tool in providing high quality clinical care, but also a critical decision-making challenge. In a large scale project for purchasing high cost equipment of the latest technology, special attention is required in needs assessment and strategic planning to achieve the best possible and long lasting results. Additionally, technical specifications (TSs) to be used in the call for tenders are of prime importance, from cost and safety points of view. The Bulgarian Ministry of Health (MoH) won an EU project of 150M euro to procure medical equipment. Following an initial needs assessment stage, a team of local experts identified five sets of high priority equipment to be placed in 13 hospitals all over the country. At the next stage the MoH prepared the TSs following a three-phase approach. First, Working Groups (WGs) of renowned specialists developed preliminary sets of parameters, which were placed on the Ministry's web-site for public consultation. Following the feedback from equipment providers, and the incorporation of the accepted comments, a final set was prepared and used. After the project approval, new WGs proposed the final/updated TSs, with additional requirements. However, due to major discrepancies, the MoH went to a fourth stage, in collaboration with the WHO, in order for independent external experts' opinion to be provided. The Institute of Biomedical Technology (INBIT), recognized as an objective, independent, non-profit organization, was contracted to perform this task, which included the revision of 65 TSs and resulted in a final report incorporating a number of major and minor proposals for improvement. Overall, the experience of this international collaboration approach, guided and coordinated by the WHO, has proved very positive and resulted in procuring the highest quality equipment with guaranteed long-term maintenance and 28% savings, allowing three more hospitals to be equipped.

Medical equipment technical specification chart (CET): A tool for the selection for procurement of medical equipment in Mexico

Mr. Roberto Ayala, Ms. Elsa Arellanes Jarquin, National Center for Health Technology Excellence, Mexico

In Mexico, the procurement of medical equipment is performed by national and international biddings for public sector. In many cases, the acquirer who almost always is an administrator does not have enough detailed information to make the decision about which medical equipment is better for the Hospital. In order to solve this problem, the Mexican Ministry of Health through the National Center for Health Technology Excellence (CENETEC), begins to perform medical equipment technical specification charts (CETs), since 2004, which is one of the most important tools consulted by people in the website: http://.cenetec.salud.gob.mx/interior/cet.html. CETs represent a very helpful tool, during the procurement process to select the appropriate technology according to the Hospital necessities, due to their stratification (for example, for the infant incubator we have three different alternatives: general care infant incubator, intensive care infant incubator or transport infant incubator) and their detailed description of technical specifications for every medical equipment. Besides each one has additional information such as: national and international nomenclature (Mexican codes and GMDN codes), definitions, accessories (indispensable or optional), consumables, spare parts, installation requirements and certificates of local or international standards. CETs are performed by biomedical engineers following a methodology specified in which is indicated that is necessary to include two brands at least. Currently, CENETEC has 390 CETs from 107 different technologies. Also CENETEC, as a collaborating center of the World Health Organization (WHO), has been participating in working groups, with the Diagnostic Imaging and Medical Device Unit in 2011 and 2013, to establish a WHO template for technical specifications, this template includes detailed information by specific sections such as name, category and coding, purpose of use, technical characteristics, training and installation, like a standard template. This tool will permit to have reliable information for those who are looking for technical specifications about medical equipment.

Specifications for procurement of medical technologies

Dr. Mery Wilma Teran Carreon, Unidad de Medicamentos y Tecnologia en Salud, Brazil; Victoria De Urioste, OPS/OMS, Bolivia

Our work provides a mechanism to list technical specifications for procurement of medical devices under public call for tenders, as well as the necessary documentation to prove that the devices offered by the pharmaceutical company complies with the requirements set by the organizing body such as the Autonomous Municipal Government, Autonomous Departmental Public Institutions, Management bodies of social security, and the Ministry of Defence Operation and Healing of Armed Forces. The purpose of this tool is to improve the purchase of medicines and medical devices in order to ensure access to medicines by the population, ensuring transparency, efficiency and effectiveness. The advantages of using this instrument are:
-Reliable Providers
-Better control for quality assurance purposes
-Improved mechanisms for product change –
-Improved delivery of products in accordance with terms and conditions
-Expedite the procurememt process
-Increased transparency

Technical specifications – experience and resources

Mr. Andrew Gammie, Fishtail Consulting Ltd, United Kingdom

It is well known that a good specification is key to having quality supply. 'Garbage in, garbage out' is a saying originally applied to computers, but fits equally well with the procurement process. When that process is concerned with medical equipment, then the health, and even lives, of patients are the issue. Specifications thus rightly deserve to be high up the global health agenda. This paper compares experience with the development of two national databases for technical specifications (in India and Nepal) alongside work done in establishing a database under WHO auspices. Comparison will be made with existing commercial systems that contain comparative equipment details and definitions. Through funding from DFID UK, the author was contracted from 2006 to 2011 to advise on the content and management of a specifications database for the Ministry of Health and Family Welfare, India. More than 800 specifications were developed by the local team in standard format using web-accessible data. In 2013 a similar process was started in Nepal, where over 900 specifications are now available online. In both cases, collaboration between donors, implementers and line agencies was maintained throughout the process, ensuring that the system design was aligned to needs. The large variety of stakeholders in the project (donors, civil servants, practitioners) has made progress slow but has ensured widespread awareness of this new resource. In 2011, WHO started work on an open access database of generic specifications. The design is nearing completion with some initial specifications included. The work referred to above, alongside commercially available sources, has contributed to this. Priorities now are the development of a structure that is simple enough to be accessible but detailed enough to be useful, harmonization with existing standards and nomenclature, and promotion internationally of a culture of good procurement practice.

Role of technical specifications in reducing cost and improving access to health technologies

Dr. Jitendar Sharma, Mohammed Ameel, Vatsal Chhaya, Akanksha Suri, Deepti Bhagia, T. Sundararaman, Ministry of Health & Family Welfare, Government of India

Aim: Mapping of technical specifications for ERS Medical Devices as inputs to DG (S&D) for enabling rate contracts to reduce cost of devices for improving access to health. The change in technology, product design, specifications and quality certifications have decisive role in costs of Medical Devices. Medical Devices required in equipment intensive areas require a set of features and specifications that needs to be elaborately defined. In absence of this, the suppliers may have unrequired specifications that could not only increase the cost considerably but also reduce the utility of the equipment with respect to skill levels of healthcare personnel. The lack of technical specifications has been observed as a crucial problem Methodology: To facilitate procurement of medical devices under National Rural Health Mission, National Health Systems Resource Centre frames technical specifications (TS) based on TS templates used by the WHO medical devices unit. The specifications made by the division are subjected to several rounds of expert group discussions before finalizing them in uniform templates. Director General (Supplies & Disposals) then released rate contracts based for devices. A system of rate contracts for medical devices reduces the cost of procurement of devices considerably by: a) Excluding superfluous specifications that could add to costs but are of no value to the context specific requirements b) By promoting healthier and transparent competitions among manufactures/suppliers/ bidders thus reducing baseline costs
Results: In two exercises, cost reduced from 4.6 million INR to 1.6 million INR for complete set of ambulance devices and from 7.0 million INR to 1.5 million INR for compete set of NICU equipment (60 INR= 1 USD). This exercise is being extended to 300 device cluster and has the potential to improve access by reducing cost and fostering transparent competition.

Safety of Medical Devices

(Spanish translation available)

Session Chair: Mr. Alusine Bobson Kabia

Session Co-Chair: Dr. Maria del Rosario Perez

Impact of radiation safety standards on patient safety in the medical Imaging digital era

Dr. Caridad Borrás, IUPESM, United States of America

Several international organizations –among them WHO, PAHO and the IAEA– recently revised the document colloquially known as the Basic Safety Standards (BSS). This document, used worldwide as the basis for national radiation protection regulations, requires practice justification, protection optimization and dose limitation. Doses to patients undergoing medical imaging procedures are not to be limited; however, as part of the radiation protection optimization process, "typical patient doses" and diagnostic reference levels (DRLs) –against which doses are to be compared– have to be determined. The methodologies used for patient dosimetry and DRL implementation vary considerably around the world. Part of the problem is that patient dosimetry in medical imaging has not been globally standardized, even though dose metrics have been proposed by international organizations like the ICRU. Furthermore, confusion exists between radiation-protection quantities, which are prospective, protocol or machine related, and risk-based dose estimates, which may be both prospective and retrospective and may apply to individuals. Many countries have not established DRLs for common x-ray examinations yet; others have used them both for diagnostic and interventional procedures. Some countries, like most EU countries, base the DRLs on the 75th percentile of national patient dose surveys; in the US, DRLs are derived from data resulting from exposing phantoms to standardized techniques. In addition, as a further optimization tool, both the UK and the US use the concept of "achievable dose", a value set at the 50th percentile of the dose distribution. The BSS recommends that DRLs be revised as technology changes; however, in most countries, including the US, the DRLs do not properly reflect the ever-increasing use of digital technologies. Yet, modern digital equipment can store dose metrics in the DICOM headers making data collection really easy. "Typical patient doses" and DRLs for common radiographic, fluoroscopic and CT examinations will be presented and discussed

Engaging with healthcare professionals in India to improve medical device safety: Medical equipment safety workshop series (India 2013)

Dr. Niranjan D Khambete, Sree Chitra Tirunal Institute for Medical Sciences and Technology, India; Alan Murray, University of Newcastle, United Kingdom

Safe and effective use of medical devices is essential for any healthcare system. In most industrialised countries this is achieved by implementing effective equipment management systems by trained and certified clinical engineering professionals. However, in India, newspapers report medical device accidents and clinicians report too low a priority for medical device safety. A previous pilot survey conducted in a representative Indian city of Pune revealed that of 41 clinicians surveyed, 39 reported directly experiencing medical equipment incidents. The "Medical Equipment Safety Workshop Series – India 2013" was a recent drive to confront healthcare authorities and professionals with these problems and to trigger necessary changes. One-day seminars on Medical Equipment Safety were conducted in 7 leading medical colleges and 3 renowned private or charitable hospitals in 8 cities from Trivandrum in the south to Chandigarh in the north. A questionnaire listing 15 of the most common types of medical equipment was circulated, and participants were asked to report any experience of safety incidents with these or other medical equipment. The 429 respondents belonged to six clinical disciplines, worked in government (28%), private (49%) or charitable hospitals (22%), with respondents being practicing doctors (26%), postgraduate medical students (12%), undergraduate medical students (2%), practicing nurses (40%) and nursing students (5%), but also including biomedical engineers (6%), hospital administrators (7%) and clinical technicians (8%). The respondents reported witnessing incidents with electrocautery (35%), suction pumps (33%), blood pressure apparatus (29%), patient monitoring systems (29%), infusion pumps (27%) and motorised operating theatre tables (27%). Incidents due to the other medical equipment were also significant. These findings highlight the urgent need to engage with healthcare professionals as well as medical authorities to highlight the importance of medical equipment safety and to initiate a policy change to formally establish Clinical Engineers in Indian hospitals and medical colleges.

Review of 134 reported clinical medical device incidents

Prof. Alan Murray, Newcastle University, United Kingdom

Without medical devices, the success of modern medicine would be poorer and many lives saved would have been lost. However, in countries that collate safety information, incidents are very frequent. In the UK, the National Health Service (NHS) has found that 10,000 device incidents are reported in one year. In the most recent year reported, there were over 2000 serious injuries and over 300 deaths. This is not to suggest that devices caused the deaths, but their use was a factor. In collaboration with Professor Bertil Jacobson, reports of 140 actual worldwide incidents have been studied, reported anonymously, published in English, reprinted in India for Asian readers, and now being translated into Manderin Chinese. Of these cases, 6 describe accidental death at home, and 134 are clinical incidents. They involve injury or potential injury to over 180 patents and 20 staff, and deaths to over 50 patients. They highlight the importance of collating incidents involving no injury, but having potential for harm, and over 80 are reported. It is stressed that the purpose of reporting is not to find scapegoats, but to prevent incidents from repeating. There was no case in which only one individual was at fault. Many incidents involved a combination of poor device design or a design that did not anticipate how the device might be used, poor or inadequate training, a lack of understanding the very basic device principles, poor maintenance, or inadequate or hurried clinical use. In conclusion, medical device incidents must be reported and reviewed, so that everyone involved can learn from mistakes made, including manufacturer, trainer, clinical engineer and clinician, and that health care management must ensure that incidents are reported. It is essential to be able to anticipate and thus avoid risks.

Assessment of adverse events related to the use of the computed tomography equipment

Mr. Ricardo Alcoforado Maranhão Sá, Secretaria De Estado Da Saúde De Goiás, Brazil; Walter Vieira Mendes Júnior, Escola Nacional de Saúde Pública Sérgio Arouca, Fundação Oswaldo Cruz, Brazil

Objectives: To assess the adverse events (AE) related to the use of the computed tomography equipment informed in the Brazilian and foreign notification system, to classify them accordingly to their causes following the Shepherd approaching model.

Methods: The AE notifications were collected from the Brazilian National System of Adverse Events and Technical Complaints (NOTIVISA); from the Medical Device Reporting Database (MDR) and from the Manufacturer and User Facility Device Experience Database (MAUDE). The AE were classified based on Shepherd model (The Systems Risk Model - SRM). The concept of adverse events (AE) used in this study was: "events that produce, or potentially may produce unexpected or unwanted outcomes that affect the safety of patients, users or others."

Results: There were 519 adverse events (AE) collected related to the tomography equipment, being 233 reports from MDR and 286 reports from MAUDE. No event was found from the Brazilian database. The study showed that 78.2% of AE were related to the medical device component being that 38.9% was related to the parts and circuits project sub-component. The study also showed that 64.5% of AE were ranked as malfunctioning. Our work classified the AE by flawed type, being the software error the most frequent one (20.7%).

Conclusion: In conclusion, we are able to affirm that the Shepherd model is very useful to identify causes and assess the risks of the AE surveyed. There is a large number of reports of medical device-related AE compared to the other components (facility, operator, patient and environment), which may reflect a bias, because of the Shepherd model, that focuses medical devices to the detriment of other components. For future studies, it is proposed to use the Shepherd model to evaluate AE related to the use of radiology equipment like conventional x-ray, ultrasound, MRI and mammography.

Turkish medical device tracking system (MDTS)

Ms. Funda Guler Ozdiler Copur, Ömer Faruk Kuru, Isbara Alp Sezen, Ismet Köksal, Osman Nacar, Ercan Simsek, Turkish Medicine and Medical Devices Agency, Turkey

Turkish Medical Device Tracking System (MDTS) is a database system which enables tracking of medical devices from manufacturing and/or import has not been developed all over the world except for close examples. Deficiency of that kind of tracking system causes prevention of effective use of medical devices, fight against counterfeiting, access to qualified devices, improving patient safety etc. Within this respect, a database system depends on unique tracking of medical devices that has started developing Turkey MoH. Medical Device Tracking System (MDTS) has been considered consisting of 10 different modules: Manufacturing, Notified Bodies, Clinical Investigations, Sales & Distribution, Hospitals, Maintanence & Calibration, Marketing Surveillance, Vigilance, Local Authorities, Turkish National Medical Device Database (a.k.a TITUBB). MDTS has also been planned in compliance with the UDI (Unique Device Identification System) and to be able to transfer data to EUDAMED (European Databank on Medical Devices) concurrently. In conclusion, the system will provide the opportunity tracking clinical Investigations, Notified Bodies' certification activities, effective surveillance and vigilance, effective medical device management in hospitals, transparency, data sharing with EU and also statistical data related with the market. An overview of MDTS has been provided herein.
Key Words: Tracking, Medical Device, Turkish National Medical Device Database, Certification, Transparency.

Learning from medical devices incidents in the national health service in the United Kingdom

Ms. Dagmar Luettel, Dr. David Cousins, Patient Safety for Safe Medication Practice and Medical Devices, NHS England, United Kingdom

Patient safety incidents involving medical devices are responsible for preventable deaths and serious harm in the NHS. In 2012, the National Reporting and Learning System (NRLS) received about one million incident reports from National Health Service (NHS) organisations in England and Wales; almost 40,000 of these involved medical devices and in more than 6,000 cases the patient was reported to have suffered harm as a result of the incident. The NRLS reporting system is separate from the reporting system for medical device incidents operated by the Medicines and Healthcare Regulatory Agency. In 2012, the MHRA received 13,548 incidents. Over 50% of these reports were from manufacturers and less than 25% were from the NHS. All serious incidents in the NRLS are individually reviewed to learn from errors that have occurred. The review process has led to the identification of particular risks (e.g. relating to chest drains, urinary catheters, infusion devices and suction equipment) and specific actions have been issued to prevent such incidents from happening again. See following link for further information http://www.nrls.npsa.nhs.uk/resources/patient-safety-topics/medical-device-equipment/ A quantitative analysis of medical device related incidents reported to the NRLS in 2012 shows that the majority relate to a 'failure' or the 'unavailability' of a device; beds/mattresses, infusion pumps/syringe drivers, and surgical instruments were most commonly involved in these cases. Further work will be undertaken to address these issues. The NRLS already offers a vast amount of information for learning but data quality needs to be improved and local and national systems need to be more integrated, to further enhance the learning from incidents. We are planning to establish a new 'NHS Medical Device Safety Improvement Collaborative' intended to provide continual learning and spread device safety across the NHS.

Medical devices vigilance and patient safety: need for global information extraction and dissemination means

Dr. Kallirroi Stavrianou, Zhivko Bliznakov, Nicolas Pallikarakis, University of Patras, Greece

Patient safety according to WHO 'is a serious global public health issue'. Estimates show that in developed countries 10% of patients are harmed and killed by medical errors. Some of these errors are due to adverse events related to Medical Devices (MD) failures. Although all MDs are produced and 'placed on the market' according to international standards and have the necessary certifications, they could potentially fail in clinical practice causing serious problems or death to patients and staff. MD recalls have significantly increased during the last ten years, a significant percentage of MD recalls are a result of software failure. The EU, through the Medical Device Directives, imposed the use of a vigilance system, and early warning of adverse events should be performed by users reporting to the national authorities (User Reporting System) or to manufacturers (Post-Market Surveillance). However, all countries have not yet implemented such a system and many adverse events remain unknown. The implementation of the EUDAMED application as a central EU initiative has greatly contributed to harmonization but it is a pity that final reports are not publicly accessible, as it is the case with many other similar systems. Additionally, there are relevant data on the Internet, which although not formally validated, could provide useful information for preventive actions. A modern approach based on the introduction of additional informatics tools, such as data mining, extraction, standardization and codification of the information, from different direct and indirect sources worldwide, and its systematic classification and archiving of dedicated databases, would allow improved means of elaborating data. The MEDEVIPAS-THALIS R&D project is actually oriented towards this direction, aiming to study and develop tools for continuous information extraction from structured and non-structured sources and relevant databases using data mining and specific semantics tools. The initial results of this project will be presented.

Innovative Medical Devices for Low-Resource Settings

Session Chair: Mr. Brendon Kearney
Session Co-Chair: Prof. James Abbas

A low-cost, disposable incubator for enabling point-of-care nucleic acid based diagnostics in low resource settings

Mr. Jered Singleton, Dylan Guelig, Chris Zentner, Bernhard Weigl, Paul LaBarre, PATH, United States of America; Josh Buser, Paul Yager, University of Washington, United States of America

There is a substantial global health need for simple nucleic acid-based diagnostics for use in low resource settings. Many infectious diseases, as well as some cancers are most accurately diagnosed through nucleic acid amplification and detection. The technical challenges of performing diagnostics in low resource settings are well understood: Unreliable power, minimally trained users, lack of laboratory supplies, and equipment maintenance are all critical barriers to the timely diagnosis and treatment of infectious diseases. Recent advancements in isothermal nucleic acid amplification methods, simplified sample preparation and lateral flow detection methods have made the concept of fully integrated diagnostic devices or modular kits that employ nucleic acid amplification methods (NAAT) a reality. These advancements could offer NAAT sensitivity and specificity at the point of care. However, one critical component of an isothermal nucleic acid amplification diagnostic method that cannot be achieved in areas without reliable electricity incubation as most isothermal amplification methods rely on enzymatically-catalyzed reactions that require temperatures higher than the ambient for the best results. PATH and collaborators have pioneered work toward Instrument-free, low-cost chemical heating to enable disposable nucleic acid amplification assays that are easy operate at the point of care. We present the current status and results of work towards developing disposable, low cost, temperature-controlled incubators designed to support isothermal NAATs. Heat is generated through exothermic chemical reactions, and the temperature is modulated by engineered phase change materials. By selecting appropriate exothermic and phase change materials and through optimized incubator design, temperatures can be controlled over a wide range suitable for various isothermal amplification methods, and stabilized for over an hour, and at an accuracy of +/- 1 degree C.

Fully-automated point-of-care detection of malaria and other infectious diseases with a disc-shaped diagnostic platform

Dr. Konstantinos Mitsakakis, Sebastian Hin, Oliver Strohmeier, Daniel Mark, Felix von Stetten, Roland Zengerle, Laboratory for MEMS Applications, IMTEK - Department of Microsystems Engineering, University of Freiburg, HSG-IMIT, Germany

Malaria is one of the highest mortality rate infectious diseases globally, mainly prevalent in sub-saharan Africa. Other diseases like dengue, pneumonia, typhoid fever are also present in the same areas, and, although, they emerge from different pathogenic agents, they exhibit the same clinical symptoms (acute fever). This makes reliable diagnosis extremely challenging especially due to the low resource nature of the endemic regions. Under these circumstances, existing diagnostic methods are often not efficient enough and unable to provide a generic solution:

- Blood smear microscopy is only malaria-specific;
- Lateral flow Rapid Diagnostic Tests (RDTs) are cheap but single-target specific;
- Existing molecular methods (e.g., PCR, ELISA) and/or pathogen cultivation require expensive equipment, well-trained users and long time-to-result.

The presently suggested technology aims to provide a true point-of-care diagnostic platform, by addressing key application-oriented needs:

- Portability and autonomous use, based on a disc-shaped plastic disposable cartridge (LabDisk) capable of handling liquid sample (blood) via centrifugal forces operated by a CD-player-like device (LabDisk Player)
- Full automation from sample collection to result, via a simple blood transfer device (patient-to-system interface) and on-disc integration of all biochemical components needed for the blood-based pathogen identification (e.g., molecular probes, buffers, etc).
- Rapid analysis, by using time-saving analytical protocols based on immunoassays and isothermal nucleic acid amplification (LAMP, instead of PCR).
- Multiplexity, by combining a broad diagnostic panel on the same disc (parasites, viruses, bacteria). The panel is flexible and can be tailored to the geographic-specific diseases.
- Low-cost fabrication technology based on microthermoforming of thin polymer foils, adaptable from pharmaceutical and food package production.

This work is part of the EU FP7 project DiscoGnosis, financed by the European Commission which is acknowledged, as well as all the consortium members for their contribution.

A behaviour changing syringe: Making invisible risk, visible to deter the reuse of syringes in a curative context

Dr. David Swann, University of Huddersfield, United Kingdom

Injections are one of the most common health care procedures performed in the world. Yet each year injections using a pre-used syringe accounts for 1.3 million deaths, 26 million life years lost and 5% of HIV cases. Since its introduction in 1986 the auto-destruct syringe has since become a prerequisite device for all immunization programmes. However cost has inhibited their widespread adoption for routine curative use. Our presentation describes a two-year process to develop an effective innovation strategy to deter the reuse of disposable syringes within a curative context. The research has identified two deficiencies with current syringe technologies designed to deter unsafe practices: affordability and difficulty determining syringe sterility when no packaging is present. Human behaviour can have a significant effect on risk outcomes as people often surrender decision-making to those who know more or those individuals who are in a position of trust. The outcome is super-frugal label innovation that synthesizes theories of risk perception, chromism and visual design to enhance the safety performance of any disposable syringe. Inside a nitrogen-filled package our syringe remains colourless. Following exposure to air, our syringe label rapidly absorbs CO_2 particulates to produce a dramatic colour change-- changing from being colourless to red in 120 seconds. A controlled transformation process provides sufficient time to perform the procedure and alerts future patients of its prior use. By making invisible risk visible, we seek to improve clinical compliance and empower literate and illiterate patients to make better risk decisions. The ABC Syringe is nominated for the 2014 ISCID's World Design Impact Prize and the WHO Compendium of Medical innovations for Low-Resource Settings. Following its appearance on CNN International our innovation has attracted significant commercial interest from providers in low-resource settings and global medical device manufacturers. The ABC syringe can be seen at: vimeo.com/73876804

A novel device to screen newborns for hearing loss in resource constrained settings to prevent speech loss

Mr. Nitin Sisodia, Neeti Kailas, Sohum Innovation lab, Dr. Chandrasekhar, IISc, Dr. Rakesh Lodha, Dr. Ramesh Agarwal, AIIMS, India

Permanent disabling hearing impairment (HI) is a major contributor to the global burden of disease. Annually, almost 800,000 babies are born with HI, with 90% of cases in resource-poor countries. Pre-lingual HI has a devastating impact on speech, language and cognitive development, and subsequently on educational and vocational attainment. Detection and intervention in the first year of life have been shown to significantly improve outcomes. Universal newborn hearing screening (NHS) is widely implemented in wealthy nations, but largely absent in low-income countries. A 2009 WHO convention produced a report on Newborn and Infant Hearing Screening calling for "context-specific adaptations of current practices in the developed world" for screening in developing countries. Our project innovates the space of Newborn Hearing Screening in the developing world from three complementary perspectives:

- Development of an innovative technology for resource poor settings where there are few skilled healthcare workers, extreme constraints of time and money that are spread thin over a very large number of babies
- Creating awareness among parents and healthcare workers on the criticality of timely hearing screening for saving speech loss
- Development of a novel model of service delivery and aftercare through building access to audiologists and specialized care.

We have designed a low cost ABR device for resource constrained settings:

- The unique features include: Novel algorithm that can perform in noisy settings; Non-disposable electrodes that lower cost of procedure, easy to use interface that avoids human error; Optimized product design that reduces test duration through reducing preparation time making it ideal for mass screening, and Tele diagnosis that sends data (true positive) to centralized server
- Awareness material for parents: It will increase awareness and involve parents in early detection of HI.
- Audiologist network: Sohum is building a professional network of audiologists for aftercare, in India.

GlobalDiagnostiX: Development of an entirely new, low cost and robust, digital diagnostic imaging system for low-resource contexts

Dr. Klaus Schönenberger, Bertrand Klaiber, Beat Stoll, Program EssentialTech, Cooperation and Development Center, the Swiss Federal Institute of Lausanne and The EssentialMed Foundation, Lausanne, Switzerland; Social And Preventive Medicine Unit, University of Geneva, Switzerland

Radiography and ultrasound are crucial diagnosis tools for a wide variety of conditions, such as pregnancy, road traffic accidents, tuberculosis, complications related to infant pneumonia, or cardiovascular problems. Despite this, over two-thirds of the world's population still does not have access to basic medical imaging. This is mainly due to the mismatch between existing technologies and the local context in developing countries. Equipment developed for industrialized countries is neither appropriate for the rough-and-ready or deficient infrastructure found in most resource-poor areas, nor affordable for limited available healthcare budgets. For radiography, in particular, solutions based on film technology have proven to not be adapted to district hospitals in developing countries; and modern digital imaging solutions are also too expensive, complex and fragile. Project GlobalDiagnostiX aims to develop an appropriate digital imaging system that:

Provide both essential radiography and ultrasound features;
Targets a tenfold reduction in the total cost of ownership (purchase price plus the lifecycle costs), as compared to existing solutions;
Is adapted to the context in developing countries without compromising on the quality and performance of the primary function.
The project includes not only the technological challenges but also the question of creating the value-chain that will enable the device to be manufactured, deployed, maintained, repaired and appropriately used by the locally available staff in district hospitals. A business model is being elaborated to assure a sustainable access to this essential equipment in the district hospitals. We present the project's status and first technological results.

Disruptive innovation for sustainable healthcare - Enabling technologies for portable ultrasound devices

Prof. Daniel Steenstra, Dr. John Ahmet Erkoyuncu, Cranfield University, United Kingdom

The current model of healthcare relies on diagnostics, therapy and care being delivered in hospitals using complex and costly technologies. It requires clinicians to develop high levels of technical skills and patients to be taken out of their community environment. This model is under pressure as healthcare systems struggle to adapt to economic constraints. The cost of medical technology is a key factor in the growth of healthcare spending (Appleby, 2013). Furthermore 'technology push' increases the rural and urban divide and ultimately leads to unsustainable healthcare. The UK government policy is promoting integrated care and shifting healthcare to the community. In order to implement this, diagnostic capabilities in primary care needs to be developed. Disruptive innovations are based on simplifying technologies (Christensen, 2009). Disruptive diagnostic devices will enable integrated care and the shift to community-centred healthcare as it offers affordable devices that are simpler to use. Until recently, ultrasound diagnostics was confined to hospitals due to the size and cost of the equipment and the specialist skills required. New portable and affordable ultrasound devices have been introduced that can be used in primary care. However clinicians still need extensive training to develop the skills required to capture and interpret images. Decision-makers require information of the costs/benefits of alternative pathways, enabled by portable ultrasound. The Cranfield research team developed two apps for:
-Conceptual clinical decision-support-system for clinicians in primary care with little experience of ultrasound to use portable ultrasound for specific conditions e.g. gall stones, reducing the need for training.
-Cost/benefit analysis of alternative pathways.
Both apps are generic and can be customised for other conditions; they were validated successfully by stakeholders. Portable ultrasound is a potential disruptive innovation that can enable integrated pathways and reduce healthcare cost. It requires enabling technologies to reduce training and provide cost/benefits for implementation.

Human Resources in BME

(French translation available)

Session Chair: Prof. Herbert Voigt
Session Co-Chair: Mr. Adham Ismail Abdel Moheim

Academic models for undergraduate biomedical engineering

Dr. Shankar Muthu Krishnan, Wentworth Institute of Technology, United States of America

There is a proliferation of medical devices across the globe for the diagnosis and therapy of diseases. Biomedical engineering (BME) plays a significant role in healthcare and advancing medical technologies thus creating a substantial demand for biomedical engineers at undergraduate and graduate levels. There has been a surge in undergraduate programs due to demands from the biomedical industry to cover all segments from bench to bedside. With the requirement of multidisciplinary training within allottable duration, it is a challenge to design a comprehensive undergraduate BME program. This paper's objective is to describe three different models of undergraduate BME programs and their curricular requirements, with a recommendation to apply them in low and medium resource settings.

In Model 1, based on large research intensive universities, BME curricula are divided into basic sciences, mathematics, engineering, computing, BME core and focus areas, humanities, social sciences and free electives. Focus areas depend on the institution's research expertise and training mission.
Model 2 has basic areas similar to those of Model 1, but focus areas are limited such as medical devices and systems, clinical engineering, etc. Co-op/ internship in hospitals or medical companies is required.
In Model 3, students are trained to work as BME Technicians in the initial two years and they are trained to be BME's or BME Technologists in the subsequent two years. All three models are designed to meet applicable accreditation requirements. The challenges in designing undergraduate BME programs include manpower, facility and funding resource requirements and time constraints. Each academic institution has to carefully analyze its short and long term requirements.
In conclusion, three models for BME programs are described based on large universities, undergraduate colleges, and community colleges. Models 2 and 3 can be successfully implemented in nations with low and limited resources with appropriate guidance and support from international organizations.

IFMBE role in the network of training programs in BME on low-resource countries

Prof. Mario Forjaz Secca,International Federation on Medical and Biological Engineering (IFMBE), Portugal; Andre Linnenbank, IFMBE, Netherlands; Ratko Magjarevic, IFMBE, United States of America; Herbert Voigt, IUPESM, Croatia

The International Federation of Biomedical Engineering (IFMBE), which is considered an NGO for the UN, has as its aims "to encourage research and application of knowledge, and to disseminate information and promote collaboration" in Biomedical Engineering. As part of this aim IFMBE has created some time ago a Working Group on Developing Countries (WGDC), which has as its main objective the dissemination of the importance of BME in health settings and the training and promotion of BME experts in low-resource countries. Most of the members of this Working Group are originally from, live in or have projects in low-resource countries, carrying with them a wealth of experience in this area. The WGDC has already been in active contact with different organizations, for example, Engineering World Health (EWH), and several individuals involved in separate BME training projects around the world. Because there are similar problems and common experiences and many times these initiatives should be integrated with policy and certification issues, it is very important to exchange experiences and share knowledge regarding these various projects and collaborations, taking into account specific locations and regions of the world. In low-resource countries there is a clear overlap between medical physicists and biomedical engineers and it is not very easy to distinguish between them in many cases. Considering we have close links with IOMP and IUPESM, we believe we are in a unique position to act as a node of contacts to share experiences and ideas regarding BME training programs and act as a catalyst to study and start new projects in low-resource countries all around the world.

Undergraduate engineering student clinical immersion experiences: outcomes and management of expectations

Prof. Kathleen H. Sienko, University of Michigan, United States of America; Kwabena A. Danso, Henry S. Opare-Addo, Alexander T. Odoi, Komfo Anokye Teaching Hospital, Samuel Obed, Korle Bu Teaching Hospital, Elsie Effah Kaufmann, University of Ghana; Aileen Huang-Saad, Amir Sabet Sarvestani, Frank W. J. Anderson, Timothy R. B. Johnson, University of Michigan, United States of America

Since 2008, more than 50 undergraduate students from the University of Michigan have conducted clinical observations at the Komfo Anokye and Korle Bu Teaching Hospitals in Ghana for the purpose of identifying maternal health challenges. These clinical experiences were used to identify health challenges that can be addressed through engineering course-based design projects. From an engineering education perspective, the objectives of the clinical immersion experience are to provide students with an opportunity to apply and further develop design ethnography skills, establish intercultural and interdisciplinary communication skills, develop clinical literacy on a particular health care topic, co-identify unmet needs, formulate needs statements, and gain an understanding of the local and broader contexts of design. From a clinical perspective, the health care department chairs, deans, and provosts recognize the opportunities of such programs to foster cross-fertilization across disciplines (between and within institutions) and an innovative mindset among healthcare providers. Furthermore, the time and resources invested in exposing engineering students to the clinical environment and mentoring them are perceived to be worthwhile given the likely long-term potential for some of these students to become medical device industry leaders and entrepreneurs focused on the design, development, and implementation of technological solutions for low-resource settings. Although the primary goal of the clinical immersion experience is to provide an educational opportunity for the undergraduate engineering students, there is an overwhelming desire, and often times an unmet expectation, for the student-designed prototypes to transition beyond the classroom. Therefore, to cultivate partnerships centered on trust, openness, mutual understanding and respect, the management of expectations among all participants, including the students, healthcare staff, healthcare providers, and patients is extremely important. This presentation will address both the intended and unintended outcomes of this six-year partnership.

The role of the regulatory professional in shaping good regulatory policy

Dr. Philippe Auclair, Sherry Keramidas, Regulatory Affairs Professionals Society (RAPS), United States of America; Rainer Voelksen, RAPS, Switzerland

Developing effective policies for medical devices requires alignment of scientific and technology factors, clinical, economic and social considerations, as well as legal and political factors. This process involves balancing the views of many different professionals, politicians, businesses and the public. Developing effective policies today and tomorrow must also rely on the active involvement of competent regulatory professionals. The scope of practice of regulatory professionals extends throughout the product lifecycle, bridging science and regulation, and also encompasses economic considerations within a country, a region and globally. This presentation will link the scope of practice of the profession, its essential competencies and professional code of ethics to an ongoing process for driving good policies in the future and the role of the profession is fostering harmonization of regulatory systems and healthcare standards. Finally, this presentation will discuss the relationship between developing competency based curricula for regulatory professionals and the profession's broader role in policy.

Safe care: An initiative for regulations in Kuwait

Ms. Hanan Al-awadhi, Kuwait Association for Biomedical Engineers/Kuwait Society of Engineers,Kuwait

Medical device regulatory bodies worldwide aim to achieve the highest levels of safe care, and to enhance public health by setting guidelines and regulations for the medical device industry through various activities concerned with device design, manufacturing, marketing and post marketing, recall, etc. In countries where regulatory bodies do not exist, both care providers and receivers are at risk. Kuwait is no different. This presentation explores the Kuwait Association for Biomedical Engineers efforts to promote medical device regulations in Kuwait through its Safe Care initiative and lessons learned.

A survey on the training and performance of medical engineering of professionals in Kenya

Mr. Peter Matoke, Association of Medical Engineering of Kenya (AMEK), Martin Owino, Mary Ngugi, Medical Engineering Services Division-Ministry of Health; Gordon Agalo, Peter M. Guchu, KMTC-Nairobi Campus; Shadrack Wamwayi, Francis O. Mbanga, Kenyatta National Hospital; George O.Odongo, Isaac Cheptiony, KMTC-Nairobi Campus, Kenya

Between December 24, 2011, and November 4, 2011, a survey was conducted in Kenya covering level 4 and 5 public hospitals. The purpose of the survey was to assess the effectiveness of Medical Engineering personnel in public hospitals in Kenya, in Medical Equipment management. The survey was conducted by means of 6 questionnaires that were used to sample a targeted population of 20 hospital administrators, 20 medical engineering in-charges, 60 medical engineering technologist/technicians, 60 equipment users mainly from the departments of theatre, maternity and laboratory, all Lecturers from medical engineering department of KMTC and 50 medical engineering students at KMTC. The responses to the questions were rated accordingly and the most significant items found were as follows:

1. Responses by medical engineering in-charges on update of inventory No=13%, Yes=87%;
2. Inadequate testing/measuring instruments in the workshop=8%; Technology of the equipment, Electrical/Electronics=37%,Digital/ Microprocessor=30%,Electro-mechanical=25%,purely mechanical=7%; Performance of maintenance staff, Very good=57%, Good=36%, Fair=7%;
3. Repair/maintenance of medical equipment: by Contractors=38% and by Medical Engineering staff=62%;
4. Level of education of teaching staff, Degree=13%, Higher Diploma=38%,Diploma=43%,Certificate=6%;
5. Level of complication to use the medical equipment, Complicated technology=18%, Lack of specialized skills=18%, Lack of teaching equipment=24%,
6. Students rating of curriculum and teaching: 58%(Yes), 32%(No), and 10% (I don't know)
7. Availability of teaching and learning materials: 25%(Yes), 73%(No), and 2% (I don't know).

If any conclusions may be drawn from the data, they are, perhaps, as follows:

-Most of the maintenance in public hospitals is done by medical engineering personnel.

-Lack of policy and guidelines on skills upgrading and Continued Professional Development (CPD) make both the academic staff and personnel in the field to perform below their capability.

-The curriculum meets the expectation of the students. However, they would prefer some improvement on the delivery of practical training mainly by improving the size of practical areas.

-Unavailability of spare parts and lack of funds mainly affects the performance of the medical engineering personnel in the public hospitals.

Local Production in Low-Resource Settings

Session Chair: Mr. Amir Sabet Sarvestani
Session Co-Chair: Dr. Heike Hufnagel

Importance of indigenous R&D and manufacture of medical devices in the light of Bangladesh experience

Prof. Khondkar Siddique-e Rabbani, University of Dhaka, Bangladesh

More than 90% of medical devices can be designed and developed with the expertise available in the Third World, and without indigenous development and commercialisation 80% of global population living in these countries cannot get the benefits of modern healthcare technology. This realisation made the author's team design several medical devices which are being used in hospitals, clinics or by patients themselves. These devices include:

1. Computerised EMG/Nerve conduction equipment (routinely used over 25yrs),
2. Computerised ECG (1yr),
3. Computerised dynamic Pedograph (routinely used in a foreign hospital for 3yrs),
4. Iontophoresis equipment for treatment of excessive sweating (being used by hundreds of patients over 15yrs),
5. Muscle & Nerve stimulator (being used by physiotherapists over 15yrs),
6. Mechanical prosthetic hand (1yr). Recently his group has also developed a telemedicine system including software for expert consultation and prescription, and a few diagnostic devices connected to it which includes:
    i. ECG
    ii. Microscope,
    iii. X-ray Viewbox,
    iv. Stethoscope, and
    v. Dermatology camera.

The costs are significantly lower than that of similar imported ones. For manufacture and commercial marketing of the devices the author's group founded a non-shareholding company where no person takes the profits. From experience the author realises that commercialisation of new technological products have to be done by technology innovators themselves in most Third World countries like Bangladesh where no industry exists that can do so. The main advantage of local design and manufacture is that the devices

i.Suit local weather
ii.Suit behaviour and culture of local people
iii.Gives new solutions to local diseases,
iv.Are affordable,
v.Provide ensured maintenance and repair giving a prolonged effective life and almost uninterrupted service to people.

The author's group is not patenting their innovations. They intend to open up the technology once mature so that persons in other Third World countries can provide similar services to their own people.

Challenges in local production of medical devices by domestic manufacturers in India

Mr. Balram Sankaran, Sree Chitra Tirunal Institute For Medical Sciences And Technology, India

The Indian domestic medical device Industry is emerging slowly out of infancy and is on a path of growth to meet the increasing demand for medical devices in India as well as for exports. As more and more new companies enter the medical devices sector and as existing companies attempt to grow, they are faced with the sector specific challenges of local production and marketing of medical devices in India. While the industry is collectively keen to manufacture affordable and good quality products in India, they feel disadvantaged as compared to importers or multinational companies. The challenges faced by the domestic companies were echoed in a series of brainstorming sessions by the captains of several leading domestic industry in a series of meetings held at New Delhi, Mumbai, Chennai and Trivandrum during late 2011 as part of an initiative taken by the Sree Chitra Tirunal Institute for Medical Sciences and Technology, a premier national research and development Institute in India. The key perception of the domestic manufacturers was that medtech industry in India was a neglected sector as far as the policy makers are concerned and therefore the growth of domestic industry was adversely affected either due to absence of policies or implementation of policies that favored import of medical devices in tothe country rather than local production of medical devices. This paper summarizes the collective voice of the domestic medtech industry in India regarding the challenges perceived by them in innovating, local manufacturing and marketing affordable medical devices and the aspirations of the industry regarding their expected support from the policy makers to nurture the growth of domestic industry segment.

Facilitating local production for improved access to in-vitro diagnostics

Dr. Ruth McNerney, London School of Hygiene & Tropical Medicine, United Kingdom

In vitro diagnostic (IVD) medical devices are needed for appropriate patient management and evidence-based disease control strategies. Test devices that may be used at the point of care, without referral to laboratory facilities, can improve access to healthcare in developing countries. Local production of such tests could be a first step towards improving equity in access. Currently, developing country capacity to manufacture is limited and production mainly occurs in the emerging economies, with little activity in Africa. Factors such as availability of finance, quality of manufacture and national procurement policy are important to the success of local production. There are not a consensus set of policies for technology transfer to establish local production of diagnostic devices. Although there are some examples of success, there are concerns about the quality of tests being manufactured in developing countries. To address the shortfall in capacity a framework is required to create a coherent policy environment of incentives, standards and regulation for manufacture of IVD medical devices in developing countries. The development of a policy framework and a strategic plan to map out a critical path for technology transfer and local production, define standards and roles and responsibilities of different stakeholders would be critical to achieving the ultimate goal of increasing access to diagnostics to save lives and reduce disease burden. We shall discuss the development of a road map for establishing local production of IVD and the setting of minimal and optimal standards for local production of in-vitro diagnostics in developing countries. Target audience is test developers and manufacturers, policy makers, regulators, donors and other stakeholders interested in local production of medical products.

Improving access to medical devices in low-resource settings through local production and technology transfer: WHO 2013 survey results

Prof. James Abbas, Arizona State University, USA; Amir Sabet Sarvastani, University of Michigan, USA; Mladen Poluta, University of Cape Town & University of Pretoria, South Africa; Peng Si, Nanyang Technological University, Singapore; Adriana Velazquez-Berumen, WHO

In Resolutions WHA61.21 and WHA62.16, the World Health Assembly set forth the goals to improve the transfer of and access to medical technology in developing countries. Local production may provide an important mechanism to increase access to medical devices. The WHO's Medical Devices Unit is currently conducting the second phase of a project that includes a survey to gather information about technology transfer and local production of medical devices. This survey was performed to better understand the barriers and challenges related to sustainable local development and production of medical devices. The survey included questions regarding the environment for product development and manufacturing, policy and partnerships, intellectual property protection, regulation and technology transfer, policies for acquisition, procurement and reimbursement. Respondents' background, training information, and their role in the technology development and commercialization process were also collected and matched to their input. Responses were received from 173 stakeholders in 47 countries. Analysis indicates that the most frequently cited barriers to access of medical devices in low-resource settings were cost and maintenance issues. Medical device developers indicated that the major obstacles to develop and commercialize their products in low-and middle-income countries (LMICs) were the lack of financial resources and inadequate local facilities. Respondents indicated that the top challenges to manufacture medical devices locally in LMICs are international competition, expensive startup costs, lack of trust in locally produced products and bureaucratic procedures to setup local manufacturing facilities.

Seating fabrication system for clinical rehabilitation settings in low income countries: the experience of Mexico and Colombia

Dr Jorge Letechipia, Abel Arredondo, Aldo Alessi, Luis Hernández, Graciela Fregoso, Andrés Torres, Robinson A. Torres, Yeison J. Montagut, Ibero Ciudad de Mexico, Mexico

The benefits experienced by assistive technology (AT) users include increased independence and comfort, however, only a small percentage of the world population with a disability has access to AT. In low income countries AT is rarely available. Sustainable methods for designing, producing and distributing AT within these are required. This paper describes the design and implementation of a seating fabrication system to be used in clinical rehabilitation settings in urban areas of low income countries. The system was implemented and tested in a collaborative project between Mexico and Colombia. More than 100 seating systems were fabricated. Therapists approved and adopted the system easily. Children and adults with disabilities were provided with a custom made seating system. Numerous additional devices need to be developed before the AT needs of these countries are met. However, international teamwork between local universities proved to be an effective method to address the AT needs of their communities. This approach could be implemented in other low income countries.

Procurement of Medical Devices *(French translation available)*

Session Chair: Mr. Andreas Seiter
Session Co-Chair: Mr. Prem Prakash Chopra

Global price system - project to collaboration in economic information about medical devices

Mr. Murilo Contó, Eduardo Coura Assis, Clarice Petramale, Vania Canuto, Ministry of Health of Brazil

One of the biggest challenges in HTA analysis in supporting the decision making process for the adoption of new technologies is to obtain reliable information about the real prices in different markets to set the fairest price in order to obtain a good cost-effective ratio. In the pharmaceutical market, agencies and ministries of health maker use of instruments and legislation in order to reduce the information asymmetry and assure incorporation with a fair price. However, when it comes to medical devices, the difficulty in promoting these same practices is complicated as there is not a standardized nomenclature, with names being different in different countries. Considering this problem, DGITS-CONITEC within the Ministry of Health of Brazil, is launching an initiative to facilitate the exchange of prices. The project involves the development of a web registration system for pricing information based on the brand/model of each device which is an almost unalterable standard in any country. The system will provide management units in each partner (Government Institutions) so they can register local users such as universities and hospitals who constantly purchase these technologies and can feed the system. The system will have a structure based in separate device groups, such as cardiology, orthopedics, neurology, and sub-groups, such as stents, catheters, valves, which will expand themselves, according to the needs. English will be the default language, but the system will allow each country to work with an interface in their language. The default currency will be the American Dollar or Euro and will also allow each country register in their local currency. This tool will be developed and made freely available to partners allowing the establishment of a network of very significant economic information to support the decision-making process for the adoption of technologies and negotiation process with the medical device industry.

Need for care operators to increase efficiency in medical device procurement through volume pooling, resources and expertise

Mr. Charles-Edouard Escurat, GIP Resah-Idf, France

“Facing many challenges, including financial restrictions for healthcare systems, it is now essential for the care operators to increase the efficiency of medical devices procurement. This can be achieved by pooling volumes but also means of action, resources and expertise. In this perspective, RESAH coordinates the procurement network of Paris region non-profit hospitals and leads the Specific Interest group on group purchasing of the International Hospital Federation.”

Mechanisms for introducing large medical devices into developing countries. Avoiding the pitfalls of the past and providing possible solutions for the future

Dr. Maurice Paul David Burke, Abiodun Adeyemi, Paula Horne, Kate Ricketts, Royal Berkshire Hospital, James Annkah, Ivan Rosenberg, Gary Royle, University College London, Shauna Mullally, Tropical Health and Education Trust (THET), United Kingdom; Eric Addison, Komfo Anokye Hospital, Theophilus Sackey, Korle Bu Teaching Hospital, Ghana

The predicted emergence of cancer as a major NCD in developing countries by 2020 has already prompted some governments to invest in cancer treatment. The large medical devices required to provide comprehensive radiotherapy are both expensive to purchase and to install. Manufacturers have therefore started producing a range of large medical devices which are specifically designed for the emerging market in developing countries. This market, however, can produce unforeseen problems. The lack of experience of the logistics involved in the delivery and installation of such large pieces of equipment can often lead to underestimations in time scales by the recipients. Advice and assistance on the clinical procurement process is essential for avoiding long delays. Within the UK, the lifecycle of radiotherapy machines can often be ten years or less, which in most cases is well below the actual lifetime of the machines. Therefore many machines are decommissioned to be scrapped well within the usable equipment lifetime. However, if decommissioning was performed so that the machine could be salvaged, the extra cost would be relatively low. Such machines could be serviced and donated to developing countries allowing them to increase their radiotherapy coverage greatly for the cost of the decommissioning, servicing and installation process. Therefore it would seem that with a small change to the decommissioning process of large medical devices, developing countries who could benefit from equipment, which otherwise would be scrapped, could attain a large number of life changing pieces of equipment within their tight budgetary constraints and make a real impact on the predicted increase in cancer deaths.

HIV diagnostics: Procurement, selection and use

Dr. Elliot Cowan, Partners in Diagnostics, LLC, United States of America

Access to accurate and reliable good quality diagnostics is the cornerstone of cost-effective and high impact HIV prevention, treatment and care programmes. For many years, WHO has recommended the use of HIV rapid diagnostic tests (RDTs) to expand access to HIV testing and counselling (HTC). Task shifting has increasingly led to non-laboratory trained health workers and lay people using RDTs. High staff turnover, inadequate training, inadequate supervisory mechanisms, ambiguous instructions, and busy clinics have the potential to contribute to the risk of poor quality testing practices. We propose to hold a training workshop to highlight the issues that most contribute to quality of testing and provide practical guidance to improve procurement and quality assurance for diagnostics, including improved capacities for post-market surveillance. This session will address issues related to the selection and use of diagnostics as well as to procurement and supply chain management of diagnostics. With respect to guidance on better practices for selection and use of HIV diagnostics, the following topics will be discussed: implementation of WHO HIV testing strategies, validation of national testing algorithms, issues that relate to inaccurate use/misuse of HIV RDTs such as instructions for use and results interpretation, potential for use of currently available HIV RDTs for self-testing, and post-market surveillance for diagnostics. Improved practices for procurement will be explored, including the newly launched WHO guidance on procurement of diagnostics which contains advice on better planning to improve procurement efficiency and cost-effectiveness, and better specifications to allow transparent and evidence-based selection of products. Procurement practices will inevitably be improved when procurement officers are linked with laboratories and other users who should be engaged in making the decision on which products to use.

Experience of procurement in Myanmar

Prof. Tun Tun Lin ,Yangon General Hospital, Ministry of Health of Myanmar

Experience of Procurement in a Developing Country Prof Lin Tun Tun

I am a radiologist currently working as the head of department of Radiology in a Medical University in Myanmar. Apart from teaching and clinical duties, I am responsible as a member for procurement of Radiological equipment for government hospitals for the last eleven years. Since Myanmar is a poor country, we cannot purchase much. Our health care budget as a whole is very small under previous governments. There are about 1000 hospitals in Myanmar with a population of 60 million people. Mostly we bought cheaper equipment and cannot buy high end ones. We bought X-ray machines, Ultrasounds, Fluoroscopy, CT, MRI and Angiography systems. Lately we have a new government and with political change, we have a larger health care budget and have spent approximately 100 million US dollars in buying Medical equipment and devices. For radiology departments in Myanmar, we could buy many CTs, 1.5 T MRI, Ultrasound and several X-rays. I prepared the specifications with my own previous experiences in using equipment, journals and brochure. The preparation time for the procurement process is too short. We still need so much to consider for maintenance process. Our FDA still needs to consider standardizing equipment and devices. Once we get the equipment, we are facing that our infrastructure is not yet ready to accommodate the developments. Apart from the equipment, we need proper buildings, electricity etc. We also need to train more technologists and specialists as we need more manpower. We are trying to get better skill by collaboration with friends and sending fellows for training and inviting experts. Another tender for medical device will be opened soon and it will hopefully bring needs for our poor people.

Challenges facing medical engineering services in Kenya

Ms. Salome Wangari Mwaura, Ministry of Health of Kenya

Medical engineers in Kenya deal with the maintenance and management of all medical equipment and hospital equipment, which includes electrical, civil, mechanical works and plants. Thus medical equipment are not given enough attention. There are many challenges which include equipment life cycle, budgetary allocations, technical competency, poor health facility management, lack of technical documentation, inadequate testing and measuring equipment, sabotage and donated equipment. It has been realized that one of the main reason for poor state of equipment is lack of management of that resource and predominantly this arises from lack of understanding and awareness of complexity of the medical equipment seen. There is therefore a need of medical equipment planning which includes inventory, installation, training, maintenance (PPM), repair and disposal. Also, risk management, quality assurance, technology assessment, facility design and equipment life cycle needs to be put into consideration. To analyse the effective use of equipment we must identify the various components of the technology package and the role as medical equipment maintenance managers which include selection, procurement, operation and maintenance. The introduction of the Public Procurement and Disposal Act (PPDA) of 2005 and the Procurement Regulations of 2006 has introduced new standards for public procurement in Kenya. There are six objectives of procurement which include: procure the RIGHT ITEM, Procure the RIGHT QUALITY goods, works or services from a reliable supplier, do it in the RIGHT QUANTITY ensuring cost effectiveness, delivered at the RIGHT TIME, deliver to the RIGHT PLACE and Paying the RIGHT PRICE while achieving the lowest possible total cost. With adherence to the act, there has been tremendous improvement in public procurement in the country and hospitals are getting better equipment. For us to achieve this, policy guidelines, continuous professional development, improved curriculum in our training institutions and innovations are supposed to be put into consideration.

PROCOT – Cooperation program to capture technical and economics information about medical equipment

Mr. Murilo Contó, Erlon Cesar Dengo, Marcio Luis Borsio, Ministry of Health of Brazil

The Brazilian Ministry of Health (MH) offers a list of medical equipment to hospitals and health centers across the country to apply for funding of new acquisitions. The request occurs through project proposals containing the identification of the equipment with technical specifications and required values, with the MH being responsible for the analysis, price compatibility and specification of each device and then to authorize financial transfers. The information needed to support these analyses were collected through the internet and specific contacts with suppliers who sent price quotations upon request of an individual technical analyst. Due to the high number of project proposals increasing each year, this process has become unproductive due to the excessive time needed. Thus, in order to receive such information in advance and a spontaneous way from suppliers, the MH has released a Technical Cooperation Programme called PROCOT, establishing an incentive to the participating companies the possibility of conducting technical presentations to MH technicians, monitored technical visits to reference hospitals and disclosure of their names and contact information in the medical equipment system called SIGEM, with free access on the internet. PROCOT also consists of a centralized system with specific repositories of information, such as prices, brochures, studies and data of supplier companies, separated by year and linked to nomenclature of equipment. The information began being received continuously, and after validation, are archived in a central database where all technical analysts have access to the same specifications and reference prices, increasing the speed of the analysis and reducing the subjective factor, which was a critical point as a lot of information was scattered in several computers. The number of investment proposals approved increased significantly, as well as the speed of issuing the authorization for release of funds.

Patient Safety

Session Chair: Dr. Edward Kelley

Session Co-Chair: Ms. Helena Ardura-Garcia

Injection safety: a new WHO global initiative building upon recent progress

Prof. Benedetta Allegranzi, WHO, Switzerland

According to 2000 WHO estimates, each year unsafe injection practices cause 260,000 human immunodeficiency virus infections, 21 million hepatitis B virus infections (32% of the global burden) and 2 million hepatitis C virus infections (40% of the global burden). This leads to 1.3 million early deaths, a loss of 26 million years of life, and direct medical costs of 535 million USD. Major issues concerning unsafe injections include unjustified injections and needles and syringes reuse. WHO, the Safe Injection Global Network and other key players have fostered technology transfer for safety engineered injection devices (SEID) and implemented strategies to change practices and behaviour. Progress in recent years have resulted in the reduction of the reuse of injection equipment from 39.6% in 2000 to 5.5% in 2010 (88% decrease). However, achievements were not equal in different parts of the world. While much progress has been made in immunization, the safety of therapeutic injections remains a challenge. The panel will review recent publications about the burden of unsafe injections and related infections. Lessons learned and challenges from projects to improve safe injections implemented by WHO and other agencies will also be discussed. Finally, the perspectives of a new WHO global initiative to avoid unnecessary injections and to promote the exclusive use of SEID, especially for therapeutic purposes, will be presented, including cost-effectiveness estimates. The burden of unsafe injections worldwide: highlights on recent improvements and areas requiring urgent attention.

Lessons learned and challenges in implementation planning for injection safety initiatives

Prof. Benedetta Allegranzi, WHO, Switzerland

Perspectives of a new WHO injection safety initiative focusing on therapeutic services

Dr. Edward Kelley, WHO, Switzerland

Medical Software

Session Chair: Dr. Edward Kelley
Session Co-Chair: Ms. Helena Ardura-Garcia

Medical software: are clinical engineers ready to face the challenge?

Dr. Ernesto Iadanza, Clinical Engineering Division/IFMBE, Italy

One of the main and most important changes brought by the Directive 2007/47/EC refers to software. Given that it is intended for diagnostic/therapeutic use, a stand-alone medical software must now be treated, in all respects, as an active medical device (software intended for general purposes, although in a healthcare setting, is not a medical software). According to the newest literature, as well as to the main incident reporting databases worldwide, the incidents that are related to software are growing together with the increasing presence of medical software in the diagnostic-therapeutic process. The manufacturers are constantly increasing their demand for specialized competences in this field. The healthcare managers and the patients are asking for more safety. This opens a brand new field of action for clinical engineers: the whole process of medical software management (from CE marking to periodical tests) requires competences, sensibilities, process knowledge, standards and tools that are part of the body of knowledge and of the cultural baggage of clinical engineers. Hence, it is vital that a profound redesign of the academia and postgraduate courses in order to drive this transition of clinical engineering. Assisting the manufacturers in designing, developing and testing their software in a logic of risk management require a deep knowledge of concepts like software life-cycle, risk assessment, usability, human factors, process analysis and engineering, disaster recovery, etc. These are not in the traditional set of skills that clinical engineers acquire in their studies and training periods, therefore it is necessary to rethink their course of studies in order to give them the full mastery of this concepts and tools. International organizations such as WHO and IFMBE have to put their efforts in assisting this worldwide transition for the patient safety.

When will official training in telemedicine will be available for doctors & nurses?

Prof. Olga Ferrer-Roca, UNESCO Chair Of Telemedicine, Spain

Official training in telemedicine will be available for doctors and nurses when:

- Economic recession limits social support including health care;
- Telemedicine is provided as a solution for health expenditure;
- Integrated health Transversal Units (TU) bring the solution for elderly populations;
- Home care should be integrated in the social an welfare solutions;
- Quality of Care (QoC) is taken as essential and Reverse Innovation a solution; and
- IT improvements are in place to build 4P medicine (Predictive-Personalized-Preventive-Participative) based on the 4T medicine (Telemedicine-Telehealth-Telemanagement-Telemonitoring)

University is teaching our future doctors and nurses, without introducing the essential thirteen topics of the Body of Knowledge of telemedicine that will assure, if taught in their training, the acceptance of new technologies and introduction of telemedicine with a quality of care guarantee. We should never forget that telemedicine is provided by doctors, nurses and healthcare personnel, never by engineers or technical people.

Developing interoperability standards for personal health devices

Prof. Daidi Zhong, Chongqing University, Xiaolian Duan, Chongqing Academy of Science & Technology, China, Michael Kirwan, Continua Health Alliance, United States of America

The lack of open interoperability standards between personal health devices (such as thermometers, glucose meters, pulse oximeter, etc.) and personal computing equipment had posed considerable challenges to technology providers and service providers in personal health and disease management service domains. Many current deployments of personal health service system mainly rely on proprietary solutions, which are very likely to become unsustainable and irreproducible. To fill this gap, global experts from academia, industry, regulatory agencies, and medical and patient communities had jointly put persistent efforts on developing the interoperability standards for device connectivity. The IEEE 11073 Personal Health Device (PHD) WG, as the leading international standard developing organization (SDO) in personal health domain, has developed a technical framework for converting the collected personal health information into an interoperable transmission format so the information can be exchanged between devices, and can be further communicated to health information system. PHD standards are dedicatedly designed for personal health devices, which are normally embedded consumer devices with very limited power resource and computing capability. PHD standards can be ported by many existing commercial transport technologies, which ensure quick and massive market adoption. Since 2008, PHD WG has published 18 international standards within the past five years. These standards have been globally adopted and implemented by many device vendors and service providers, and they have been recognized or mandated by many countries and regions (US, UK, Denmark, Singapore, etc.). In this presentation, we will introduce the background, outcome and roadmap of IEEE PHD WG. We will share our experience and concerns of developing PHD standards with the stakeholders, and we are looking forward to working with interested parties to further enhance the quality, efficiency and adoption of PHD standards.

Innovative Medical Devices for Low-Resource Settings *(Spanish translation available)*

Session Chair: Mr. Martin Raab
Session Co-Chair: Ms. Keiko Fukuta

Assessment of male circumcision devices for HIV prevention in East and Southern Africa

Ms. Julia Samuelson, Tim Farley, Gaby Vercauteren, Irena Prat, WHO, Switzerland; Renee Ridzon, United States of America; Tim Hargreave, Scotland; Stephen Watya, Uganda

Male circumcision (MC) reduces heterosexual HIV risk in males by about 60%. In 2007, WHO and UNAIDS recommended medical MC as part of comprehensive HIV prevention in high HIV burden countries. Fourteen countries in East and Southern Africa have initiated medical MC scale-up. Rapid scale-up among adolescent and adult males will maximize impact of MC on HIV. However, challenges posed by conventional surgical circumcision including limited human resources, restrict expansion. WHO and global partners explored alternatives to surgical circumcision through a landscape analysis of devices; developed a clinical pathway and evaluation criteria that balanced the need for systematic assessment of safety, efficacy and acceptability with the imperative to support rapid scale-up. In 2013 clinical data on the PrePexTM and ShangRingTM devices were assessed by WHO experts. This evaluation informed one component of the WHO Prequalification of Male Circumcision Devices Programme and one device, PrePexTM, is currently prequalified. WHO has also issued normative guidance on Device Use.
Lessons Learned: Clinical evaluation requirements for medical devices are seldom clearly specified and regulations vary considerably between countries. In many jurisdictions, circumcision devices require no clinical data prior to marketing, which was considered inadequate for a large scale HIV-prevention intervention on healthy men. Clearly defined clinical evaluation pathways and assessment of efficacy, safety and acceptability by independent experts were deemed essential. WHO with global partners and experts developed a rigorous process to assure countries on safety, efficacy, and quality of such devices. Adult circumcision devices have the potential to accelerate scale up by simplifying the procedure, reducing the time, and involving more mid-level providers.
Next steps: Device approvals and introduction should be accompanied by ongoing safety and acceptability monitoring and global review of new evidence. Prices for programmes should be fair to support responsible use of public sector funds.

Design to improve pressure ulcer care in the community

Mr. Gianpaolo Fusari, Jonathan West, Ed Matthews, The Helen Hamlyn Centre for Design, Royal College of Art, United Kingdom

Background: With the ageing demographic in the UK (ONS 2012), primary care is becoming increasingly important. An estimated 12.5% of patients develop a pressure ulcer (PU) in a care home (Bennett, et al., 2004). Improved access to innovative, cost-effective technologies for PU care in community is urgently needed. The NHS QIPP's Safety Express aims included minimizing PUs in the community by 30% by 2012 (McIntyre et al., 2012). PU care is further complicated in the community by additional factors such as involuntary muscular contractures. Project aims to design innovations to improve pressure ulcer care in community, outside of hospital environments.
Methods: Following a review of relevant PU equipment, the research included interviews with tissue viability specialists, district nurses and observations in care-homes. The system of care and stakeholders were mapped out with staff. Identified problems were the focus of co-creation sessions, leading to a number of testable prototypes.
Results: A low-cost remote position sensor was prototyped, supplying data to allow mobile careres to prioritise their patients according to real-time information. A small pressure alternating pad was also produced to address involuntary muscular contractures.
Interpretation: Outputs were a series of prototype products and supporting systems. Initial user response has been positive; further testing is required to gather a firm evidence base.
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3D Virtual reality for prosthetic myoelectrical training

Ms. Rosa Itzel Flores Luna, Garcia Del Gallego, Mariano, Juarez Mendoza, Ana Marissa, Ayala Ruiz, Alvaro, Dorador González, Jesus Manuel, Universidad Nacional Autónoma De México (Unam), Mexico.

We tried using 3D environments to get the feedback of the design and the user is still missing the real sensation. This paper presents the 3D CAD designs and environments with virtual reality, but using bioelectrical signals to move a prosthetic limb. This paper describes the work done to get an interaction between the patient and the 3D model in a virtual reality auditórium. Prosthetic myoelectric training system was designed at the Mechanical Design and Technological Innovation Centre. The scope of the project is to reduce time and money during patient rehabilitation (physical and psychological) and also to design and manufacture better prosthetic devices using user's feedback.

Increasing accessibility to safe surgical practices by training non-physician clinicians (NPCs) using a battery-powered anesthesia device.

Mr. Denver Phiri, Gisela Abbam, GE Healthcare, United Kingdom; Janeen Uzzell, GE Africa, Ghana; Kallol Mukherji, GE Healthcare, India; Karim Asaad, GE Healthcare, Egypt; Thomas Muithya, Kenyatta University, Kenya

Low-resource settings present a series of serious challenges for the implementation of innovative surgical solutions to improve health outcomes. Constraints include unstable electricity, extreme environmental conditions, limited budgets and inadequate human resources. Resultantly, in Sub-Saharan Africa surgical conditions represent 38 DALYS (disability adjusted life years) lost per 1,000 population. Of this, obstetric and perinatal conditions account for close to 25% of the burden. A key component of surgery is anesthesia. Most anesthesia machines need access to electricity and may require significant knobology training to work them. With the WHO encouraging task shifting in surgery, anesthesia devices that possess a battery option and require a short training can be a solution that helps in increasing access to surgery and anesthetic services and potentially impact key health indicators. An anesthesia device with a battery option was used to deliver clinical training and to assess the acceptability, duration of training required and ease of use. A total of 150 NPCs were offered eight hours training in six locations in Kenya with support from the National Association of Anesthesia Clinical Officers. The training was evaluated using a post-test questionnaire. Fluid Resuscitation and Transfusion Therapy, that form fundamental elements of obstetric and gynecological surgical needs, were rated as either “VERY GOOD” (76%) or “GOOD” (24%) by the participants and were ranked among the top four topics. With a six hour battery power capacity this solution has implications on surgery in remote locations that lack reliable power. The ease of use after a short training session could also impact on the roll out to a larger number of NPCs especially because of the local training model. The total impact increases accessibility to safe surgical practices in remote low-resource settings. It is highly recommended that studies be commissioned to understand the full potential of such device oriented training.

Using mobile technology to collect medical device usage data in real time

Ms. Hallie Sue Cho, OttoClave, United States of America

OttoClave is a pressure cooker based medical instrument sterilizer (autoclave) designed to fit the needs of rural health clinics in developing countries. OttoClave consists of a pressure cooker retrofitted with a thermal sensor and a cycle monitor module that can speak the local language to provide step by step instructions. The OttoClave team has developed many features that are attractive to the user to promote sustained utilization of the device on the field. Comparing user feedback from previous prototypes to the most recent, OttoClave team knew that they were making improvements with every update. Unfortunately, outside the user testing sessions, the team was unable to collect reliable data on actual usage of the device when the team was not on site to observe. To accurately measure the impact of OttoClave, the team developed a data collection system that logs all the events from the cycle monitor, pushes it to the cloud via SMS, parses collected information, and displays meaningful statistics and graphs on a dashboard. Using this data collection system, OttoClave is conducting two research projects with data collected from 50+ public health clinics in Nepal over six months. First project aims to study the effect of sustained autoclave usage on post surgical infection rates. Second project aims to compare the usage patterns of OttoClave versus other low-cost options (autoclave or instrument boiler) to see if the novel features influence uptake and sustained usage. OttoClave was developed at Massachusetts Institute of Technology (MIT) with funding from MIT, Singapore University of Technology and Design (SUTD), and Xerox.

Phase I results of a simplified negative pressure wound therapy device for use in low resource settings

Dr. Gita Mody, Robert Riviello, Brigham and Women’s Hospital; Danielle Zurovcik, Massachusetts Institute of Technology, United States of America; Grace Kansayisa, Dominique Mugenzi, Georges Ntakiyiruta, National University of Rwanda and Kigali University Teaching Hospital, Gemimah Uwimana, Rwinkwavu District Hospital, Rwanda

Wounds are a major source of morbidity worldwide. Negative pressure wound therapy (NPWT) has been demonstrated to speed wound healing; however, limitations to widespread implementation include: electrical requirements, high cost, lack of technical knowledge, specific materials and only local distribution channels. We have developed and field-tested a mechanical, low-cost NPWT device, which is composed of a bellows suction source and an occlusive dressing.

Methods: The simplified Negative Pressure Wound Therapy (sNPWT) device was piloted at two hospitals in Rwanda. Patients with wounds ranging from 2-150cm^2 and meeting inclusion and exclusion criteria were enrolled. Wounds were graded according to anticipated difficulty of dressing application. Primary outcomes included maintenance of negative pressure and occurrence of adverse events. An iterative design process was used to improve the dressing in real-time.

Results: Thirty-seven patients were treated with sNPWT; 86 dressings were done and 5 dressing iterations were tested.

Overall, the system maintained negative pressure for 25.2 hours on average, and the final design maintained negative pressure on easy to dress wounds for 50 hours on average. Durability of the dressing and patient movement were the main barriers to longer intervals of negative pressure delivery. No unexpected adverse events occurred.

Conclusion: This is the first report of a non-powered negative pressure wound therapy device designed specifically for use in the developing world. Our device is safe and feasible for use in low resource settings, and clinical efficacy will be studied in subsequent trials. Equal access to medical technology such as NPWT will help bridge healthcare delivery gaps worldwide.

Human Resources in Technology Life Cycle Management

Session Chair: Dr. Caridad Borrás
Session Co-Chair: Ms. Laura Alejandra Velez

Improving patient outcome through technology life cycle management: The role of biomedical engineers

Dr. Caridad Borrás, Dr. Yadin David, Prof. Nicolas Pallikarakis, Institute of Biomedical Technology (INBIT), Greece

The dependency of medical services on the availability of reliable and safe technologies has reached an all-time high. The technologies are more integrated and sophisticated, and require to be managed throughout their life cycle by professionals with unique competencies. Given the wide variety of technologies and the many stages of their life cycle, technology management can positively affect patient outcome when performed by competent and trained health professionals. The type and number of these professionals depend on the complexity of the patient population served, the facility service level, and the diversity of medical devices. Typically, these professionals include biomedical engineers, clinical engineers and medical physicists. This presentation will focus on the roles these professionals play and where overlapping responsibilities may exist. Biomedical engineers focus on research and development as well as in manufacturing and assessment of medical devices. In close collaboration with clinicians and the industry, they apply engineering knowledge and skills in the creation of new technologies and products. Among the main functions of clinical engineers are insuring optimal selection, installation, integration and safe performance of technology. To insure safe performance, they develop verification programs and maintenance strategies. Medical physicists interact with clinicians and other staff in the medical applications of both non-ionizing and ionizing radiation. In the latter case, they are responsible for radiation safety. In medical imaging, medical physicists review/modify image acquisition protocols and assess quality and dose; in radiotherapy, they calibrate devices, measure the characteristics of the treatment machines, and assure correct radiation therapy simulation and treatment planning. All three professions are involved in writing and/or reviewing standards, technical and software specifications, performing acceptance tests, commissioning of technology and developing/implementing QA/QC programs. To acquire and maintain the necessary knowledge, experience, skills and competences, these key professionals require specific education and training, which will also be discussed.

Human Resources in Medical Physics

Session Chair: Dr. Kin Yin Cheung

A new initiative of IOMP to support professional development of medical physicists in Africa

Dr. Slavik Tabakov, IOMP, United Kingdom; Kin Yin Cheung, IOMP, Hong-Kong; Fridtjof Nuesslin, IOMP, Germany; Madan Renahy, IOMP, Austria; Raymond Wu, IOMP, United States of America; Joannis Damilakis, IOMP, Greece; Stephen Keevil, IPEM, United Kingdom; Ahmed Ibn Seddick, FAMPO, Morocco; Rebecca Nakatudde, FAMPO, Uganda; Taofeeq Ige, FAMPO, Nigeria

It is well known that one of the main problems with the effective and safe use of medical technology in developing countries is the lack of properly educated and trained medical physicists and clinical engineers. The International Organization for Medical Physics (IOMP) has led a number of events to help professional development in various countries and regions. The first International Conference on Medical Physics Education and Training (Budapest 1994) was pivotal for the advancement of medical physics education and training in Eastern Europe. The experience from this Conference was transferred to Asia through several International Workshops, satellite to the 2003 World Congress on Medical Physics and Biomedical Engineering in Sidney and the 2006 World Congress in Seoul. Similar activities were further carried out in Latin America, notably the Education and Training Workshop at the ICMP2011, Porto Alegre, Brazil. The results from these events are seen in the rapid growth of medical physics in Asia and Latin America. The recent book “Medical Physics and Engineering Education and Training” (available from: http://www.emerald2.eu/mep_index.html) with presentations from 27 countries (including 4 from Africa) and the recent Workshop “Medical Physics in Africa – Status and Way Forward” (satellite to the ICMP, 1- 4 September, 2013, Brighton, UK) revealed the need and planned steps toward this goal. These include collection of data from all African Medical Physics Societies through the Federation of African Medical Physics Organisations (FAMPO) and further Workshops in Africa to plan the following steps ahead. The paper describes the information gathered so far and the first steps of this large project, supported also by the WHO, IAEA and IPEM.

Pivotal role of the medical physicist in diagnostic imaging: The new challenges of hybrid imaging technology

Prof. Habib Zaidi, Geneva University Hospital, Switzerland

The past century was the century of "big hit science" for medical physics where major discoveries and inventions were brought to the world by brilliant scientists that revolutionised the practice of medicine. Medical physics is a very demanding and certainly not an easy profession given its complex and multidisciplinary nature. Medical physicists should be talented and have plenty of additional skills to be able to handle these issues efficiently. They should also be clever, diplomatic and excellent communicators to convince their administrators (usually inexpert in applications of science in medicine) about the importance of their work and its implications on healthcare delivery. Novel technologies are driving the growth of healthcare delivery and cutting-edge biomedical research. Taking diagnostic imaging as an example, the medical imaging community is witnessing a revolution in its daily clinical practice following the introduction of hybrid multimodality (SPECT/CT, PET/CT and PET/MR) devices. The hope is that this technology is going to alleviate the complexity of the clinical decision making process and improve patient management. Even though hybrid imaging systems have been accepted commercially, the clinical benefits and need of these systems remain controversial and are still being debated. PET, for example, contains alone enough information to answer clinically-relevant metabolic problems for many malignant diseases offering a sensitivity and specificity in excess of 90%, and some argue that an incremental improvement in specificity or sensitivity beyond that point probably cannot justify the cost of performing image fusion systematically for all patients on a routine basis. The marketing strategy of vendors supported by many scientists aiming at diffusing the hybrid technology in the clinic is that the added value of combined units is well established and represents the ultimate solution for image co-registration allowing appropriate combination of imaging technologies to yield useful fusion of functional and anatomical images. It is the role of clinical and academic medical physicists providing physics support to clinical diagnostic imaging facilities and involved in today’s biomedical imaging research enterprise to debate about important issues related to design aspects of this technology and optimal data acquisition and processing protocols with the aim to improve image quality, reduce artefacts and obtain accurate quantitative measures. This talk reflects the tremendous increase in interest in hybrid imaging systems and the challenges faced in their clinical implementation focusing on the pivotal role of medical physicists from a

Medical imaging training in low-resource countries - a case study in Mozambique

Prof. Mario Forjaz Secca, International Federation on Medical and Biological Engineering (IFMBE); Clara Ramalhão, Hospital Pedro Hispano, Portugal

Some low-resource countries around the world have installed highly technological imaging devices in their central hospitals, like MRI machines, as is the case in Mozambique. Although this type of equipment is highly sophisticated it makes some sense for some countries to have such a system in a central hospital that could benefit the whole population for some specific diseases. However the proper use of this equipment requires a high level of technical and medical expertise. With this in mind a group of four people working in Portugal, two radiologists, one technologist and a medical physicist / biomedical engineer, have set a project with funding from Gulbenkian Foundation of Portugal to implement a training program for doctors, technologists and physicists in Mozambique. The project lasted for two years, 2011 and 2012, and during that period two different groups of three people from Mozambique (two radiologists and one technologist) went to Portugal for a one month period each year, and the Portuguese team went to Maputo for a two week period each year. The visit of the Portuguese team to Maputo involved not only a hands-on-training in the equipment, but also involved a two week lecture course aimed at all the intervening people. Throughout the whole project the team from Mozambique had close contact and easy electronic access to the team in Portugal. The extension of the principles of this collaboration to other low-resource countries was proposed to the International Society of Magnetic Resonance Imaging, but they opted for a program that required that local doctors and physicist had international papers published in high level journals, clearly out of touch with the reality of most of these countries. We are now looking for an alter-

The role of medical physicist on strategic planning and acquisition of appropriate technology in radiation medicine

Dr. Kin Yin Chueng, IOMP, China

The provision of appropriate medical devices for clinical service is an important consideration in healthcare planning, particularly in resource limited countries, where medical services are mainly provided by the government. Planning and acquisition of expensive medical devices such as radiotherapy and imaging equipment should be considered based on a set of country specific criteria. The criteria used may include: Compatibility with national clinical needs; Sustainability in maintaining the operation and functionality of the equipment; Availability of staff who can be trained to make full use of the devices; The cost effectiveness of the devices in the management of the types of diseases; Compatibility with the local environmental conditions; Compatibility between service demand and equipment throughput; Compatibility and connectivity with equipment facilities currently in use; Life cycle costs; Alternative options available. These criteria and the parameters used in them are country specific and the latter can change with time so that they should be updated in each equipment acquisition programme. To ensure that appropriate technologies are acquired to the best interest of the healthcare system, a technology acquisition committee or advisory group on major medical devices should be established to give professional advice and recommendation to government. The role of the expert group is to advise on: Appropriate devices for radiation medicine; Procurement mechanism; Budgetary planning; Manpower needs and staff training; Building and building services provisions; and equipment replacement/upgrade. Membership of the advisory group should include experts from radiation oncology, radiology and imaging, medical physics, healthcare and finance ministries. Medical physicists have good knowledge on the physics and engineering principles of this type of medical devices. They are familiar with the functionality, performance, quality, limitation and safety of such devices of different brands and makes. They can contribute to the strategic planning and acquisition of such major medical devices.

Professional accreditation of medical physicists, IOMP perspective

Dr. Kin Yin Chueng, IOMP, China; Raymond Wu, IOMP and Barrow Neurological Institute, United States of America

Medical physicists (MPs) also play a key role in the operation of medical devices used in radiation medicine. They are responsible/contribute to the planning, acquisition, commissioning, testing, proper use, radiation safety, calibration and QA of these devices. As defined in IOMP Policy Statement 1, MPs working in medical institutions with clinical duties are health professionals. They shall demonstrate competency in their discipline by obtaining the educational qualification and professional competency training in one or more subfields of medical physics. The quality of their education and professional training has a direct impact on the standard of their practice. Professional certification of MPs should be mandatory, as it is with most other health professionals. It helps to achieve a homogeneous professional standard at the national and international level to ensure quality and safety in radiation medicine. The certification should be conducted by national boards. International certification board exams can provide guidelines on the standards, requirements and format of certification, and perform accreditation of certification boards. The International Medical Physics Certification Board (IMPCB) has been established jointly by IOMP and a group of national member organizations for this purpose. IMPCB is an independent body registered in the US. Its primary function is to accredit national certification boards thereby ensuring that the professional standard adopted by all national certification boards can meet or exceed the minimum standard. The registry of professional certification as maintained by the national certification board should be recognized by the government either as a legal registration for professional MP or as a pre-requisite for obtaining a professional license to practice. Government recognition of the professional certification system helps in the implementation of an effective QC mechanism to ensure professional competence of medical physicists uniformly across the country, in a similar manner to requirements for regulating other professionals, (e.g.) architects and medical practitioners.

Appendix 6

Poster list and abstracts

Posters	
A. Economics of medical devices	
A.01	Atrial septal defect (ASD) device closure using a device sizing formula without balloon sizing or invasive echocardiography is safe, cost effective and increases access to treatment Gamini Galappatthy, Ruvan Ekanayaka, *The National Hospital of Sri Lanka, Sri Lanka*
A.02	International regulatory convergence: meeting patients needs Jo Groves, *International Alliance of Patient's Organizations*
A.03	Medical device procurement strategies at a glance in Turkish public hospital organization Ali Riza Demirbas, *Ministry of Health, Turkey; Fetin Rüstü Yildiz, Zehra Yaman, Turkish Public Hospital Organization, Turkey*
A.04	Computerization and rationalization of the investment in medical technologies in hospitals Lisa Giuliani, Fugieri Stefania, *Elettronica Bio Medicale, TBS Group, Italy; Tulli Giorgio, Azienda Sanitaria Locale Nr 10, Italy*
A.05	Cost effectiveness of medical devices to reduce mortality from pre-eclampsia in low-resource settings Zoë M McLaren, John P Hessburg, Amir Sabet Sarvestani, Ethan Parker, Timothy R B Johnson, Kathleen H Sienko, *University of Michigan, United States of America; James Akazili, Navrongo Health Research Centre, Ghana*
A.06	Comparison of reimbursement systems: Turkey, Germany and United Kingdom Gorkey Turgut, *Turkey; Funda Özdiler, Ismet Köksal, Osman Nacar, Ercan Simsek, Turkish Medicine and Medical Devices Agency, Turkey*
A.07	Standarisation des equipements biomedicaux des laboratories Dr. Tra Bi Yrié-Denis, *Ministére de la Santé et de la lutte contre le sida, Republique de Cote d' Voire*
A.08	Cost-effectiveness of the WelTel mHealth program to improve adherence to antiretroviral therapy in Kenya Anik Patel, Richard Lester, Zafar Zafari, Carlo Marra, *University of British Columbia, Canada; Scott Braithwaite, New York University, United States of America; Mia Van Der Kop, Karolinska Institutet, Sweden*
A.09	Portuguese approach in promoting a rational use of medical devices Mariana Madureira, Emilia Alves da Silva, Helder Mota Filipe, *INFARMED - National Authority of Medicines and Health Products, Portugal*
B. eHealth	
B.03	Better informed pregnancy referrals towards increased health coverage Goncalo Salvador Ribeiro e Castro, *Swiss Tropical and Public Health Institute, Switzerland*
B.04	MEDBOX - quality assurance of health related humanitarian action Joost Butenop, *Medical Mission Institute - The Advisory Group for International Health, Germany*
B.05	Priority needs assessment at Guayaquil University Hospital Ricardo Silva, *National Secretary of Higher Education, Science and Technology, Ecuador, Jorge Medina, School of Medicine, Guayaquil University, Ecuador; Luis Villavicencio, University Hospital at Guayaquil, Ecuador*
B.06	Healthcare continuum, a turning point for Colombia Vladimir Quintero, Mendez Alexis Messino, *Simon Bolivar University, Colombia; Paul Pelaez, Chamber of Commerce Barranquilla, Colombia; Antonio Hernandez, American College of Clinical Engineering, United States of America; Mario Castañeda, United States of America*
B.07	Inter-observer reliability in the use of cellphone technology as a community based limb loss screening tool Jose Alvin Mojica, Josephine R. Bundoc, *University of the Philippines, Manila*
B.08	Telemedicine: can we start today? Miguel Pro Quintana, *France*
B.09	Lab tests online – Patient-centric, non-commercial, peer-reviewed resource for limited resource settings Shweta Kulkarni, Philippe Jacon, *European Diagnostic Manufacturers Association, Belgium; George Linzer, American Association for Clinical Chemistry, United States of America*
B.12	Implementation of mHealth projects in Africa: what works? what doesn't? and why? Neo M Mohutsiwa-Dibe, *Ministry of Health, Botswana; Clara Aranda Jan, Institute of Manufacturing, University of Cambridge, United Kingdom; Svetla Loukanova, Institute of Public Health, University of Heidelberg, Germany*
C. Healthcare delivery: the role of medical devices	
C.01	Complete mobile care units in rural areas Jean Marie Jigte, Kamdem Moyou, Samuel Joel Ildevertadjeme, *Care Help Cameroun, Cameroon*
C.02	Situational analysis of an NGO delivering health care services and medical devices, and their needs in Togo Komi Agbeko Tsolenyanu, *Association for Maternal, Neonatal and Child Health, Togo*
C.03	Web-based self-check software screening test to determine susceptibility to indoor chemical exposure and prevent adverse effects on children's health Emiko Todaka, Hiroko Nakaoka, Masamichi Hanazato, Chisato Mori, *Center for Preventive Medical Science, Chiba University, Japan*
C.04	Optimal benefits from international aid and support of medical devices for developing countries Faisal Mujamal, *Ministry of Public Health and Population, Yemen;Hanady Ahmad AlDughaish, Civil Society Organization IT, Yemen*
C.05	Destruction of waste from care in health centers in Burkina Faso Zida Ouambi Emmanuel, *Ministry of Health, Burkina Faso*
C.06	Drug Resistance Index (DRI): A tool for managing antibiotic resistance Aditi Sharma, Ramanan Laxminarayan (*Princeton University), Nikolay Braykov, Center for Disease Dynamics, Economics and Policy, Public Health Foundation of India, India*
C.09	A meeting, a plan and the creation of a dialysis centre in Benin Jean Pierre Garcia Perez, *Benin*
D. Healthcare Technology Management (HTM) (Clinical Engineering)	
D.01	A new validation method proposal for electrical performance in electroscalpels using finite element analysis (FEA) Sebastian Torres Montoya, Yesid Montoya Goez, Claudia E. Echeverri Cuartas, *Antioquia Engineering School, CES University; Lina María Tapias, IO Interquirofanos, Colombia*
D.02	Immediate impacts of an inventory on the procurement, donations, maintenance and use of medical equipment Alusine Bobson Kabia, *Connaught Government Hospital, Sierra Leone*
D.04	Protegemed – An alternative to reduce electric microshock risk during surgery Luiz Eduardo Schardong Spalding, *Universidad de Passo Fundo and Hospital São Vicente de Paulo, Brazil; Marcelo Trindade Rebonatto, Universidad de Passo Fundo and Pontificia Universidad Catolica, Brazil; Kristofer Becker Kochhann, Hospital São Vicente de Paulo, Brazil*

D.05	Healthcare Technology Foundation - Advancing the safety of healthcare technology John Tobey Clark, *University of Vermont, United States of America;Yadin David, United States of America*
D.06	Matchmaking between low-end medical devices and primary care units via a non-profit platform -- experience from China Li Yang, Daidi Zhong, Xingmin Guo, Xiaolin Zheng, Xuelong Tian, Wenshen Hou, Xitian Pi, Zhong Ji, Yanjian Liao, Jin Tan, *Chongqing University, China*
D.07	Certification of biological safety cabinets Beth W Wanjohi Njaramba, *Ministry of Health, Kenya*
D.09	Importance & benefits of clinical engineering departments in Turkey Omer Faruk Kuru, Cihan Karinca, Serbay Bahceci, Ismet Koksal, Osman Nacar, Ali Sait Septioglu, *Turkish Medicine and Medical Devices Agency, Turkey*
D.11	Evidence-based mathematical maintenance model for medical equipment Abdelbaset Khalaf, *A Tshwane University of Technology, South Africa; K Djouania, Y Hamama, University of Paris; Y Alayli, France*
D.12	Second hand medical equipment challenges in a remote area of a LDC: Experience of cardiac centre Shisong Emmanuel Kouemo Tchokodjeu, *St Elizabeth Catholic General Hospital, Cameroon; Roberto Musi, Associazione Bambini Cardiopatici nel Mondo, Italy*
D.14	Capacity building and supporting clinicians in medical equipment refurbishment Mideksa Mulugeta, *Addis Ababa University, HSC, Tikur Anbessa Specialized Hospital, Ethiopia*
D.15	Qualification of medical technology management in a health care network Eduardo Coura Assis, *Department of Science and Technology, Secretariat of Science, Technology and Strategic Inputs, Ministry of Health, Brazil; Murilo Conto, Department of Management and Incorporation of Health Technology, Secretariat of Science, Technology and Strategic Inputs, Ministry of Health, Brazil*
D.16	The use of oxygen concentrators in the Gambia: A study of over five years of experience in a setting with BMET support Beverly Bradley, Samantha Chow, Yu-Ling Cheng, *University of Toronto, Canada; Ebrima Nyassi, Biomedical Engineering Unit, Medical Research Council, The Gambia; David Peel, United Kingdom; Stephen RC Howie, Child Survival, Medical Research Council*
D.17	The problem of acquisition and maintenance of biomedical equipment in Burkina Faso Zida Ouambi Emmanuel, *Ministry of Health, Burkina Faso*
D.18	Ubiquitous management methodology for medical equipment William Alberto Cruz Castañeda, Renato Garcia Ojeda, *Biomedical Engineering Institute, Federal University of Santa Catarina, Brazil*
D.19	Health technology management model applied in primary healthcare in Brazil Rubia Santos, Renato Garcia Ojeda, *Institute of Biomedical Engineering, Federal University of Santa Catarina, Brazil; Carlos Daniel M S Moutinho Junior, Secretaria Municipal de Saude de Florianopolis, Brazil*
D.21	Improving maintenance of medical equipment in Uganda Keiko Fukuta, *Japan Association for Clinical Engineering, Japan and University of Leeds, Nuffield Centre for International Health and Development, United Kingdom*
E. Health Technology Assessment (HTA) for medical devices	
E.01	Health technology assessment : Specificity of medical devices evaluation in Singapore Laurent Dominique Michel Metz, *Singapore; Jayashree Mapari, India*
E.02	Healthcare technology assessment for non-pneumatic anti shock garment for obstetric shock prevention Vatsal Chhaya, Jitendra Kumar Sharma, Mohammed Ameel, *National Health Systems Resource Centre, India*
E.03	Mini HTA: An effective tool for clinical governance, resource allocation and conflict management at local (regional) level Gaddo Flego, Cardinale Francesco, *Azienda Sanitaria Locale Nr 4, Italy*
E.04	A systematic review of health technology assessment tools in resource-limited settings: How much do we know about the assessment of medical devices in Sub-Saharan Africa? Christine Kriza, *University of Erlangen-Nuremberg, Germany; Jill Hanass-Hancock, Nicola Deghaye, Health Economics and HIV/AIDS Research Division, University of KwaZulu-Natal, South Africa; Emmanuel Ankrah Odame, Ghana College of Physicians and Surgeons, Accra, Ghana; Rashid Aman, Centre for Research in Therapeutic Sciences, Nairobi, Kenya; Peter Kolominsky-Rabas, Interdisciplinary Centre for Health Technology Assessment and Public Health, Germany*
F. Biomedical engineering education	
F.01	Improving medical devices management in the hospitals by introducing a health technology lecture in the syllabus of the national advanced school of administration and magistracy in Cameroon Vincent Ngaleu Toko, *Cameroon*
F.02	Characterizing the next generation of medical device innovators: Ghanaian student perceptions of biomedical engineering Elsie Effah Kaufmann, *University of Ghana, Ghana; Ibrahim Mohedas, Shanna R Daly, Kathleen Sienko, University of Michigan, United States of America;*
F.03	Undergraduate biomedical engineering students as design ethnographers Ibrahim Mohedas, Shanna R. Daly, Kathleen Sienko, *University of Michigan, United States of America*
F.04	Multinational undergraduate engineering student clinical immersion experience in obstetrics Kathleen Sienko, Amir Sabet Sarvestani, *University of Michigan, United States of America; Elsie Effah Kaufmann, University of Ghana; Moses Musaazi, Makerere University, Uganda; Samuel Obed, Korle Bu Teaching Hospital, Ghana*
F.07	The role of clinical engineering in the process of incorporating technology based on procedures Marcelo Hayashide, Priscila Sousa de Avelar, Renan Feltrin, Renato Zaniboni, Renato Garcia Ojeda, *Institute of Biomedical Engineering, Federal University of Santa Catarina, Brazil*
F.08	Brazilian industrial complex and innovation in health: Biomedical engineering training in Brazil, achievements and challenges Sergio Santos Mühlen, *Universidade Estadual de Campinas, Brazil; Paulo Henrique Dantas Antonino, Eduardo Jorge Valadares Oliveira, Carlos Augusto Grabois Gadelha, Ministry of Health, Brazil*
G. Innovation	
G.03	Brazil: Research, development and innovation activity on medical devices Paulo Henrique Dantas Antonino, Kellen Santos Rezende, Naira Valente Mayrink Bisinoti, Eduardo Jorge Valadares Oliveira, Leonardo Batista Paiva, Carlos Augusto Grabois Gadelha, *Ministry of Health, Brazil*
G.07	Open-source medical device compendium for global health Amir Sabet Sarvestani, Kathleen H Sienko, *University of Michigan; Lonny Grafman, Humboldt State University, United States of America*
G.08	Innovative materials and technologies in orthopedics Serian Doma, Bedriye Akdemir, Funda Özdilier, Osman Nacar, Ismet Köksal, Saim Kerman, *Turkish Medicine and Medical Devices Agency, Turkey*

G.09	R&D and innovation in medical technologies in Lebanon
	Sandy Rihana, *Biomedical Engineering Department, Holy Spirit University, Lebanon*
G.10	Brazilian industrial complex and innovation in health: Basic production process inducing technological development
	Marcio Jose Batista Cardoso, Marco Aurelio de Carvalho Nascimento, Paulo Henrique Dantas Antonino, Eduardo Jorge Valadares Oliveira, Carlos Augusto Grabois Gadelha, *Ministry of Health, Brazil*
G.11	Improving access to medical devices in low-resource settings through local production and technology transfer: WHO 2013 survey results
	Peng Si (*Nanyang Technological University, Singapore); James Abbas (Arizona State University, United States of America); Mladen Poluta (Univerisity of Cape Town, South Africa); Amir Sabet Sarvastani (University of Michigan, United States of America); Adriana Velazquez-Berumen, World Health Organization, Switzerland*
H. Innovative health technologies	
H.03	Hand-held diagnostic ultrasound system to be used by general practitioners in routine medical examinations
	John Makinnon, Rodrigo Maureira, Vader Johnson, Javier Moya, *Chile; Manuel Duarte, Nicolas Beltran, Carlos Conca, Facultad de Ingenieria, Universidad de Chile*
H.04	A low-cost, low-power syringe pump for the delivery of magnesium sulfate to pre-eclamptic women
	Kelley Maynard, Kevin Jackson, Jinwoo Peter Jung, Glenn Fiedler, Lemuel Soh, Pablo Henning, Rebecca Richards-Kortum, Z Maria Oden, *Rice University, United States of America; Rohith R. Malya, AD Noland, University of Texas Medical School at Houston, United States of America*
H.05	Fully-automated point of care detection of malaria and other infectious diseases with a disc-shaped diagnostic platform
	K.Mitsakakis, S. Hin, F. von Stetten, R. Zengerle, *University of Freiburg, Germany*
H.06	An electrical impedance based neonatal respiration monitor for pneumonia detection
	Khondkar Siddique-e Rabbani, Shahnaj Parvin, Imtiaz Ahamad Khan, Muhammad Abdul Kadir, *Department of Biomedical Physics & Technology, University of Dhaka, Bangladesh*
H.07	A smartphone-based mobile multi-modal optical imaging platform for cervical cancer screening
	David Levitz, Ariel Beery, Amit Safir, *Israel*
H.09	Digital tomosynthesis of the chest: serial radiographic response in patients with pulmonary tuberculosis
	John Sabol, *United States of America; Hyesun Hwang, Myung Jin Chung, Won-Jung Koh, Kyeongman Jeon, Kyung Soo Lee, Department of Radiology and Center for Imaging Science, Samsung Medical Center, Sungkyunkwan University School of Medicine, Korea*
H.10	The design of a traditional adult male circumcision device
	Amir Sabet Sarvestani, Kathleen H Sienko, *University of Michigan, United States of America*
H.11	Non-invasive hemoglobin screening for diagnosis and monitoring of anemia
	Laurent Choppe, *on behalf of Lior Mayaan, OrSense Ltd, Israel*
H.12	Design of mobile wireless sensors in amputee screening via cellular network
	Maria Regina Justina Esguerra Estuar, Nadia Leetian, *Ateneo de Manila University, Philippines; Josephine R. Bundoc, Physicians for Peace, Philippines*
H.13	Affordable Multisensor Perinatal Monitoring Concept - The importance of signal quality indices for successful mHealth implementation
	Lisa Stroux, Gari Clifford, *University of Oxford, United Kingdom*
H.16	German healthcare stakeholders perspectives regarding the value of a diagnostic device for heart failure: First results of a multi-criteria decision analysis (MCDA)
	Philip Wahlster, *University of Erlangen-Nuremberg, Germany; Mireille Goetghebeur, Department of Health Administration, University of Montreal, Canada; Sandra Schaller, Christine Kriza, Charlotte Niederländer, Peter Kolominsky-Rabas, Interdisciplinary Centre for Health Technology Assessment and Public Health, University of Erlangen-Nuremberg, National Cluster of Excellence Medical Technologies, Medical Valley EMN, Germany*
H.19	Maker for MNCH: A model for locally made medical devices in Kenya
	Edwin Mbugua Maina, *Concern Worldwide, Kenya; John Odero Ong'Ech, Kenyatta National Hospital, Kenya; Kamau Gachigi, University Of Nairobi, Kenya; Natasha Kanagat, John Snow Inc, Center For Health Information, United States of America*
H.20	Assistive device to facilitate NG tube insertion
	Agyeya Dwivedi, *Stanford India Biodesign, India; Himanshu Gupta, Medha Tyagi, Neha Shetty, All India Institute of Medical Sciences, India*
H.24	Low cost near infrared measurement of subcutaneous fat for newborn malnutrition
	Alistair Mcewan, *The University of Sydney, Australia; C Rosiak, P Jones, F Mustafa, S Bian, School of Electrical and Information Engineering, The University of Sydney, Australia; G Garguilo, Bioelectronics Neuroscience Lab, The University of Western Sydney, Australia; H Jeffery, School of Public Health, The University of Sydney, Australia*
H.28	Brazilian industrial and innovation complex in health: Non-invasive intracranial pressure measurement methods
	S Mascarenhas, *G H F Vilela, B Cabella, A C Cardim, C Wang, L Gomiero, M Vicentini, University of São Paulo, Brazil; Y M Mascarenhas, P R Mascarenhas, Brazil; D Cardim, Federal University of São Carlos, Brazil; M R SIgnori, P H D Antonino, E J V Oliveira, C A G Gadelha, Ministry of Health Brazil*
H.29	Mobile-connected Doppler analyzer for fetal health evaluation in low-resource settings
	Jeremy Wallis, *Council for Scientific and Industrial Research, South Africa; Rita van Rooyen, mHealth Inc., United States of America; Josef Mufenda, Stellenbosch University, South Africa*
H.30	Postpartum uterus model
	Ingrid Lærdal, Ida Neuman, *Norway*
H.31A	Innovative health technologies: Infant radiant warmer for neonatal thermoregulation
	Ashish Gupta, *India*
H.31	Innovative health technologies: Infant LED phototherapy for neonatal jaundice
	Ashish Gupta, *India*
H.32	Improving access for maternal and infant health through the use of compact portable ultrasound
	Gisela Abbam, *United Kingdom; Janeen Uzzell, Africa*
H.33	Tissue generator based on combined physical factors: Clinical effectiveness study in painful shoulder
	Maria Teresa Arista Rivera, *Hospital Nacional Dos de Mayo, Peru; L. Vilcahuamán, Pontifical Catholic University of Peru*

H.35	Technological innovation in the diagnosis of enteroparasitosis Jose Carlos Lapenna, *Brazil*
H.36	The MRI cleaner Guillaume Metenier, Pascal Challande, Maria Vargas, *Hôpitaux universitaires de Genève (HUG), Switzerland*
H.38	The Polypropylene Technology: An appropriate response to enable access to mobility devices Olivier Chappuis, *Switzerland*
H.39	Oxygen concentrator-driven baby bubble CPAP Robert Neighbour, *United Kingdom*
H.40	GNU Health: interfacing and interoperability Luis Falcon, *GNU Solidario, Spain*
H.41	A Universal Anaesthesia Machine: General anaesthesia for austere environments Paul Fenton, *United States of America*
H.43	Modulated Electro-Hyperthermia: Improving cancer treatments in low resource settings Carrie A Strauss, *South Africa*
H.50	Interoperability maturity roadmap for medical devices Fred Hosea, *Kaiser Permanente*
I. Medical imaging	
I.02	Knowledge extraction of thoracic radiology reports using statistical natural language processing Leandro Zerbinatti, Lincoln de Assis Moura Jr, *Universidade de São Paulo, Brazil*
I.03	Increasing access to diagnostic imaging in developing countries: The Asha Jyoti mobile clinic Nandish Shah, Kathryn Everton, Anna Starikovsky Nordvig, Bianca Nguyen, Daniel Mollura, *RAD-AID International, United States of America; Niranjan Khandelwal, Postgraduate Institute of Medical Education and Research in Chandigarh, India*
I.04	The IOMP used equipment donation program Mohammed Kazmain Zaidi, *Idaho State University, United States of America*
I.05	Acquisition of four digital imaging devices in Benin: Weaknesses of the project and a proposed solution Maliki Seidou Adjaratou, Pascal Soroheye, *Ministry of Health, Benin; Marcelin Oyedokoun, National University Hospital, Benin*
I.06	Medical devices for screening and diagnosis Tekin Kaya, Isbara Alp Sezen, Hüseyin Altug, Osman Nacar, Ismet Köksal, Ali Sait Septioglu, *Turkish Medicine and Medical Devices Agency, Turkey*
J. Policies for medical devices	
J.01	Brazilian industrial and innovation complex in health: Product development partnerships (PDP) to guarantee access to health technologies in Brazil Valeria Monteiro do Nascimento, Paulo Henrique Dantas Antonino, Eduardo Jorge Valadares Oliveira, Carlos Augusto Grabois Gadelha, *Ministry of Health, Brazil*
J.02	Brazilian industrial and innovation complex in health: Access to health technology, offsets, procurement and delivery in radiotherapy Silvia do Amaral Pereira, Paulo Henrique Dantas Antonino, Eduardo Jorge Valadares Oliveira, Carlos Augusto Grabois Gadelha, *Ministry of Health, Brazil*
J.03	Brazilian industrial and innovation complex in health: Strengthening the local industry using the government purchasing power Marcos Salomão, Paulo Henrique Dantas Antonino, Eduardo Jorge Valadares Oliveira, Carlos Augusto Grabois Gadelha, *Ministry of Health, Brazil*
J.04	Clinical engineering experience in the National Cancer Institute Sandra Luz Rocha Nava, Abelardo Meneses Garcia, Angel Herrera Gomez, Patricia Volkow Fernandez, Yolanda Villaseñor Navarro, *Instituto Nacional De Cancerologia, Mexico*
J.05	Brazilian industrial complex and innovation in health: PAHO/WHO technical cooperation with the Ministry of Health of Brazil in the context of the WHA 60.29 resolution Flavia Poppe, Christophe Rerat, *Pan American Health Organization, Brazil; Paulo Henrique Dantas Antonino, Eduardo Jorge Valadares Oliveira, Carlos Augusto Grabois Gadelha, Ministry of Health, Brazil*
K. Regulation of medical devices	
K.03	On regulatory policies for medical devices in low-resource countries Khondkar Siddique-e Rabbani, *University of Dhaka, Bangladesh*
K.05	Consumer health market demands balance and granularity in regulation policy Prof Daidi Zhong, *Chongqing University, China; Xiaolian Duan, Chongqing Academy of Science and Technology, China; Michael Kirwan, IEEE, United States of America*
K.06	Regulations of medical devices in Turkey Abdullah Ozdemir, *Turkish Medicines and Medical Devices Agency; Olgun Sener, Department of Health Technology Assessment, General Directorate of Health Research, Ministry of Health, Turkey*
K.07	Metrology in post market medical devices Diego Schirmer Spall, Renato Garcia Ojeda, *Biomedical Engeneering Institute, Brazil*
K.08	Medical device clinical investigations and performance evaluation studies in Turkey Asim Hocaoglu, Ahmet Gökhan Demir, Cihad Göker, Osman Nacar, Ismet Koksal, Ali Sait Septioglu, *Turkish Medicine and Medical Devices Agency, Turkey*
K.09	Turkish National Medical Device Database (TITUBB) Mehmet Erden, Funda Özdiler, Esra Demir, Osman Nacar, Ismet Koksal, Ercan Simsek, *Turkish Medicine and Medical Devices Agency, Turkey*
K.11	Arthroplasty registry and tracking system (ARTS) in Turkey Serian Doma, Ismet Köksal, Osman Nacar, Saim Kerman, *Turkish Medicine and Medical Devices Agency, Turkey*
K.12	Worldwide Arthroplasty Registry System (ARS) applications and outcomes Serian Doma, Senay Sat, Ismet Köksal, Osman Nacar, Saim Kerman, *Turkish Medicine and Medical Devices Agency, Turkey*
K.13	For the standardization of measures performed with IVDs, the need for laboratory accreditation Semra Koyunoglu, Osman Nacar, Ismet Köksal, Saim Kerman, *Turkish Medicine and Medical Devices Agency, Turkey*
K.14	Delivering as One UN to strengthen regulatory framework for medical devices in Kenya: The case of condoms regulation in Kenya Regina Mbindyo, *World Health Organization, Kenya; Geoffrey Okumu, United Nations Population Fund (UNFPA), Kenya*
K.15	Brazilian industrial and innovation complex in health: improve domestic standards and harmonize international medical device standards Marcos Roberto Signori, Marco Aurelio de Carvalho Nascimento, Paulo Henrique Dantas Antonino, Eduardo Jorge Valadares Oliveira, Carlos Augusto Grabois Gadelha, *Ministry of Health, Brazil*

L. World Health Organization Medical Device Projects	
L.01	Compendium of innovative health technologies for low-resource settings
	Jennifer Barragan, Heike Hufnagel, Adriana Velazquez Berumen, *World Health Organization, Switzerland*
L.02	Global medical device pricing survey
	Olumurejiwa Fatunde, Adriana Velazquez Berumen, *World Health Organization, Switzerland*
L.03	Global Atlas of Medical Devices 2013
	Ricardo X. Martinez, Adriana Velazquez Berumen, *World Health Organization, Switzerland*
L.04	MEDEVIS: WHO Medical Device Information System
	Heike Hufnagel, Yukiko Nakatani, Laura Alejandra Velez Ruiz-Gaitan, Adriana Velazquez Berumen, *World Health Organization, Switzerland; Mladen Poluta, University of Cape Town, South Africa; Hans-Peter Dauben, German Institute of Medical Documentation and Information, Germany*
L.05	H4 Interagency List of Medical Devices for Essential Interventions (ILMDEI) for Reproductive, Maternal, Newborn and Childhood Health (RMNCH)
	Laura Alejandra Velez Ruiz-Gaitan, Yukiko Nakatani, Adriana Velazquez Berumen, *World Health Organization, Switzerland*
L.06	Priority medical devices for Noncommunicable Diseases (NCDs) and Ageing Population
	Yukiko Nakatani, Adriana Velazquez Berumen, *World Health Organization, Switzerland*
L.07	National Regulatory Authority (NRA) assessment tool for medical devices
	Yukiko Nakatani, Adriana Velazquez Berumen, *World Health Organization, Switzerland*
L.08	WHO Global Biomedical Engineering Education and Professional Database
	Jennifer Barragan, Adriana Velazquez Berumen, *World Health Organization, Switzerland*
L.09	United Nations Commission on Life-Saving Commodities
	Yukiko Nakatani, Laura Alejandra Velez Ruiz-Gaitan, Jennifer Barragan, Adriana Velazquez Berumen, *World Health Organization, Switzerland*
L.10	WHO technical specifications for medical devices
	Adriana Velazquez Berumen, Laura Alejandra Velez Ruiz Gaitan, Yukiko Nakatani, *World Health Organization, Switzerland; Andrew Gammie, United Kingdom; Mladen Poluta, South Africa; Peng Si, China; Roberto Ayala, Mexico; Niranjan Khambete, India; James Abbas, United States of America; Tom Nakazaki, Japan; Nicolas Pallikarakis, Greece; Didier Vallens, France; Kamel Abdul Rahim, Jordan; Firas Mustafa Abu-Dalou, Jordan*

Poster abstracts

Posters

A. Economics of medical devices

A.01 Atrial septal defect (ASD) device closure using a device sizing formula without balloon sizing or invasive echocardiography is safe, cost effective and increases access to treatment

Gamini Galappatthy, Ruvan Ekanayaka, *The National Hospital of Sri Lanka, Sri Lanka*

Aim:To assess the outcome of a modified method for ASD device closure without balloon sizing or invasive echocardiography.Background: ASD device closure in USA costs approximately USD 7000 excluding device cost and uses balloon sizing and invasive trans-oesophageal or intra-cardiac echocardiography routinely. The sizing balloon costs approximately USD 500. Balloon sizing increases radiation and procedure times.Device closure without balloon sizing is described but not fully determined. We derived a sizing formula from our initial results and oversized the device 4-6 mm to maximum ASD diameter by trans thoracic echocardiogram(TTE). Following a 2007 feasibility study this modified method is used routinely at our centre. In Sri Lanka estimated cost by this method excluding device cost is about USD 300.Method:Registry and follow up data of 511 consecutive ASD device closures by a single operator using the modified technique during 54 months from 2007 to 2012 were analyzed. Procedures were done under local anaesthesia and per local protocols. Device size was selected using above sizing formula. Fluoroscopy and TTE imaging were used for device positioning.Results and discussion: Procedural success rate 93% (attempted 511, failed 39) and complication rates (minor 5%, major 0%) are comparable to studies with balloon sizing. Mean age 33 years (7-76 years). Females 388 (76%). Mean ASD diameter 20 mm. Mean device size 24 mm. Mean over sizing 4mm. Up or down-sizing of device done in 25 patients with large ASD (5%). No device erosions seen at 1 year (68% follow-up). Average procedure time was about 15 minutes. Mean device closures done in a routine mixed cath list was 3 (range 1-12). Conclusions:Device closure using a sizing formula instead of balloon sizing and TTE instead of invasive imaging is feasible, safe and reduces cost, fluoroscopy and procedure times thereby increasing access to treatment.

A.02 International regulatory convergence: meeting patients' needs

Jo Groves, *International Alliance of Patient's Organizations*

A.03 Medical device procurement strategies at a glance in Turkish public hospital organization

Ali Riza Demirbas, *Ministry of Health, Turkey; Fetin Rüstü Yildiz, Zehra Yaman, Turkish Public Hospital Organization, Turkey*

In parallel to the tremendous improvements and advancements in Turkish Health Care System between the period of 2003 and 2013, Ministry of Health of Turkey has been restructured in 2012 to handle the role of stewardship more effectively on the health care market. In this regard, some organization including public hospitals have had semi-autonomous positions and being seen as subsidiaries. In compliance with the new role of public hospitals, central procurement department within the organization has been set up to regulate the medical devices purchasing and leasing activities. Chiefly, the organization has a mixture of all procedures related to purchasing and leasing options and uses framework convention and the separate bids methods, which are somewhat new approaches in this sector. The organization has been saved up approximately 80 million dollars by using mass purchasing strategies as of 2012 up to the now. In 2013, 6 (six) framework conventions and 6 (six) separate bids have been handled respectively. Total procurement value was approximately 45 million dolars in 2013 and saved up 20 million dollars. All comparisons regarding savings have been matched with electronic public procurement platform data used in Turkey for public procurements. The aim of this study is to analyze and explain medical device procurement strategies in Turkish Public Hospital Organization by deeply looking into the abovementioned strategies and ascribing further details with regards to status quo. The procurement process of Public hospitals affiliated with the Ministry of Health has been exemplified as a case study to indicate the position of central procurement department in the system. It has been thought that this study will give a chance to gain much more insights in the area of medical device procurement and make contributions to share best practices around the World.

A.04 Computerization and rationalization of the investment in medical technologies in hospitals

Lisa Giuliani, Fugieri Stefania, *Elettronica Bio Medicale, TBS Group, Italy; Tulli Giorgio, Azienda Sanitaria Locale Nr 10, Italy*

Introduction: The computerisation of some processes in the life cycle of medical equipment can result in hospitals better managing and rationalising the resources. By way of example, we will show how two software modules, developed by a private Italian clinical engineering services company, may automate and facilitate the processes for management of equipment purchases and the preparation of the renewal plans, in a public healthcare provider in Florence (ASL10).

Outcomes: Since 2006 the ASL has easily processed 5 equipment renewal plans by means of the software, combining seven technical parameters. In 2010, the purchase request forms and validation process were tailored to the needs of the ASL and more than 140 users were trained. In 2011, in collaboration with the Intensive Care Unit (ICU), supplementary clinical data were collected (project "Prosa") to obtain a more exhaustive renewal plan. This allowed us to identify the equipment mostly in need of replacement (385 KEUR) among the 1.196 devices of the ICU. Since March 2010, the ICU has processed 93 purchase requests (more than 1 MEUR) .

The 2011 and 2012 data about purchase requests for improvement, innovation or substitution, will be presented as a demonstration of the efficacy of the method. In these two years, out of 88 requests for purchase (among which 30 for substitution, 35 for improvement and 23 for innovation), 54 have been authorized, 18 refused while the rest is waiting for evaluation.

Conclusions: The computerisation facilitated the hospital managers in monitoring the investments and vindicating the purchases. In 2013, 37 requests for purchase have been submitted and the software has recorded approximately 500 accesses. The "Prosa" project highlighted the need for tools to support clinicians in the purchase requests, too. Therefore, an additional software module was developed, to allow comparisons of equipment among different Units and/or hospitals.

A.05	Cost effectiveness of medical devices to reduce mortality from pre-eclampsia in low-resource settings
	Zoë M McLaren, John P Hessburg, Amir Sabet Sarvestani, Ethan Parker, Timothy R B Johnson, Kathleen H Sienko, *University of Michigan, United States of America; James Akazili, Navrongo Health Research Centre, Ghana* Maternal mortality remains a major health challenge facing developing countries, with pre-eclampsia accounting for up to 25 percent of maternal deaths. Many of these deaths are preventable if diagnosed and appropriately managed. Diagnosis requires skilled health providers and devices that are appropriate for low-resource settings. This study presents the first cost-effectiveness analysis of multiple medical devices used to diagnose pre-eclampsia in low- and middle-income countries (LMICs). Blood pressure and proteinuria measurement devices, identified from compendia focusing on health technologies for LMICs, were included in this study. We developed a decision tree framework to assess the cost-effectiveness of each device using parameter values that reflect the generally available standard of care based on a survey of relevant literature and expert opinion. We examined the sensitivity of our results using one-way and second-order probabilistic multivariate analyses. Because the DALYs averted for each device were very similar, the results were primarily influenced by the per-use cost ranking. The most cost-effective device was a semi-automatic blood pressure measurement device with the lowest per-use cost of 0.4 cents and an average cost per DALY averted of $0.495 relative to a baseline with no access to diagnosis devices. When access to treatment is limited, it is more cost-effective to improve access to treatment than to increase the testing rate or diagnostic device sensitivity. Cost-effectiveness analysis considers every stage of implementation in the local environment from when the patient presents at a health facility through diagnosis, treatment and patient outcome. The results underscore the desirability of two design features for LMICs: reusability and accuracy in the absence of calibration. Our findings have important implications for policy makers, health economists, health care providers and engineers.
A.06	Comparison of reimbursement systems: Turkey, Germany and United Kingdom
	Gorkey Turgut, *Turkey; Funda Özdiler, Ismet Köksal, Osman Nacar, Ercan Simsek, Turkish Medicine and Medical Devices Agency, Turkey* Comparison Reimbursement Systems of Turkey & Germany & UK Health Technology Assessment (HTA) is an interdisciplinary process that summarizes and provides medical, social, economic and ethical information about the use of technology in a systematic, transparent and impartial manner. The main purpose of HTA is to provide information in order to obtain efficient, patient focused and safe health care policies. In Turkey, there was a 21% increase in healthcare payments made by the public institutions, and peaked at 22 million dollars in 2012. In order to reduce health care payments, HTA plays a crucial role. Within this respect, two new departments have been established under the Ministry of Health; General Directorate of Health Research and Social Security Institution. The responsibility of departments is to implement evidence-based health care pricing policy and produce high quality assessment reports. A pilot project has been undertaken, using published sources and visiting equivalent agencies. In this study, a detailed comparison between Turkey, Germany and the UK's reimbursement systems has been provided.
A.07	Standarisation des equipements biomedicaux des laboratories
	Dr. Tra Bi Yrié-Denis, *Ministére de la Santé et de la lutte contre le sida, Republique de Cote d' Voire*
A.08	Cost-effectiveness of the WelTel mHealth program to improve adherence to antiretroviral therapy in Kenya
	Anik Patel, Richard Lester, Zafar Zafari, Carlo Marra, *University of British Columbia, Canada; Scott Braithwaite, New York University, United States of America; Mia Van Der Kop, Karolinska Institutet, Sweden* Background: Mobile health (mHealth) programs may improve treatment and care of HIV infected patients. Adherence to antiretroviral therapy (ART) has been shown to decline over time, and patient support from clinicians is key to improving long-term treatment adherence. The WelTel Kenya1 trial demonstrated that weekly engagement between clinicians and patients via text messages increased adherence to ART by 23%. An economic evaluation of the WelTel service has not been conducted and is an important step to proceed from research to implementation and scale-up. Objective: To evaluate the cost-effectiveness of weekly interactive text messages to improve adherence rates to ART in a Kenyan setting. Method: We employed a validated HIV decision analytic model to describe the lifetime costs and health-related outcomes based on trial data. The model has been calibrated using cohort data from AMPATH to reflect the economic and humanistic burden of HIV in Kenya. Model parameters such as gender distribution, baseline CD4 count and age were taken from trial data. A scenario analysis varied the rate of adherence among non-adherent patients and annual programmatic costs to account for uncertainly in future costs. Results: Our analysis suggests a cost-effectiveness of $1403 USD/QALY in our base case analysis assuming programmatic costs of $8 per patient per year (pppy) and non-adherent patients in both strategies had an average level of adherence to ART of 60%. This program falls below the very cost-effective threshold in Kenya according to the WHO guidelines. Eight WelTel text messages remained cost-effective or very cost-effective in most scenario analyses by WHO standards. In cases where adherence rates among the non-adherent patients were greater than 70% the program was no longer cost-effective. Conclusion: The WelTel text messaging program is a cost-effective strategy up to an adherence threshold of 70% in those categorized as non-adherent

A.09	Portuguese approach in promoting a rational use of medical devices
	Mariana Madureira, Emilia Alves da Silva, Helder Mota Filipe, *INFARMED - National Authority of Medicines and Health Products, Portugal* Medical devices market in Portugal is estimated to be 1000 M €. According to literature, public hospitals are the principal end-users of medical devices, accounting for more than three-quarters of the total market. Given the growing burden of medical devices on the NHS expenditure it is necessary to implement measures to control it. An adequate market characterization is fundamental to achieve this objective. Since January 2013, the Portuguese Competent Authority for medicines and medical devices, INFARMED, is implementing a phased coding system for medical devices. A number of groups were already codified. This year, the codification process is including implantable medical devices. The legislation related to this process is also promoting the use and registry of the code within the NHS internal information system, covering the acquisition, the prescription and the use. This approach requires strong coordination with NHS Hospitals and Institutions within the Portuguese health system, in order to identify the best practices for promoting harmonized acquisition and prescription processes and for improving systems interoperability from the acquisition to the use of these products within the NHS Hospitals. In regards to market characterization, we have already available information on different medical device groups comprising of mostly Cardiology and Orthopedics, covering 55, 000 different codified references. Some results were already obtained from Hospital's data collection in regards to the acquisitions by using the codes. With regard to the group of Pacemakers, CDI and Electrocateters, the economic impact analysis of possible measures to minimize costs, according to one of the scenarios set, led us to conclude that the savings would be estimated at 7.4 million corresponding to 22.5% of the total spent. These results demonstrated to be an important for the control of NHS expenditure.
	B. eHealth
B.03	Better informed pregnancy referrals towards increased health coverage
	Goncalo Salvador Ribeiro e Castro, *Swiss Tropical and Public Health Institute, Switzerland* With a population over 40 million people and dimension similar to metropolitan France, Ukraine faces difficulties in offering uniform standards of healthcare to both rural and urban populations, given resource constraints of its health system. In the particular case of perinatal health, a referral system is in place in which hospitals at major urban centres are available to receive women from peripheral hospitals for appropriate treatment in case of complications during pregnancy. However, these referrals are at times not taking place as good medical practice would recommend. Gaps at lower-level health facilities lead sometimes to late referrals, which have serious impacts in pregnancies and overall mortality and morbidity of mothers and children. On the other hand, too early referrals due to unjustified fear of complications result in extra costs in transportation and personal expenses of the patients. The receiving institution is also facing increased unjustified demand for its services in that case, with potential consequences in overall levels of quality of care. The availability and quality of key pregnancy information as an effective mean to efficiently trigger and follow-up referrals justified the implementation of a health information system that would allow real-time information about pregnancies within the Volyn region's hospital network. In this context, the Ukraine-Switzerland Mother and Child Health Program and the regional healthcare administration implemented a "Perinatal Registry". This registry allows the recording of key clinical information that can be used both for pregnancy risk assessment at the institution in which the woman is being followed, and at the referral institution who might potentially receive the patient. Clinicians therefore have the opportunity to remotely discuss and agree on referrals and appropriate follow-up approaches. This ensures that referrals are used as efficiently as possible, while bridging the gap in the access to healthcare between urban and rural settings.
B.04	MEDBOX - quality assurance of health related humanitarian action
	Joost Butenop, *Medical Mission Institute - The Advisory Group for International Health, Germany* Humanitarian health workers around the world can act effectively if they have access to the necessary tools. The lack of access to such tools costs lives, as was proven in various scientific investigations, cumulating in the following observation: "It is a shameful fact that […] people are still dying because their healthcare workers don't have access to the information they need". This is even more valid in situations of crisis or catastrophe, when chaos prevails and real-time access to technical information is vital. MEDBOX aims at closing this gap by collating quality, open-access, practical documents such as clinical guidelines, assessment checklists or textbooks on one homepage, thereby allowing real-time access for humanitarian practitioners. The challenge is to better apply what we know already by allowing easy access to what is available. In addition, MEDBOX will generate innovative generic checklists and survey tools for humanitarian practitioners for all aspects of work. These tools can be adjusted to any given setting and can be tailored for a variety of needs. The direct access of operationally relevant documents and innovative checklists through MEDBOX will improve the quality of health-related humanitarian action, especially at local/national levels, and will ultimately contribute to quality patient care, increased efficiency and standardisation of health action and accountability. The vision of this project is to contribute to quality assurance in health work. Health workers around the world can act professionally if they have access to the necessary tools.
B.05	Priority needs assessment at Guayaquil University Hospital
	Ricardo Silva, *National Secretary of Higher Education, Science and Technology, Ecuador, Jorge Medina, School of Medicine, Guayaquil University, Ecuador; Luis Villavicencio, University Hospital at Guayaquil, Ecuador* The Teaching Hospital System at University of Guayaquil (THSUG), started operations in April 2005; Milton Maridueña, Professor of Computer Systems at the Faculty of Mathematics constituted a research group to systematize the development of software for the THSUG. Today THSUG possesses a reliable Hospital Information System (HIS), with efficient Electronic Medical Records (EMR). This system has never been used for needs assessment. The Informatics Medical Program (PROMEINFO) was created with the participation of the schools of medicine, computer systems and multimedia at Guayaquil University (GU). PROMEINFO studied both Laboratory (LA) and Imaging (IA) requests from the Emergency Room (ER) at THSUG. Patients are classified in one of three categories: MSP (Ministry of Public Health referral), SOAT (Compulsory Traffic Accidents Insurance) and SHDUG (Spontaneous Admittance). Once a patient is admitted at the ER, the EMR is updated and every clinical activity registered. We concentrated in LA and IA requests for ER admitted patients for the period January 01, 2012 – September 11, 2013 (619 days). A total of 68,914 patients were registered, requesting 96,822 LA and 30,502 IA. Epidemiological profile of MSP and SHDUG was similar, but there was a relevant drift regarding SOAT patients. SOAT demanded an average of 2.62 IA and 0.75 LA per patient; MSP: 0.32 IA, 1.14 LA and SHDUG 0.29 IA, 1.61 LA. Most relevant studies for SOAT are IA whereas LA is the priority for the clinical patients. The ten most requested analysis for each category also differ, LA are aimed towards life support rather than diagnoses for SOAT. THSUG does not count with a Trauma Shock Unit (TSU) or with a dedicated emergency laboratory. This study suggests that THSUG requires an independent and self-sufficient TSU to take care of SOAT patients that average seven per day; we could also determine medical equipment needs assessment regarding epidemiological profile.

B.06	Healthcare continuum, a turning point for Colombia

Vladimir Quintero, Mendez Alexis Messino, *Simon Bolivar University, Colombia; Paul Pelaez, Chamber of Commerce Barranquilla, Colombia; Antonio Hernandez, American College of Clinical Engineering, United States of America; Mario Castañeda, United States of America*

Healthcare-Continuum, a Turning Point. Health is one of four sectors identified by state government as strategic for regional development. Since 2011 the Chamber of Commerce of Barranquilla has promoted the strengthening of the corresponding clusters through continuous activities convene representatives from academy, private and public sectors, following the national strategy to reinforce this three-sided initiative. Healthcare-continuum was selected as a priority line of work, and a medium term plan was designed to enhance the structured commitment of the three actors. The analysis identified an adequate awareness level, and the need of more definite actions. To this purpose, Simon Bolivar University, the Chamber, and the National Learning Service (SENA) came together to design a project, in cooperation with the American College of Clinical Engineering (ACCE), and the Health Technology Consulting firm HealthItek Inc. The objective was to improve regional competitiveness of the Healthcare Cluster around opportunities of Continuum-Healthcare to better serve the population. The project was divided into four phases focused on Technology Assessment and Development, Operations, Financing, and Implementation of Healthcare Services. The first phase included a workshop on Health Technology Management and Innovation presented by the ACCE. It focused on current status and trends of technology and interoperability as the backbone of the continuous of care model. By the fourth phase, ten Project Profiles (technology, policy, research) were identified, developed and ready for funding. Projects will be developed in a sample population of 200,000, then scaled-up to the Barranquilla's 2.5 million, and to the Atlantic Coast of Colombia. Colombia is nearing a political and technological crossroads characterized by an impending Health Reform, mandatory Integrated Service Networks, and use of EHR by 2014. This represents a friendly environment for interoperability. So, it was decided to create the National IHE Committee (Integrating the Healthcare Enterprise), and promote

B.07	Inter-observer reliability in the use of cellphone technology as a community based limb loss screening tool

Jose Alvin Mojica, Josephine R. Bundoc, University of the Philippines, Manila

Introduction: The Philippines is composed of 7,107 islands with a geographic architecture that makes it difficult to deliver health services. The Amputee Screening through Cellphone Networking (ASCENT) is an electronic system designed to facilitate screening of amputees by health workers in the community.

Aim: Determine the applicability of cellphone technology as a screening tool for amputees in the community.

Methods: Pilot testing was done on 40 amputees with 12 medical interns rotating in the Rehabilitation Medicine department as data gatherers. Prior to data gathering, the interns were trained on how to use the cellphone to input and send data to a designated website. In turn, the website administrator evaluated the data received and recommended appropriate management. Overall agreement, defined as the percentage of exact agreement observed between the medical student and web administrator, were calculated in the following constructs: laterality, stump level, and recommendation for prosthetic use. Inter-observer reliability was calculated using the kappa (k) formula, where k values = .75 denote excellent agreement. Feedback on the use of the cellphone was done through group interview after data gathering. Results: Overall agreements were 98% for laterality, 98% for stump level, and 85 %for recommendation for prosthesis use; k values were excellent for laterality (.98), stump level (.98) and recommendation for prosthesis use (.83). The students commented on the ease of cellphone use to gather and send data.

Conclusion: Use of cellphone technology has excellent overall agreement and interobserver reliability. Results of the present study also suggest that the use of cellphone technology is an easy and fast way to screen amputees in the community.

Key Words: cellphone technology, amputee screening, screening

B.08	Telemedicine: can we start today?

Miguel Pro Quintana, *France*

Telemedicine: can we start today? Telemedicine promises a cost-effective, time-efficient solution of expanding health care coverage to underserved areas. But different factors seem to be show stoppers for the effective use of telemedicine:

- Poor technology infrastructure
- Cost of the remote equipment
- High skilled personal requirements
- Lack of resources: funding
- IT education, and insufficient training for clinicians
- Doctors' and patients' resistance.

From our point of view, most of these obstacles can be vanished (or at least reduced) with the recent technological & behavioural evolutions. Coming from automation, IT and Telecommunication industries, we started reviewing our knowledge about healthcare and technology: what is really available, what is mandatory, what is behind obstacles, what is missing, what is really expected. After some trials, we were able to define and integrate a Biometric non-invasive screening modular station, that

- Can be operated by non-specialists personnel (even patient in some cases)
- Requires very "limited infrastructure" to be connected to specialized centers
- Is integrated with a platform that provide patient and specialist expectations
- Can be owned, maintained and operated with a minimum cost
- Start proven benefits in specific applications (chronic disease monitoring and wellness programs).

A room of progress for cost remains possible, but present configuration can already justify its use "as it is" in several niche applications (Remote monitoring, Primary or specialist remote diagnostic, etc.).This was our first "technological" step, but we also learned that Telemedicine, to be efficient, requires a global coordinated action. Without this, Telemedicine technology would be useless. We have two goals with this presentation:

- Show you what is possible to do, and convince you that we can (must) start today!
- Request/ propose collaboration for next steps wishing to be part of future coordinated actions. We trust in a pragmatic and collaborative movement that goes step by step until the final goal!

B.09	Lab tests online – Patient-centric, non-commercial, peer-reviewed resource for limited resource settings
	Shweta Kulkarni, Philippe Jacon, *European Diagnostic Manufacturers Association, Belgium; George Linzer, American Association for Clinical Chemistry, United States of America* Lab tests provide clinicians with vital information for disease prevention and mitigation, diagnosis, and monitoring. With today's increasing number of rapid tests available, patients in limited resource settings have the opportunity to receive treatment when needed. The American Association for Clinical Chemistry's (AACC) initiative - Lab Tests Online [www.labtestsonline.org] explains these tests in easy to understand language, enabling doctor-patient dialogue and improving health outcome. The resource is also a go-to-place for primary physicians to identify the appropriate test for diagnosis. Lab Tests Online (LTO) delivers vital lab testing information to patients in 14 languages, including French, English, Spanish, and Chinese. One-third of the world's population can learn from LTO in its national language. Despite its diverse linguistic accessibility, the AACC recognises that a lack of Internet connectivity inhibits use by populations in need. In order to address this problem, AACC partnered with the Chinese Society of Laboratory Medicine (CSLM) in 2009 to simultaneously launch a Chinese-language version of the site and to publish the content of the site in book form for distribution to the 13 western and mostly rural provinces of mainland China, where Internet access is limited. Unlike the book version, two strengths of the web version of LTO is that it is easily kept current with scientific advances, and the relatively low cost of updating and distributing the revised content. The LTO mobile app may provide the best of both distribution options: an easily and inexpensively updated digital edition that is downloaded in its entirety to a mobile device. Once downloaded, no Internet connection is required to access the technical content. Additionally, AACC and its partners such as European Diagnostic Manufacturers Association (EDMA) agree that LTO is an extremely valuable tool when professional expertise may be scarce.
B.12	Implementation of mHealth projects in Africa: What works, what doesn't, and why?
	Neo M Mohutsiwa-Dibe, *Ministry of Health, Botswana; Clara Aranda Jan, Institute of Manufacturing, University of Cambridge, United Kingdom; Svetla Loukanova, Institute of Public Health, University of Heidelberg, Germany* Background: Access to mobile phone technology has rapidly expanded in developing countries. In Africa, mHealth is a relatively new concept and questions arise regarding reliability of the technology used for health outcomes. This review documents strengths, weaknesses, opportunities, and threats (SWOT) of mHealth projects in Africa. Methods: A systematic review of peer-reviewed literature on mHealth projects in Africa between 2003 and 2013 was carried out using PubMed and OvidSP. Data was synthesised using a SWOT analysis methodology. Results were grouped to assess specific aspects of project implementation in terms of sustainability and mid/long-term results, integration to the health system, management process, scale-up and replication, and legal issues, regulations and standards. Results and Discussion: Forty-five studies on mHealth projects in Africa were included and classified as: "patient follow-up and medication adherence" (n=20), "staff training, support and motivation" (n=3), "staff evaluation, monitoring and guidelines compliance" (n=4), "drug supply-chain and stock management" (n=2), "patient education and awareness" (n=1), "disease surveillance and intervention monitoring" (n=5), "data collection/transfer and reporting" (n=9). Two included studies were reviews. In general, mHealth projects demonstrate positive health-related outcomes and their success is based on the accessibility, acceptance and low-cost of the technology, effective adaptation to local contexts, strong stakeholder collaboration, and government involvement. Threats such as dependency on funding, unclear healthcare system responsibilities, unreliable infrastructure and lack of evidence on cost-effectiveness challenge their implementation. mHealth projects can potentially be scaled-up to help tackle problems faced by healthcare systems like poor management of drug stocks, weak surveillance and reporting systems or lack of resources. Conclusion: mHealth in Africa is an innovative approach to delivering health services. In this fast-growing technological field, research opportunities include assessing implications of scaling-up mHealth projects, evaluating cost-effectiveness and impacts on the overall health system.
	C. Healthcare delivery: the role of medical devices
C.01	Complete mobile care units in rural areas
	Jean Marie Jigte, Kamdem Moyou, Samuel Joel Ildevertadjeme, *Care Help Cameroun, Cameroon* The CARE HELP Cameroon is divided into additional mobile unit providing specialized quality care to poor people living in rural, remote and isolated areas of specialized centers. She developed a method based on a support care by mobile teams consisting of many disciplines to meet the health needs more effectively insofar structures eye health are non-existent in rural areas and that 77% of health districts in Cameroon do not have eye clinic. For example, a complete eye care unit of Care Help Cameroon consists of an ophthalmologist, an optometrist, orthoptist, an ocularist, nurses and a charge of data collection.
C.02	Situational analysis of an NGO delivering health care services and medical devices and their needs in Togo
	Komi Agbeko Tsolenyanu, *Association for Maternal, Neonatal and Child Health, Togo* INTRODUCTION: NGO delivering health care services are very active in the implementation of 3 millennium goals; however their medical devices are precarious affecting the efficiency of services. OBJECTIVES: Carry out a situational analysis of NGO delivering health care services medical devices in Togo-Identify NGO delivering healthcare services contribution to specific and vulnerable populations- Evaluate their medical devices improvement needs. METHODOLOGY: Literature review, key stakeholders consultation, interviews, experiences sharing, observation, questionnaire administration. RESULTS: NGO delivering healthcare services medical devices are fragile because of lack of sufficient medical tray due to high cost of this equipment. Most of Associative structures can't deliver minimum packet of services to beneficiaries; care continuum is incomplete and unavailable; this situation affects the quality of services. However, NGO contribute a lot in delivering health care services to most at risk persons: sex workers, men have sex with men, Drugs users, prisoners, persons living with HIV/AIDS. These specific groups prefer NGO health care centers because of the low cost they practice and the stigmatization and discrimination in public health care centers. Another important target groups served by NGO's are vulnerable populations, of rural and urban communities. NGO play a complementary role in health care services delivery in Togo. NGO medical devices improvement needs are: increase donations to reinforce their technical tray. Medical equipment, little medical material, laboratory equipment, surgical bloc material, etc. CONCLUSION: NGO delivering health care services are suffering of their medical devices which are fragile; their technical tray is weak affecting care services efficiency. PERSPECTIVES: Improve advocacy toward north partners: -To increase medical equipment's donations to NGO delivering health care services in Togo

C.03	Web-based self-check software screening test to determine susceptibility to indoor chemical exposure and prevent adverse effects on children's health
	Emiko Todaka, Hiroko Nakaoka, Masamichi Hanazato, Chisato Mori, *Center for Preventive Medical Science, Chiba University, Japan* Adverse health effects such as allergic disease and neurological developmental disorders by uncountable chemicals in the environment are a concern to the health of children. Currently, about 2-20% of Japanese population is reported to have sensitivities or actually showing some symptoms such as headache, throat ache, dizziness in newly built or remodeled buildings, that is called "Sick-building syndrome (SBS)." The major causes of SBS are suspected to be volatile organic compounds (VOCs) indoor air, and lower the sum of the VOCs, less people claim the symptoms (Nakaoka et al., 2013). Once people get the syndrome, the life becomes very difficult in the problem room, and it is extremely important to prevent the sickness. The adverse health effect of chemical exposure such as SBS will become a big issue in near future in the developing countries also. Although SBS occurs in people who are sensitive to chemicals, there was no way to easily determine one's sensitivity. We developed web-based software to screen chemically sensitive people. This is a questionnaire, asking about the level of sensitivity to chemicals, called as "Chemiless Necessity Test." People will know their sensitivity to chemicals by trying the test. Since its launch in April 2009, more than 8,000 people have tried the test. So far, the results suggest that the percentage of high-risk group is 64% who answered the questionnaire. Further, after learning their own sensitivity, respondents are asked if they would pay attention to avoid exposure to unnecessary chemicals. The results show that more than 85% of people answered that they would more carefully avoid chemical exposure. This indicates that recognition is important to take action and the number of people who will suffer from SBS is expected to decrease. English and Korean version of this test were also developed and Chinese version is under construction.
C.04	The optimum benefits from international aid & support of medical devices for the developing countries.
	Faisal Mujamal, *Ministry of Public Health and Population, Yemen;Hanady Ahmad AlDughaish, Civil Society Organization IT, Yemen* As known that developing countries suffer from many of the problems (economic, social and political) adversely affect the utilization of available resources and use the optimal use and those resources international support in the field of medical equipment, which must be utilized optimal use to cover as much as possible of the health services to serve more the most important segment of the population. Objective: Provide medical equipment prevent complications satisfactory parasitic diseases and injuries and epidemiological viruses and other infections for the age group from the age of 5 - 18 years of periodic laboratory services. International support is providing mobile laboratory units carry out periodic campaigns of tests aimed at schools and health facility are periodic examination of blood , feces and urine of students enrolled (mandatory) and all age groups wanting authorized examination of those schools and health facilities like EPI campaigns . - Estimate the actual requirement for medical furnishings in two ways: The First method delivered mobile laboratory each Governorate contain all the necessary basic equipment to achieve all required for general chemistry and blood parasites and viruses and immunoassays The second method supported a central laboratory medical devices needed in each province and equipping mobile units to work campaigns periodic sampling of the schools in and around the work number code for every person on the sample taken from him and compilation of all samples and transferred via the mobile unit to the central laboratory to be tested and then received the results and recommend in certificate of inspection through the health facilities in the district and does not accept any student in the school , except under periodic inspection certificate . Economically the second method is more economic from the first way in the number of required equipment, materials and solutions operational and manpower as it will be the most comprehensive to cover all the tests via devices laboratories in all categories (Chemistry, Hematology viruses, Immunity, Microbiology.) - Important Purchases for devices at low rates appropriate to provide services with quality assurance through the provision of equipment from companies holds an international quality recognized in and work calibration rotating them to make sure quality that companies are qualified and have the local engineers and able to deliver after sales service , spare parts, maintenance Optimum utilization of international aid in medical divorce for actual needs at the lowest economic cost prevent complications satisfactory of the community economically and socially. Outputs Get a true generation free from diseases and healthy from diseases and infection to reduce the economic and social burden resulting from these diseases.
C.05	Destruction of waste from care in health centers in Burkina Faso
	Zida Ouambi Emmanuel, *Ministry of Health, Burkina Faso* Background: In Burkina Faso, there is, in addition to the major centers of care a multitude of small public and private health centers across the country. Those clinics usually do not have adequate facilities for the disposal of waste from care. Therefore, these wastes are crammed into a corner of the yard, or placed in a hole to be burned. These practices are dangerous to the neighborhood, users and staff. To resolve the problem, a craftsman has made an incinerator with local materials that give good results. The materials used: the incinerator is made from sand, cement, quartz and rebar. The characteristics of the incinerator Volume: 0,225m^3 Ignition system: 90 °alcohol or creeping oil Time to reach the maximum temperature: 20 minutes Maximum temperature: 800 °Celsius Life: about 7 years Ignition system:90 °alcohol or creeping oil Easy to use for unskilled staff Maintenance: routine cleanings The number of prototypes installed: 25 health centers use these incinerators and satisfy. The difficulties encountered by the craftsman: the workers of health care refuse the collection and treatment of waste, they still prefer to depositing waste in the yard or in pits. In the lack of resources, to promote and popularize the equipment Government, technical and financial partners have less interest on the issue of waste treatment from the care of small health centers. Conclusion: The issue of waste treatment of the facilities from health care is the most important. We need to extend the incinerator

C.06	Drug Resistance Index (DRI): A tool for managing antibiotic resistance

Aditi Sharma, Ramanan Laxminarayan (*Princeton University), Nikolay Braykov, Center for Disease Dynamics, Economics and Policy, Public Health Foundation of India, India*

Background: Antimicrobial resistance is an increasing threat to human health worldwide. As a result, polymixins, most commonly colistin (Polmixin E), have been re-introduced into clinical practice due to the rising prevalence of multi-drug resistant Gram-negative organisms (MDR-GNOs). The aim of this research is to use the sales data of colistin for worldwide surveillance of MDR-GNOs.

Methods: The IMS Health MIDAS database was used to track annual sales of systemic antibiotics under ATC class J1X2 Polymixins between 2000-2010. Retail and hospital data was available for 60 countries in Europe and Central Asia (n=28), East Asia & Pacific (n=8), Latin America & Caribbean (n = 4), Middle East & North Africa (n=5), North America (n=2), South Asia (n=2) and Sub-Saharan Africa (n=11). Volume was measured in standard units (smallest dosing unit, i.e. capsules, vials), adjusted for annual population levels. No distinction could be made between colistin for intravenous use or inhalation. Trend significance was measured by the Cochran -Armitage test.

Results: Figure 1 presents country use levels of colistin in 2010 (panel A) and regional trends for the period from 2000-2010 (Panel B). Levels were the highest in countries of Northern Europe, followed by the Mediterranean region. Use increased 1.8-fold in Europe and 1.4-fold in North America ($p = 0.00$), and declined in East Asia ($p < 0.001$) and Latin America ($p = 0.04$), fluctuated in the Middle East, and was near-zero levels in Sub-Saharan Africa and South Asia.

Conclusion: Colistin is increasingly used in Europe and North America coinciding with a rise in MDR-GNOs. The higher baseline levels in Europe are likely due to the use of colistin by cystic fibrosis patients. The decline in colistin use in Southeast Asia is not consistent with the rise of MDR-GNOs in that region. This could potentially be due to the fact that, in this region, colistin is considered to be an old antibiotic and less likely to be used because newer antibiotics are typically preferred.

C.09	A meeting, a plan and the creation of a dialysis centre in Benin

Jean Pierre Garcia Perez, *Benin*

Dialysis, being the treatment of kidney insufficiency, is a costly and technical form of health care which demands certain knowledge of multidisciplinary fields. The meeting between the association “Agence Solidaire des Dispositifs médicaux (ASDM)”- The Solidarity Agency for Medical Devices – and Doctor APETE will help to reach the goal of setting up a dialysis centre in BENIN. To be successful in this, first of all, means sharing one’s mutual values: respect, confidence and willingness.

As a coordinator of the project, ASDM determines the necessary resources for its high-level quality realization within a realistic budget knowing that the lives of human beings depend upon it. ASDM has both ground and technical experience together with a real capacity for solving problems. A race against time has begun between the recuperation of medical devices and the actual setting up of the activity. The technical constraints and the demands of regulations are considerable. Training is essential. Working with key local people is indispensable. The project was finally settled in 2011 when the first patients were accommodated. Setting up a dialysis centre is not an end in itself, it must be perpetuated by a follow-up process of activity with quality indicators. This project is of vital importance for afterwards it can allow the development of the dialysis within the country with treatment accessible to all at less cost by pooling expendable parts and equipment. ADSM is relying on you to continue the spread of its operation. Presently, our projects are situated in Senegal, Cameroon and Laos in partnership with “L’Association des Médecins Laotiens de France” – The Association of Laotian Medical Practitioners of France.

We are studying the possibility of setting up a humanitarian structure for post-emergency situations such as those in the aftermath of the earthquake in Haiti.

D. Healthcare Technology Management (HTM) (Clinical Engineering)

D.05	Healthcare Technology Foundation - Advancing the safety of healthcare technology

John Tobey Clark, *University of Vermont, United States of America; Yadin David, United States of America*

The Healthcare Technology Foundation was founded in 2003 on the principle that achieving improvement in the safe use of healthcare technology requires diverse stakeholders to come together in order to utilize their collective knowledge on the design, use, integration and servicing of healthcare technology, systems and devices. The mission of HTF is to: "Improve healthcare delivery outcomes by promoting the development, application and support of safe and effective healthcare technologies. "The Foundation supports: •The promotion of excellence in clinical engineering leadership through research, education and certification• Funding of related research and programs,• Effective collaborations between medical device producers, regulators, users and clinical engineers,• The creation of safety-related education material that is useful to members of the public HTF is the host organization Clinical Engineering Certification. Key projects are: Patient Education on Technology Safety - HTF has developed videos and brochures in English and Spanish on Home Medical Devices (general), Infusion Safety, Hemodialysis Safety, Ventilation Safety, and Oxygen Therapy. Clinical Alarm Hazards - HTF began an initiative to improve clinical alarms in 2004 with a national survey, white paper and focused meetings. In 2011 of 4287 clinicians completed the HTF survey where nearly 20% of the responders reported adverse events occurred in their hospital. In 2012 and 2013, the Food and Drug Administration (FDA), ECRI Institute, AAMI, and the Joint Commission have established clinical alarm hazards as a top priority patient safety hazard.Managing Risks of Integrated Systems & Networks in Healthcare Environments – In a joint effort with the Association for the Advancement of Medical Instrumentation, HTF is developing seminars, webinars and online courses to reduce risk for healthcare IT systems. The primary basis is ANSI/AAMI/IEC 80001-1 Risk Management for Integrated Systems.T he foundation also sponsors the ACEW International Award and the Marv Shepherd Patient Safety Award.

D.06	Matchmaking between low-end medical devices and primary care units via a non-profit platform -- experience from China
	Li Yang, Daidi Zhong, Xingmin Guo, Xiaolin Zheng, Xuelong Tian, Wenshen Hou, Xitian Pi, Zhong Ji, Yanjian Liao, Jin Tan, *Chongqing University, China* As a developing country with huge population, China has insufficient healthcare resources. The high-end healthcare assets are usually owned by central hospital which only represents a very small portion among all the healthcare units in China. In contrast, the healthcare assets (especially the medical devices) in primary cares are usually insufficient and inappropriate to services they are providing. One of the reasons is the mismatch between the performance and cost of medical device and the demand of primary care units. The manufactures of high-end medical device normally concentrate on the demand of central hospitals; while the manufactures of low-end medical devices, although concentrate on the demand of primary care unit, but have very limited chance to cooperate with primary care doctors and conduct enough amount of field trials. The manufactures of low-end medical devices are usually small- or middle-size companies, who often are lack of R&D resource and negotiating power. Without sufficient feedbacks from the primary care units, they are not able to sustainably develop products for primary care market. The end result will be the aggravation of the unbalanced configuration of healthcare resources in China. To fill this gap, China government launched a large-scale trial at 2010, aiming to establish a non-profit public platform to help the matchmaking between low-end medical devices and primary care units. The goal is to encourage more primary care doctors to learn and use low-end medical devices, and to continuously provide feedbacks to manufactures. The implementation of this platform has led to a win-win situation where the demands of both sides have been satisfied. This poster summarizes the lessons learned from this project, and may become a useful reference for other developing countries.
D.07	Certification of biological safety cabinets
	Beth W Wanjohi Njaramba, *Ministry of Health, Kenya* Introduction: In line with the laboratory safety regulations, BSCs are installed to ensure a safe working environment for the laboratory staff. There are more than hundred in Kenya within the MOH facilities. As a consequent of this, there is need to have them certified during installation, annually, after repair and when relocated to ensure compliance with the internationally set security and operation policy for the BSCs. Most of these BSCs have never been certified since installation hence posing a health risk to the society and environment. There are many challenges, budgetary allocations, technical competency, and lack of technical documentation, inadequate testing and certifying equipment. There is a need of BSCs certification planning which includes inventory, installation, training, technology assessment, facility design and equipment life cycle. It has been realized that one of the main reasons for the poor state of BSCs is lack of technical skills. To analyze the effective application, we must identify role of the BSCs Certifiers which include Selection, Operation and Maintenance. Objectives: To give an overview of how BSCs certification is carried out in Kenya and challenges certifiers encounter. To highlight various recommendations that would assist in improving the BSCs certification in the country. Results: Certification helps in good containment of BSCs leading to a safe laborotalian, product and environment.
D.09	Importance & benefits of clinical engineering departments in Turkey
	Omer Faruk Kuru, Cihan Karinca, Serbay Bahceci, Ismet Koksal, Osman Nacar, Ali Sait Septioglu, *Turkish Medicine and Medical Devices Agency, Turkey* A Clinical Engineer is a professional who supports and advances patient care by applying engineering and managerial skills to healthcare technology. The department of Clinical Engineering plays an important role beginning from procurement process and facilitates effective management of medical devices which are especially used in health care facilities. Additionally, Clinical Engineering department increases life cycle of medical devices, optimizes spare parts and technical services' costs of medical devices in order to improve the quality of health care. In this respect, as Turkish Competent Authority, local regulatory actions are on the verge of establishing process. In these local regulations focus on improving the quality of healthcare, which will also contributes reducing the Turkey's current account deficit in the near future. In this overview, considering the circulation of medical devices in Turkish Hospitals, the importance and benefits of Clinical Engineering Department has been explained briefly.
D.11	Evidence-based mathematical maintenance model for medical equipment
	Abdelbaset Khalaf, *A Tshwane University of Technology, South Africa; K Djouania, Y Hamama, University of Paris; Y Alayli, France* Although medical equipment maintenance has been well planned and executed for more than 30 years, very few studies have been conducted to measure and evaluate its effectiveness in terms of reliability and availability for service delivery. The ongoing unresolved debate in clinical engineering is whether preventive maintenance (PM) is actually necessary and, if so, how often and which tasks need to be performed. A mathematical maintenance modelling approach is used to analyse the survival probability of various medical equipment. This approach allows exploring the impact of PM, CM and combined PM/CM on the availability of equipment and will contribute to the intensified debate regarding PM. Maintenance strategies is analysed and a new failure-cost model was developed, which allows adopting appropriate PM intervals for various types of medical equipment. The analytical model to calculate the number of failures and costs associated with PM and CM is a significant contribution. The optimisation problem related to preventive maintenance scheduling using a Mixed-Integer Mathematical Programming solver was solved and compared to a proposed Greedy Algorithm. Simulation results based on the survival model show that the Greedy Algorithm gives the same solution in terms of schedule plan as the mixed integer approach.

D.12	Second hand medical equipment challenges in a remote area of a LDC: Experience of cardiac centre Shisong

Emmanuel Kouemo Tchokodjeu, *St Elizabeth Catholic General Hospital, Cameroon; Roberto Musi, Associazione Bambini Cardiopatici nel Mondo, Italy*

Introduction: Healthcare technologies are a major strategic factor in determining a healthcare system's performance and its perception by community in the Least Developed Country (LDC). There is not durable development without an efficient healthcare system. The experience of the CARDIAC CENTRE (CCS), unique center of cardiac surgery in Central Africa; specialized in the cardiovascular diseases shows the benefits of second hand medical technologies in a LDC context when properly managed. Objective: Present some keys factors for an efficient second hand MD management in specialized LDC Hospitals Challenges Necessity of Quality Environmental Conditions Non Availability of Specialized Maintenance Company Limited Funds and sustainability of the Hospital Energy Problem Delivery Delays No renewal plan for MD. The MD should work properly and last "forever" Medical Technologies waste management. Key Factors include: --Selection process & Management strategies of second hand MD Electricity Safety & Functional checks
-Impact of Preventive Maintenance and Quality control
-Manufacturers / Donors / Receiver Technical Collaboration
-Specialized Maintenance Training
-Spare Part Management
-Technical Documentation
Results: 42% of MD in use are second hand; value of the MD= 360.000€; Real Value New = 1.600.000€- 75%. Problems are detected during pre-use functional checks- 100% In House Preventive or corrective maintenance- 75% MD failures are resolved within 24 hours- From 2012 to 2013: Second Hand DM Acquisitions = 12 000 € Real Value = 105.000€ Perfect electrical safety and functional checks results- Annual electrical safety and functional checks by NOVAURA srl, Italian Company for free.
Conclusions: The analysis of Second Hand MD issues at the CCS shed light on the fact that with the right MD management policies and procedures; a skilled technician and trained users, second hand technologies can be cost effective, safe and beneficial in condition of hospital or patient limited resources.

D.14	Capacity building and supporting clinicians in medical equipment refurbishment and TT/LP

Mideksa Mulugeta, *Addis Ababa University, HSC, Tikur Anbessa Specialized Hospital, Ethiopia*

Objectives:
1. To enable the clinician to be investor instead of employee
2.To alleviate the accessibility of the low resource healthcare system
3.To promote the healthcare system in Ethiopia (low resource setting)
4. To support and/or image guiding for the clinician to treat or diagnose the patient.
5. To reduce child mortalities (to meet the MDG 4 and 6)

Abstract: The paper presents the purpose, methodology and the system design developed of the capacity building in the Medical Equipment donation, Refurbishment, Technology Transfer and Local production in Ethiopia(Low resource Setting). This project is all rounded and multilateral benefit for society, government and all clinician (including BME) in the counter. The clinicians are able to create their own business in the field by organizing themselves instead of employed. The donor (companies) will provide the capacity building in Technologies to be transferred, new and the second hand equipment for organized BME unit in the country then this organization will refurbish the old equipment and make leased it for all group of clinician team. The group of clinician team works together their own business based on their skill and professional license. The leased medical equipment should handle by biomed. The final results are promoting the access of medical equipment in Low resource setting

D.15	Qualification of medical technology management in a health care network

Eduardo Coura Assis, *Department of Science and Technology, Secretariat of Science, Technology and Strategic Inputs, Ministry of Health, Brazil; Murilo Conto, Department of Management and Incorporation of Health Technology, Secretariat of Science, Technology and Strategic Inputs, Ministry of Health, Brazil*

Introduction/Background: The main objective this project (QUALISUS-Network) is to contribute within the Brazilian Health System (SUS), for the qualification of care and health management, through the organization of regional networks of health care and qualification of health care.
Objectives: Qualify the management of health technology, focusing on medical care equipment for technicians belonging to fifteen health regions, called "QualiSUS-Network Project". Methods: We developed electronic surveys to verify whether there is a process of management of medical equipment in Health Care Establishments, as is done the management process and the profiles of these services included in this project. The surveys aimed to identify information such as the profile of professionals responsible for the maintenance of such equipment, whether there is an information system to manage these resources, infrastructure to perform the services, operating procedures and technical documentation available, systematized and organized. After completing these questionnaires, site visits were carried out to collect the evidence reported in the electronic survey. Completed this step, this information will be compiled for later we select regions that require training for management of medical equipment. The training will be provided by educational institution with expertise in Clinical Engineering in Brazil.
Conclusions: The achievement of the survey was able to show the performance of medical equipment management and is the first step towards the description of installed capacity in terms of infrastructure and human resources existing in thematic networks of Emergency and maternal and child health, identifying problems and solutions for improving the quality of equipment management in these networks
Discussions: Hopes to result in the strengthening of the capacity of medical equipment management in thematic networks and emergency as a way to improve the safety, quality, productivity and rationalization of investments within the regions of Qualisus-Network Project.

D.16	The use of oxygen concentrators in the Gambia: A study of over five years of experience in a setting with BMET support
	Beverly Bradley, Samantha Chow, Yu-Ling Cheng, *University of Toronto, Canada; Ebrima Nyassi, Biomedical Engineering Unit, Medical Research Council, The Gambia; David Peel, United Kingdom; Stephen RC Howie, Child Survival, Medical Research Council* Background: The cost-effectiveness of oxygen concentrators over cylinders as a source of medical oxygen in resource-constrained settings has been demonstrated, however, evidence of their long-term effectiveness in the field is scarce. Our objective is to share evidence and best practices concerning oxygen concentrator use at the Medical Research Council (MRC) Unit, The Gambia. The MRC's Biomedical Engineering department currently manages and maintains 28 concentrators (mean age: 5.0+/-2.1 years) distributed at several sites across the country, and has kept electronic "work order" (WO) records of all repairs, preventive maintenance checks (PMs), and inventory inspections since 2006. We present an analysis of concentrator reliability in a low-income setting with biomedical engineering technologist (BMET) support. Methods and Results: 819 WOs were analyzed (640 PMs, 34 repairs, 145 inspections). Repair WOs were categorized by main cause of failure, and spare parts were tallied. On average concentrators received 3.4+/-0.7 PM checks per year. Twenty-five PMs resulted in repairs. Eight concentrators have never needed a repair (excluding minor PM-related repairs) (mean age: 5.1+/-2.2 years). For the other 20 machines, the first repair occurred after 2.0+/-1.4 years of service, on average. The most common repairs, filter and check valve replacements, are the least expensive and require a low skill level. The most expensive repairs, sieve bed and compressor replacements, require a higher skill level but were rare. We estimate that less than 2,500 USD has been spent on spare parts since 2006 - about 18 USD per machine per year of service. Conclusions: Our experience of oxygen concentrator use in a low-income setting demonstrates that low failure rates and repair costs, and lifespans exceeding five years, are possible given a support framework that includes basically trained technicians and routine preventive maintenance. These findings are relevant to project planners interested in implementing oxygen concentrators in developing world health systems.
D.17	The problem of acquisition and maintenance of biomedical equipment in Burkina Faso
D.18	Ubiquitous management methodology for medical equipment
	William Alberto Cruz Castañeda, Renato Garcia Ojeda, *Biomedical Engineering Institute, Federal University of Santa Catarina, Brazil* Ubiquitous computing represents a paradigm in which information processing is thoroughly integrated into everyday objects and activities. Therefore, in this paradigm emerges ubiquitous health (u-health) that is defined from two perspectives: Concerning the application of pervasive computing technologies for healthcare. How to do that healthcare available anywhere, anytime and for anyone. From the point of view of Clinical Engineering u-health presents many opportunities in technology management, spreading and taking challenges from multiple technological perspectives allowing the acquisition, processing, diagnosis, transmission and sharing of information of medical equipment in real time. The current technological development offers new techniques and advanced methods to support this approach. Thus it is necessary to develop dynamic models to collaborate on clinical engineering activities into the technological process, incorporating policies and information and communication technologies (ICT) that enable ubiquitous access to deal with changes in the user context and the availability of resources. Predictive analytics is a broad term that describes a variety of statistical and analytical techniques used to develop models that predict future events or behaviors. Therefore, this work presents a dynamic model for clinical engineering ubiquitous management with ICT sustained in three areas: infrastructure, technology and human resources. This model implement predictive analytics techniques that describes a variety of statistical and analytical techniques used to develop models that predict future events or behaviors.

D.19 Health technology management model applied in primary healthcare in Brazil

Rubia Santos, Renato Garcia Ojeda, *Institute of Biomedical Engineering, Federal University of Santa Catarina, Brazil; Carlos Daniel M S Moutinho Junior, Secretaria Municipal de Saude de Florianopolis, Brazil*

Over 80.0% of the Brazilian population depends on the Unified Health System (SUS), which is a responsibility of State. In 2008, The Brazilian Federal Government launched the More Health Program: Right of all, in order to improve the system. Among the measures adopted, it could be highlighted the implementation of support and reference units for primary care, the creation of Centers for Dental Specialties (CEOs), Immediate Care and Diagnosis Support Units (UPAs), and Polyclinics. This situation directly impacts on the increase of the medical technology complexity installed in primary care and creates the need for specialized services in Clinical Engineering focused in Health Technology Management (HTM).Based on the Health Technology Management Model adopted by the Institute of Biomedical Engineering-Federal University of Santa Catarina (IEB-UFSC) and presented at the First WHO Global Forum on Medical Devices, an advisory and consulting program regarding Clinical Engineering was implemented in the primary care network of Health Department in Florianopolis city, Santa Catarina state, Brazil. The model of HTM is based on three domains: infrastructure, human resources, and technology, allowing more quality to the technological process in health. As part of this program, the IEB-UFSC advised and monitored the implementation of two polyclinics, two UPAs, besides the reform and construction of new primary healthcare units. Among other activities, consultancies are carried out about the equipment dimensioning based on relevant standards, technical analysis of the purchasing processes, receiving, installation, functionality testing and users training. In 2007 in the program's implementation, the park of equipment was approximately R$2 million. Nowadays the amount is R$ 5.5 million. These activities of the Clinical Engineering intend to increase safety, reliability, and effectiveness of the primary care system, which are key indicators of quality of the HMT model.

D.21 Improving maintenance of medical equipment in Uganda

Keiko Fukuta, *Japan Association for Clinical Engineering, Japan and University of Leeds, Nuffield Centre for International Health and Development, United Kingdom*

Medical equipment (ME) is important features in delivering health services and improving health outcomes; however, many low and middle income countries (LMICs) are contending with serious issues regarding appropriate implementation and maintenance. In the Republic of Uganda (Uganda), considerable numbers of ME are donated and then left idle. Insufficient maintenance is one of courses, results in an inadequate, inequitable and unsafe health service to patients and health staff. The aim is to develop strategies for the improvement of the maintenance of ME to achieve good health outcomes. The objectives are to analyse factors influencing the maintenance of ME, to explore strategies in Uganda from international experiences and finally to recommend strategies. This in-depth study use a conceptual framework, interventions in other LMICs was introduced and assessed and appraisal tools for analysing. Predominantly related factors included: superficial explanation of maintenance in the national health technology policy, scarcity of budget, scarce consistent user knowledge and skills, an absence of or incomprehensible operating manuals, deficiency in the number of qualified maintenance personnel , low knowledge and skills district technician , no regular maintenance training and excluding district technician, non-effective use of local market, long complex processes and expensive spare parts, low contract service vendor numbers and ineffectual supervision relating to ME maintenance at the facility and individual level. The valuable and feasible strategies included: training and graphic instructions and checklists for regular users, the improvement of Bio-Medical Engineer/Technicians, recruiting other related engineers and basic training with maintenance materials for maintenance personnel and enhancing local markets for non-critical spare parts, standardisation of sophisticated equipment and regular communication for management personnel. Various interventions for each actor are different but they also remain interconnected and overlapping to a degree. Accelerating strategies will produce an appropriate and effective for improving the implementation of ME maintenance in Uganda.

E. Health Technology Assessment (HTA) for medical devices

E.01 Health technology assessment : Specificity of medical devices evaluation in Singapore

Laurent Dominique Michel Metz, *Singapore; Jayashree Mapari, India*

Spiralling costs of healthcare delivery have increasingly necessitated policy makers to adopt rigorous frameworks to appraise clinical and cost benefits of newly introduced medical interventions. As we embark on exploring the probable frameworks for establishing an effective HTA system, it is essential to understand some of the intricacies associated with the applicability and transferability of HTA evaluations. The scope for Adoption and Transferability of Health Technology Evaluations from other markets is limited, due to intrinsic differences in healthcare costs, standards of care, prevalent clinical practices and overall healthcare delivery mechanisms. Although there exist, a plethora of international guidelines for conducting HT evaluations, these have been primarily developed for pharmaceuticals, and adapted for evaluating medical devices. Therefore they do not necessarily conform to the unique requirements posed by medical device evaluations. The adoption of any new medical device is associated with a learning curve, thus, apart from its efficacy; the resultant clinical outcomes are highly dependent on the skills and adeptness of the surgeon, which evolve over time. Therefore the HT evaluation of a medical device unlike that of a drug needs to be an ongoing process. As newer devices enter the market, there could be a possible redundancy and price erosion of older devices, which could unfavourably impact the “Cost effectiveness” considerations of newer devices, if not judged appropriately. Also, adoption of a medical device may cause a significant alteration in the healthcare delivery and standards of care. Therefore the economic benefits need to be evaluated within the context of a particular healthcare system, and not just from an immediate cost-benefit, but a wider system wide or societal perspective. Health Technology Assessment is thus a powerful tool which if applied in the right context and through a well-informed approach, can result in the rational use of available evidence for making informed decisions.

E.02 Healthcare technology assessment for non-pneumatic anti shock garment for obstetric shock prevention

Vatsal Chhaya, Jitendra Kumar Sharma, Mohammed Ameel, *National Health Systems Resource Centre, India*

Obstetric shock is fatal condition that may occur in case of third stage labour due to excessive blood loss called as Post-Partum Haemorrhage. Non-pneumatic anti shock garment (NASG) is an innovative healthcare technology used in several developing countries /low resource settings for obstetric shock prevention. It is designed to apply circumferential pressure to woman’s body and diverts blood towards heart and brain and thereby preventing shock with proper blood supply to vital organs. The cluster randomised clinical trials in countries like Africa, Egypt, Nigeria and India shows positive results .Thus, to consider it for its uptake in public health system in India, Healthcare Technology Assessment was conducted. NASG found to be clinically effective with significant reduction in mortality in intervention group. Moreover over the current cost in India, cost at which the device was cost-effective was also calculated deriving cost per life saved. The regulatory and market statuses were also reviewed and NASG was identified with great potential to give a rise to Indian Textile Industries and also strengthening Emergency Response Systems care delivery.

E.03	Mini HTA: An effective tool for clinical governance, resource allocation and conflict management at local (regional) level
	Gaddo Flego, Cardinale Francesco, *Azienda Sanitaria Locale Nr 4, Italy* The Italian Region of Liguria has introduced in 2011 mandatory mini-HTA for the introduction of new technologies (except drugs, which are under different regulations) in hospitals and local health units (ASL) of the local branch of the National Health System. Our ASL, that hosts the Scientific Committee and the Coordinator of the Ligurian Network for HTA, has been pioneering this approach with great attention and involvement, applying it to all the decisions about biomedical instruments (including radiology) and medical devices, not only in relation to the implementation of new technologies, but also in the framework of dismission of old ones (disinvestment). The mini-HTA approach (mainly based on the Danish model of Hospital based HTA) has rapidly grown up to a fundamental tool for decision making, as the General Director (CEO) of the Health Unit will not consent any acquisition of medical devices that has not undergone the full process. In our two year experience and more than 40 reports processed, we have shown that health expenditure for medical devices can be absolutely put under control and stabilized; moreover, the mini-HTA approach strongly involves clinicians and it is a most useful tool for managing conflicts between front line health operators and managers, bringing the discussion on the ground of evidences matched with sustainability (organizational, technical, financial) and filling the gap between clinical issues and resources availability. All the documents and reports produced at Regional level are freely available on the web (http://www.liguriainformasalute.it), and the Ligurian Network for HTA is part of the Italian Network RIHTA. Our experience in a National Health System struggling to continue to offer effective health care in a Country undergoing a severe economic crisis indicates that great emphasis should be put on mini-HTA in a global health perspective.
E.04	A systematic review of health technology assessment tools in resource-limited settings: How much do we know about the assessment of medical devices in Sub-Saharan Africa?
	Christine Kriza, *University of Erlangen-Nuremberg, Germany; Jill Hanass-Hancock, Nicola Deghaye, Health Economics and HIV/AIDS Research Division, University of KwaZulu-Natal, South Africa; Emmanuel Ankrah Odame, Ghana College of Physicians and Surgeons, Accra, Ghana; Rashid Aman, Centre for Research in Therapeutic Sciences, Nairobi, Kenya; Peter Kolominsky-Rabas, Interdisciplinary Centre for Health Technology Assessment and Public Health, Germany* Objectives: Health Technology Assessment (HTA) is mostly used in the context of high-and middle-income countries. Several tools exist for resource-constrained settings but widespread use of HTA in most Sub-Saharan African (SSA) countries is still limited. Some HTA aspects do not fit into these settings and methodologies need to be adapted appropriately according to specific needs. This research study aims to provide an overview of HTA tools used in resource constrained settings, with a specific focus on the assessment of medical devices in SSA. Methods: A systematic review in line with PRISMA guidelines was conducted for studies sufficiently detailing HTA tools that are applicable for resource-limited settings, published between 2006 and 2012. The following databases were searched: PubMed (Medline), ScienceDirect (EMBASE) and Academic Search Elite (EbscoH). Results: From 24 identified research studies, two appropriate tools have been identified that are applicable in resource-limited settings, and cover methodological robustness and ease of use. The KNOW ESSENTIALS and Mini-HTA tool fulfil these criteria, but have not been applied in a low-income SSA setting yet. In addition, Multi-Criteria Decision Analysis shows value in assessing evidence and has a strong potential to be used as a complementary tool with HTAs. HTAs often focus on pharmaceuticals, and the assessment of medical devices is limited, especially in resource-constrained settings and SSA in particular. Conclusions: Many resource poor settings, which often have the greatest need for critical assessment to make appropriate and affordable investments in health technology, have a limited basis for making evidence-based choices. This can lead to inappropriate use of technologies, which do not address health needs, and inefficient use of resources. A better overview and related analysis of the HTA tools used is required for resource-constrained settings and especially SSA, specifically concerning a knowledge gap related to a robust assessment of medical devices.

F. Biomedical engineering education	
F.01	Improving medical devices management in the hospitals by introducing a health technology lecture in the syllabus of the national advanced school of administration and magistracy in Cameroon
	Vincent Ngaleu Toko, *Cameroon* Five years ago, a "Hospital Administration" section was implemented in the National Advanced School of Administration and Magistracy in Cameroon. This school is in charge of training most of the managerial staff of the Cameroon Administration. Three years after, we introduced Health Technology Management course on the syllabus of this newly implemented section. Objectives: To insure that all hospital managers will have good knowledge not only on general management but also on health technology management, To insure that in the future all hospitals will be provide with good medical devices, well managed, and in good working condition. Results: For three years now every year, 30 new trained hospital managers are appointed on various posts where they are involved in medical devices management process in the ministry and in hospitals. The training focuses on the following main topics: The health system in Cameroon Hospital environment Managing hospital assets from planning to disposal Hospital maintenance. We expect participants to give their opinion the pertinence of the training program and its importance.
F.02	Characterizing the next generation of medical device innovators: Ghanaian student perceptions of biomedical engineering
	Elsie Effah Kaufmann, *University of Ghana, Ghana; Ibrahim Mohedas, Shanna R Daly, Kathleen Sienko, University of Michigan, United States of America;* Human capacity building through training and education is a key component to increasing the quality and availability of healthcare in low- and middle-income countries (LMIC). While a variety of programs have increased the numbers and improved the training of healthcare providers in LMIC, there has been little emphasis on the training of the next generation of medical device innovators. Medical devices are still almost exclusively imported into LMIC and often fail to function effectively due to their inappropriate design for these settings. Human capacity in fields such as biomedical and clinical engineering must increase in LMIC in order to promote and support the local design, development, and production of medical devices that address local needs. To this end, over the past decade, undergraduate biomedical engineering programs in sub-Saharan African countries, including Ghana, have been established and expanded. However, a need exists to assess program outcomes, specifically in supporting students to think of themselves as future designers and innovators in the field. We report on a study in which we explored the ways Ghanaian undergraduate biomedical engineering students perceive their discipline. An open-ended response instrument was developed and distributed to students at a large university in Ghana, which consisted of five open-ended questions focused on students' perceptions of what biomedical engineers do, the experiences that informed these perceptions, their motivation for studying biomedical engineering, their future job prospects, and where they believe the field is going. A qualitative analysis conducted with student responses revealed patterns within and across students from various years of study, specifically in how Ghanaian students describe their future careers and their motivations for studying biomedical engineering. The results suggest that it is necessary to devise strategies to motivate students entering biomedical engineering programs and to sustain their interest as they pursue the curriculum.
F.03	Undergraduate biomedical engineering students as design ethnographers
	Ibrahim Mohedas, Shanna R. Daly, Kathleen Sienko, *University of Michigan, United States of America* The desire for technologies that truly meet the needs of local stakeholders has led an increasing number of academic programs to focus student effort on tackling global health challenges through the design of context-specific medical devices. In order to design effective medical devices suited to different cultures, engineering students must learn design strategies for discovering local data from stakeholders and incorporating those data into their designs. Design ethnography methods support designers in understanding the true, and sometimes hidden, needs and preferences of stakeholders. These methods include observing and interacting with stakeholders in their natural environment to gain insights that might otherwise not be discovered. While the utility of design ethnography has been extensively promoted in the context of professional design, student learning of design ethnography has lacked study. The research presented here sought to address this gap by investigating the ways engineering students use design ethnography methods while designing a medical device to address a global health challenge. Student design teams that participated in clinical immersion experiences were studied throughout their design course via semi-structured interviews, analysis of their design reports, and surveys. Furthermore, their design reports and specifically, their design decisions made during the generation of user requirements and translation of the requirements to engineering specifications were studied. Our findings revealed that students perceived benefits of design ethnography; however, these were often superficial in nature. Students also had significant frustrations that they attributed to their use of design ethnography, however, these often stemmed from challenges unrelated to design ethnography. The results illustrate the need for the development of effective tools and pedagogy to support students when learning and practicing design ethnography that will in turn prepare students to better solve global health challenges in the future.
F.04	Multinational undergraduate engineering student clinical immersion experience in obstetrics
	Kathleen Sienko, Amir Sabet Sarvestani, *University of Michigan, United States of America; Elsie Effah Kaufmann, University of Ghana; Moses Musaazi, Makerere University, Uganda; Samuel Obed, Korle Bu Teaching Hospital, Ghana* Numerous universities have implemented needs assessment programs in low-resource settings, typically involving students only from high-resource settings. The shortcomings of such programs include the involvement of a limited number of local stakeholders (predominantly, healthcare providers) and the failure of promising concepts developed in follow-on design courses to emerge from the classroom. It is therefore increasingly recognized that local engineering talent in low-resource settings must be further developed in order to increase the likelihood that local solutions will be generated, manufactured, adopted, and successfully implemented. This will require stronger and more effective partnerships among the international and local academic and clinical institutions involved. To address these issues we developed and implemented a unique program for students from the University of Michigan, University of Ghana, and Makerere University to gain practical experience co-identifying unmet maternal health needs in Ghana in collaboration with multicultural and multidisciplinary stakeholders. During 2011, engineering students from these three universities participated in a joint month-long clinical immersion project scoping experience in the Department of Obstetrics and Gynecology at the Korle Bu Teaching Hospital in Accra, Ghana. Three distinct design project topics were selected among more than 85 needs identified in consultation with the department head and engineering faculty. Following the clinical immersion experience, the students returned to their home institutions and either completed their capstone design project or mentored a group of capstone design students on one of the three topics identified during the immersion experience. The pilot program outcomes included the generation of multiple prototypes, conference and journal publications, and peer-to-peer mentoring of non-participant Ghanaian biomedical engineering students. We believe that assembling a multinational engineering student team for this clinical immersion experience provided benefits for all partners: clinical and cultural immersion for the American students and an introduction to an innovative design culture for their African peers.

F.07	The role of clinical engineering in the process of incorporating technology based on procedures
	Marcelo Hayashide, Priscila Sousa de Avelar, Renan Feltrin, Renato Zaniboni, Renato Garcia Ojeda, *Institute of Biomedical Engineering, Federal University of Santa Catarina, Brazil* The Instituto de Engenharia Biomédica da Universidade Federal de Santa Catarina (IEB-UFSC), Brazil, has been developed a medical technology management program in 15 Health Care Facilities (HCF) in collaboration with the State Secretary of Health of Santa Catarina (SES/SC) for more than 12 years. Ten of the facilities have a Local Center of Clinical Engineering (CELEC) and the others five have support of the Center of Management and Development of Health Care Technology (Ceged-TMH) of IEB-UFSC. Based on the management model developed by UFSC-IEB, one of the activities for the technological process in healthcare is related to the acquisition and incorporation of medical equipment. Together, CELECs teams and Dimensioning and Incorporate Technology Center (DIT) of Ceged-TMH, work actively in to incorporate technological needs. Studies from medical equipment technology are developed according to the necessities of the public network. Technology settings are based on normative and regulatory requirements in Brazil. The incorporation of the new technology is followed by studies from, technical specification, public bidding process analysis for acquisition, acceptance and installation, as well technical training, before being released at the hospital. The methodology is based on the three domains of the technological process: human resources, infrastructure and technology, and management model by IEB-UFSC. The results obtained by the inventory of facilities with CELECs have the average of 150 beds per hospital, with a total of 7400 equipment. From 2003 to 2012, it was acquired approximately 13,500 equipment, 868 incoming inspections were realized and the total investments were around USD $24 million. In conclusion, the technology incorporation process allowed the renewal of medical devices, improving the quality indicators in healthcare services. The development of the Ceged-TMH technology as a organized structure based on procedures contributed to the successful actions of technological analysis with quality.
F.08	Brazilian industrial complex and innovation in health: Biomedical engineering training in Brazil, achievements and challenges
	Sergio Santos Mühlen, *Universidade Estadual de Campinas, Brazil; Paulo Henrique Dantas Antonino, Eduardo Jorge Valadares Oliveira, Carlos Augusto Grabois Gadelha, Ministry of Health, Brazil* The Brazilian government has put efforts in Health and Industrial Policies in order to increase overall access to health, promote regional development and decrease the trade deficit in the Heath Industrial Complex sector. In order for that to be achieved, policies and instruments designed to promote technological innovation and competitiveness of the national medical devices industry has been put into effect. The Basic Production Process (BPP) in one of such instruments. The BPP, as defined by Law nº 8.387 of December 30, 1991, consists of describing the minimum necessary steps in fabrication so that a product can be considered Brazilian and was Introduced by means Interministerial Ordinances, signed by the Ministers of Development, Industry and Foreign Commerce (MDIC) and Science, Technology and Innovation (MCTI). The benefits granted by the Federal Government are fiscal benefits designed to the Free Economic Zone of Manaus and advantages found in the Law of Informatics, such as margin of preferences, and inclusion in the Unified Health System's (UHS) list of strategic products. Since the beginning of 2013, in the context of the Health Industrial Complex, the Health Ministry has been supporting the BPP, aiming at the development of resources of strategic relevance to the Unified Health System, in order to learn and incorporate technologies crucial to the manufacturing of medical devices. The first BPP aligned to this philosophy for medical devices was put into practice in 2013, and defined the Basic Production Process for Ultrasound with Spectral Doppler Analysis. Other BPP currently in phase of public consultation are: Digital Mobile X-Ray with "C" arc, Fixed X-Ray Machine with flat-panel digital detector image acquisition, and Positron Emission Computerized Tomography device

G. Innovation	
G.09	R&D and innovation in medical technologies in Lebanon
	Sandy Rihana, *Biomedical Engineering Department, Holy Spirit University, Lebanon* Where is the situation of health technologies and emerging medical devices in Lebanon? Where is the aurora when industries, small, medium and even the biggest firms carry out the R&D activity concurrently with the business already emerged culture in the Lebanese market? Like any kind of organizational analysis, this paper presents the strengths, weakness, opportunities, and threats analysis of the development of a platform of medical technologies innovation and research in the country. The study will be studied from two perspectives, an external one based on the security of the region, emphasizing the different external factors affecting the emerging of such platform and market. Moreover, an internal analysis allows to evaluate the strengths and weaknesses factors already existent in the medical devices technologies. Any R&D activity is characterized by a high level of innovation and short product life cycle from idea to market, where are we situated comparing to developed country. When there is need, there is innovation. In fact the culture and the environment of a country highly influence the research and development track. Precisely health and medical R&D are considered main and crucial concerns of the people. Considering any medical device life cycle, the first stages of design, concept, prototype and devices, could be accomplished in short time assuming sufficient human technical and financial resources. The strength point of a country is the high percentage of scientists, clinicians and engineers, also the continuous increase of researchers and research projects in universities and in higher education. Creating applied and clinical research platform, hosting R&D industries in the country would help the innovation lifecycle of medical devices. This could help bridging the gap between theoretical and applied research leading to partnerships with academia, clinicians, hospitals, industries in high and low resources setting.
G.10	Brazilian industrial complex and innovation in health: Basic production process inducing technological development
	Marcio Jose Batista Cardoso, Marco Aurelio de Carvalho Nascimento, Paulo Henrique Dantas Antonino, Eduardo Jorge Valadares Oliveira, Carlos Augusto Grabois Gadelha, *Ministry of Health, Brazil* The Brazilian government has put efforts in Health and Industrial Policies in order to increase overall access to health, promote regional development and decrease the trade deficit in the Heath Industrial Complex sector. In order for that to be achieved, policies and instruments designed to promote technological innovation and competitiveness of the national medical devices industry have been put into effect. The Basic Production Process (BPP) in one of such instruments. The BPP, as defined by Law nº 8.387 of December 30, 1991, consists of describing the minimum necessary steps in fabrication so that a product can be considered Brazilian and was introduced by means Interministerial Ordinances, signed by the Ministers of Development, Industry and Foreign Commerce (MDIC) and Science, Technology and Innovation (MCTI). The benefits granted by the Federal Government are fiscal benefits designed to the Free Economic Zone of Manaus and advantages found in the Law of Informatics, such as margin of preferences, and inclusion in the Unified Health System's (UHS) list of strategic products.Since the beginning of 2013, in the context of the Health Industrial Complex, the Health Ministry has been supporting the BPP, aiming at the development of resources of strategic relevance to the Unified Health System, in order to learn and incorporate technologies crucial to the manufacturing of medical devices. The first BPP aligned to this philosophy for medical devices was put into practice in 2013, and defined the Basic Production Process for Ultrasound with Spectral Doppler Analysis. Other BPP currently in phase of public consultation are: Digital Mobile X-Ray with "C" arc, Fixed X-Ray Machine with flat-panel digital detector image acquisition, and Positron Emission Computerized Tomography device
G.11	Improving access to medical devices in low-resource settings through local production and technology transfer: WHO 2013 survey results
	Peng Si (*Nanyang Technological University, Singapore); James Abbas (Arizona State University, United States of America); Mladen Poluta (Univerisity of Cape Town, South Africa); Amir Sabet Sarvastani (University of Michigan, United States of America); Adriana Velazquez-Berumen, World Health Organization, Switzerland* In Resolutions WHA61.21 and WHA62.16, the World Health Assembly set forth the goals to improve the transfer of and access to medical technology in developing countries. Local production may provide an important mechanism to increase access to medical devices. The WHO's Medical Devices Unit is currently conducting the second phase of a project that includes a survey to gather information about technology transfer and local production of medical devices. This survey was performed to better understand the barriers and challenges related to sustainable local development and production of medical devices. The survey included questions regarding the environment for product development and manufacturing, policy and partnerships, intellectual property protection, regulation and technology transfer, policies for acquisition, procurement and reimbursement. Respondents' background, training information, and their role in the technology development and commercialization process were also collected and matched to their input. Responses were received from 173 stakeholders in 47 countries. Analysis indicates that the most frequently cited barriers to the access of medical devices in low-resource settings were cost and maintenance issues. Medical device developers indicated that the major obstacles to develop and commercialize their products in low- and middle-income countries (LMICs) were the lack of financial resources and inadequate local facilities. Respondents indicated that the top challenges to manufacture medical devices locally in LMICs are international competition, expensive startup costs, lack of trust in locally produced products and bureaucratic procedures to setup local manufacturing facilities.

H. Innovative health technologies

H.03 Hand-held diagnostic ultrasound system to be used by general practitioners in routine medical examinations

John Makinnon, Rodrigo Maureira, Vader Johnson, Javier Moya, *Chile; Manuel Duarte, Nicolas Beltran, Carlos Conca, Facultad de Ingenieria, Universidad de Chile*

We designed, developed and manufactured a hand-held battery operated diagnostic ultrasound system, simple to use, with high frame rate and good quality images. This is to be employed by general practitioners, family doctors, pediatricians, surgeons, internal medicine specialists, ICU doctors, trauma centers, emergency centers, etc. as part of the routine clinical examination of their patients. This tool will provide more information, allowing them to make better clinical judgments.

H.04 A low-cost, low-power syringe pump for the delivery of magnesium sulfate to pre-eclamptic women

Kelley Maynard, Kevin Jackson, Jinwoo Peter Jung, Glenn Fiedler, Lemuel Soh, Pablo Henning, Rebecca Richards-Kortum, Z Maria Oden, *Rice University, United States of America; Rohith R. Malya, AD Noland, University of Texas Medical School at Houston, United States of America*

Problem: The WHO estimates that 50,000 women die annually as a result of pre-eclampsia or eclampsia. The standard drug used to prevent and treat convulsions for women with pre-eclampsia and eclampsia is magnesium sulfate (MgSO4). While MgSO4 is easily delivered with intravenous (IV) infusion by a syringe pump in developed settings, these pumps are often too costly for developing world hospitals. In the absence of such pumps, low-resource hospitals often resort to intramuscular injections, which are painful and involve a complex administration protocol. There is a need for a low-cost and simple method for intravenous infusion to improve the delivery of MgSO4 to pre-eclamptic mothers in the developing world.

Solution: A team at Rice University developed AutoSyP, a low-power, low-cost syringe pump intended for IV drug infusion in developing world hospitals. AutoSyP consumes only 2W versus 20W for standard pumps and can run on battery power for an estimated 20 hours, making it more suitable for settings where the power supply is unreliable. The prototype costs $520 with a target production cost of $300, compared to >$2,000 commercial pumps. The device accommodates 5-60 ml generic syringes, so consumable costs are minimal. Initial flow rate tests show the device to be accurate within 3%. AutoSyP uses a double-pawl ratchet mechanism controlled by a stepper motor to intermittently release a constant-force spring and compress a syringe. A microcontroller with customized algorithms for specific drugs/diseases controls the device. An alarm indicates if depression stops due to a pressure occlusion or mechanical malfunction.

Current Status and Future Work: Laboratory and clinical evaluations are planned to further validate accuracy and performance. AutoSyP has the potential for a broad impact in global health, as high-accuracy IV drug delivery is required in several situations, including the treatment of stroke and cancer, and drug infusions for neonates.

H.05 Fully-automated point of care detection of malaria and other infectious diseases with a disc-shaped diagnostic platform

K.Mitsakakis, S. Hin, F. von Stetten, R. Zengerle, *University of Freiburg, Germany*

Malaria is one of the highest mortality rate infectious diseases globally, mainly prevalent in sub-saharan Africa. Other diseases like dengue, pneumonia, typhoid fever are also present in the same areas, and, although they emerge from different pathogenic agents, they exhibit the same clinical symptom (acute fever). This makes reliable diagnosis extremely challenging especially due to the low resource nature of the endemic regions. Under these circumstances, existing diagnostic methods are often not efficient enough and unable to provide a generic solution:

- blood smear microscopy is only malaria-specific;
- lateral flow Rapid Diagnostic Tests (RDTs) are cheap but single-target specific;
- existing molecular methods (e.g., PCR, ELISA) and/or pathogen cultivation require expensive equipment, well-trained users and long time-to-result.

The presently suggested technology aims to provide a true point-of-care diagnostic platform, by addressing key application-oriented needs:

- Portability and autonomous use, based on a disc-shaped plastic disposable cartridge (LabDisk) capable of handling liquid sample (blood) via centrifugal forces operated by a CD-player-like device (LabDisk Player)
- Full automation from sample collection to result, via a simple blood transfer device (patient-to-system interface) and on-disc integration of all biochemical components needed for the blood-based pathogen identification (e.g., molecular probes, buffers, etc).
- Rapid analysis, by using time-saving analytical protocols based on immunoassays and isothermal nucleic acid amplification (LAMP, instead of PCR).
- Multiplexity, by combining a broad diagnostic panel on the same disc (parasites, viruses, bacteria). The panel is flexible and can be tailored to the geographic-specific diseases. (v) Low-cost fabrication technology based on microthermoforming of thin polymer foils, adaptable from pharmaceutical and food package production. This work is part of the EU FP7 project DiscoGnosis, financed by the European Commission which is acknowledged, as well as all the consortium members for their contribution.

H.06 An electrical impedance based neonatal respiration monitor for pneumonia detection

Khondkar Siddique-e Rabbani, Shahnaj Parvin, Imtiaz Ahamad Khan, Muhammad Abdul Kadir, *Department of Biomedical Physics & Technology, University of Dhaka, Bangladesh*

There is no good detection technique for pneumonia as yet, particularly for neonatals and babies. X-ray is normally used in conjunction with other symptoms, but this is not available to most people in the Third World. Respiration rate in conjunction with other symptoms can give a diagnosis, but a baby cries on connecting diagnostic equipment, which changes the respiration rate jeopardising the measurement. We developed an electrical impedance based technique with a palm worn electrode pad made of flexible rubber sheets, to be worn by the mother or a nurse using a Velcro strap. Necessary electronic circuitry, computer interface and software were also developed. As the mother touches the baby's thorax using this palm-worn electrode pad the impedance variation with respiration is displayed and recorded in a computer. Later, using signal processing techniques the respiration rate is obtained from acquired data. Pulsating blood flow also creates changes in the data and heart beat rates may also be extracted from the same measurement. Four electrode impedance measurement technique was employed where current is passed through two electrodes and the potential is measured between the other two. A cloth covered the rubber pad to make it comfortable to the baby, with cotton buttons at the positions of the electrodes, which when soaked with water made the necessary connections. Measurement on a 2 year child was successful – the child did not cry! In future the same system with small modifications may be used to study localised lung ventilation indicating presence of any masses in the lung, lung perfusion, quality of pulsatile blood flow, stomach emptying, bladder emptying, etc., making it a multiple diagnostic apparatus. At present, giving both respiration rate and heart rate, this device is going to be of use for the detection of pneumonia, particularly in neonatals and babies.

H.07	A smartphone-based mobile multi-modal optical imaging platform for cervical cancer screening

David Levitz, Ariel Beery, Amit Safir, *Israel*

Cervical cancer is the leading cause of cancer death among women throughout much of the developing world. Vulnerability to cervical cancer is particularly high among lower income segments of the population, and many women at greatest risk come from the global poor, where access to women's health care is very limited. Cervical cancer begins in the superficial layer of the tissue, typically 200-400 um below the surface. In a low resource setting, it is important to distinguish patients with low-grade from high-grade dysplasia, as the therapy costs more than the screening. The current standard screening method in low-resource settings is visual inspection with acetic acid, which has a positive predictive value of only 17 %. The high false positive rate results in overtreatment for too many patients. To address this problem, we are adapting a set of optical imaging techniques to enable mobile screening of the cervix using a smartphone with enhanced optics. The technology consists of a hardware attachment (a proprietary compound lens that attaches to the smartphone camera and a light source made of various LEDs) and a set of algorithms. The technology consists of 3 imaging modalities: polarization difference imaging, multi-spectral imaging, and fluorescence imaging. Together, they allow for separating the superficial layer from the deep layer, and analyzing the tissue composition and oxidative stress. The technology – lens, light source, and algorithm – can integrate onto any digital camera, including smartphones and endoscopes. With its ability to separate the superficial layer from the diffuse layer, and to further analyze each layer separately, the technology is ideally suited for diseases of the epithelium in particular, epithelial cancers. The ubiquity of smartphones in health centers of the developing world make it an ideal device to use as an imaging platform for

H.09	Digital tomosynthesis of the chest: serial radiographic response in patients with pulmonary tuberculosis

John Sabol, *United States of America; Hyesun Hwang, Myung Jin Chung, Won-Jung Koh, Kyeongman Jeon, Kyung Soo Lee, Department of Radiology and Center for Imaging Science, Samsung Medical Center, Sungkyunkwan University School of Medicine, Korea*

Purpose: Digital tomosynthesis (DTS) is a new x-ray imaging technique that enables the acquisition of tomographic images at the same dose level as chest x-ray (CXR). Despite limited accuracy, low cost, ubiquitous access and rapid results have made CXR the mainstay for the detection of pulmonary tuberculosis (TB). Research has shown that DTS provides superior sensitivity over CXR for the TB detection. This research quantifies the ability of DTS to predict outcomes of antibiotic therapy. This presentation will also cover the dose of DTS exams and possible solutions to enable DTS access to the entire global public health community. Methods: Four chest radiologists retrospectively reviewed the serial DTS images of 110 patients with DSTB (n=82) and MDRTB (n=28). DTS images at presentation were examined for the presence of lung abnormalities including bronchiolitis, airspace consolidation, nodules, bronchiectasis, atelectasis or volume loss, and cavities. Serial DTS's were examined for change in the size of cavities and overall assessment of improvement or aggravation at intervals of 2 and 6 months after initiation of treatment. Overall extent of disease was scored using semi-quantitative estimation on a percentage scale. "Improvement" was defined as a decrease of 5% or more from initial extent. Results: Average DTS dose was 0.06 mSv. Using WHO guidelines, final outcomes were judged as treatment success in 104/110 patients, but as failure in 6 patients. In the two month follow up, sputum exams were negative in 72 patients in success group and 2 patients in fail group (p=0.04, Chi test). DTS showed improvement in 22 patients in success group but no patients in fail group (p=0.18). In the six month follow up, DTS showed improvement in fourty patients in success group and three patients in fail group (p=0.11).

Conclusions: Two months after initiation of antibiotic therapy, low-dose DTS imaging can help predict treatment success.

H.10	The design of a traditional adult male circumcision device

Amir Sabet Sarvestani, Kathleen H Sienko, *University of Michigan, United States of America*

HIV/AIDS is responsible for more than 25 million deaths in the last three decades. Clinical adult male circumcision (AMC) has been identified as the first and thus far only proven efficacious intervention for the prevention of sexually transmitted HIV. In sub-Saharan Africa, male circumcision occurs in both clinical and traditional settings. Traditional male circumcision (TMC) is considered as a rite of passage into manhood; however, it is associated with adverse events (up to 48%), including bleeding, infection, excessive pain, lacerations, erectile dysfunction, and death. To understand the Ugandan TMC practice and evaluate potential methods to reduce its associated adverse events our design team pursued ethnographic methodologies consisting of focus group discussions (FGDs) and interviews with stakeholders (clan leaders, traditional cutters, assistant cutters, and public health officials), observation, and contextual inquiry. Approximately 12 FGDs and 30 interviews, and observations of TMC reaffirmed the significance of the practice within Ugandan ethnic groups and confirmed the need for its safer outcomes. Our findings resulted in the design of a culturally acceptable, low-cost, single-use, and safe device that addresses the shortcomings (cultural inappropriateness, complexity, and high cost) of existing devices used in clinical AMC. The prototype was developed through a co-creative design process involving the continuous engagement of stakeholders. The preference for the selected design concept, which was selected from over 20 design concepts, was evaluated and confirmed through interviews with over 30 health policymakers and an additional 15 FGDs by local practitioners and cultural leaders in Uganda. This design case study demonstrates the value of a "process-focus" design approach that actively engages stakeholders to confirm the need and elicit continuous feedback on early prototypes. This can be an effective methodology in design for resource-limited settings, where financial, social, and cultural constraints impose challenges on designers that are unique and beyond traditional engineering design.

H.11	Non-invasive hemoglobin screening for diagnosis and monitoring of anemia

Laurent Choppe, *on behalf of Lior Mayaan, OrSense Ltd, Israel*

Anemia affects close to 2 billion people worldwide and is one of the leading public health issues in the developing world. It plays a major role as a confounding factor in the study of maternal and child health as well as in key diseases such as diabetes, HIV, malaria, and malnutrition. For example, 44% of maternal deaths are related to anemia and over 70% of HIV patients are anemic. Apart from the medical burden, anemia has a negative economic effect, estimated by 4-7% of GDP. The key to combating anemia is diagnosis and monitoring of hemoglobin. However, current hemoglobin tests involve invasive blood drawing, with the potential of infection risk to staff and patients, and pose a significant challenge in regions of the world that suffer from lack of running water, electricity, necessary hygienic infrastructure and skilled health providers. Thus, non-invasive hemoglobin screening was declared by the WHO as one of the key medical technologies to improve global health. OrSense has developed and markets the first non-invasive hemoglobin monitor, removing the need to draw blood and promising to dramatically improve anemia screening. The device is based on OrSense's proprietary Occlusion Spectroscopy technology, which uses an optical measurement combined with a ring-shaped pneumatic probe that fits on the finger. OrSense's non-invasive solution is substantially safer – eliminating potential contamination and biohazard handling. It is accurate, fast and easy to operate, enabling non-professional staff to perform accurate diagnosis. The elimination of biochemical processing allows mobile operation in rural locations and ensures lower costs. OrSense's system was adopted by blood banks, hospitals, public health and homecare programs in over 55 countries. To date, it has delivered over 10 million non-invasive tests and was used on more than 8,000

H.12	Design of mobile wireless sensors in amputee screening via cellular network
	Maria Regina Justina Esguerra Estuar, Nadia Leetian, *Ateneo de Manila University, Philippines; Josephine R. Bundoc, Physicians for Peace, Philippines* Amputee Screening via Cellular Network (ASCENT) is a mobile phone application that was developed for remote patient screening of persons with disabilities for more efficient service in providing free prosthesis to patients. However, there is a need to conduct remote monitoring in usage of prosthesis to determine compliance and correctness in gait patterns. We extend ASCENT to become a mobile wireless sensor that remotely records motion patterns of patients. We also designed a web based application that receives and displays motion patterns for visual monitoring and alerts. In this presentation, we discuss the design and development of a low cost solution in patient screening and monitoring using mobile phones.
H.13	Affordable Multisensor Perinatal Monitoring Concept - The importance of signal quality indices for successful mHealth implementation
	Lisa Stroux, Gari Clifford, *University of Oxford, United Kingdom* mHealth continues to receive increasing interest as a potential solution to pressing health needs, particularly in low- and middle-income countries (LMICs). The disparity in health outcomes between high-income countries and LMICs can be to some extent attributed to a chronic lack of trained healthcare professionals, poor infrastructure, the consequent difficulty in physically accessing healthcare, and the relative cost of healthcare delivery. In comparison, the so-called 'digital divide' has by now almost vanished. Mobile-phone penetration has reached 89% in LMICs, which motivates the use of mobile devices to address some of the challenges faced in under-served regions. The key drivers of mHealth are the growing wireless networks, handsets that are becoming progressively sophisticated yet affordable and their increased computational power, which allows recording and processing of physiological signals in real time. A key consideration for successful implementation of mHealth technology should be the unusual circumstances that arise when making mHealth technologies available to users with limited prior experience in handling those devices. This is particularly true for vital signs monitoring. Ensuring the quality of data, which forms the basis for analysis and diagnosis, is a primary concern and best controlled at point of data collection. It is therefore critical to provide the healthcare worker with feedback on the usability of the data captured to allow to recapture data if needed and to interpret a device's output in context of the quality of underlying data. The above approach is illustrated with the example of an on-going mHealth project addressing the high prevalence of perinatal mortality in LMICs. The device combines a low-cost ($20) ultrasound sensor with a smartphone for affordable and accessible fetal heart rhythm assessment. A signal quality algorithm is presented which can distinguish between signals, which are clinically useful, and those, which are not, and can inform the user accordingly.
H.16	German healthcare stakeholders perspectives regarding the value of a diagnostic device for heart failure: First results of a multi-criteria decision analysis (MCDA)
	Philip Wahlster, *University of Erlangen-Nuremberg, Germany; Mireille Goetghebeur, Department of Health Administration, University of Montreal, Canada; Sandra Schaller, Christine Kriza, Charlotte Niederländer, Peter Kolominsky-Rabas, Interdisciplinary Centre for Health Technology Assessment and Public Health, University of Erlangen-Nuremberg, National Cluster of Excellence Medical Technologies, Medical Valley EMN, Germany* Background: Health policy decision-making is based on heterogeneous opinions and criteria of participating stakeholders which are not systematically considered in current health policy. MCDA offers a solution to systematize such process and take different stakeholders' perspectives into account. Methods: An online survey was conducted by adapting a MCDA framework (EVIDEM V2.2) to explore perspectives of stakeholders and to assess the value of a pulmonary heart sensor in the German setting. One hundred German stakeholders were contacted. Participants were first asked to provide relative weight for each criterion on a scale of 1 to 5 independently of the healthcare intervention. Second, based on synthesized data available, participants scored the performance of a pulmonary heart sensor for heart failure. Finally, the MCDA value of this device was calculated by combining normalized weights and scores. Results: 53 participants completed the survey (53% respondent rate) including 7 healthcare professionals, 8 health policy makers, 10 from industry, 11 patients/citizens and 16 researchers. Most important criteria were Improvement of efficacy/effectiveness (mean 4.5, SD: 0.6), Improvement in patient reported outcomes (4.3 SD:0.7) and Disease severity (4.2 SD:0.8). The major contributors regarding the assessment of the heart sensor were the Size of the affected population (2.6 of 3 SD: 0,9), the Severity of disease (2.3 of 3, SD: 0.9) and the Limitations of comparative interventions (2.0 of 3 SD: 1,1). Conclusions: Most important criteria identified by eliciting weights in this study are currently considered in the German reimbursement process. However, current health policy does not sufficiently take severity of disease into account. In terms of the assessment of the device, the results highlight that a lack of appropriate evidence for most criteria is correlated to a low ranking of the intervention. Overall, MCDA addresses the need for explicit statements about the importance of decision criteria and value measurement.
H.19	Maker for MNCH: A model for locally made medical devices in Kenya
	Edwin Mbugua Maina, *Concern Worldwide, Kenya; John Odero Ong'Ech, Kenyatta National Hospital, Kenya; Kamau Gachigi, University Of Nairobi, Kenya; Natasha Kanagat, John Snow Inc, Center For Health Information, United States of America* Background: An assessment of health facilities in Kenya indicated that none of 40 facilities reviewed in Nairobi had all essential equipment available. Specifically, equipment and supplies considered essential for routine & advanced neonatal and maternal care lacked. This is often due to high procurement or replacement costs, supply chain problems and designs that are not tailored to meet local needs. Purpose: "Maker" harnesses the creativity of the Global Maker movement to equip MNCH practitioners with essential low-cost, high-quality, locally designed and produced MNCH equipment that save lives through a 'Maker hub' linking Makers and MNCH practitioners. Specifically, it seeks to achieve improved efficiency of sourcing MNCH-related equipment and parts; increased provision and quality of services; and demonstrated viability of local Maker networks to meet some of equipment needs of health facilities. Procedures: Using a 2-phase study design, Maker hypothesizes that the creation of a local 'Maker Hub' will result in the local production of essential MNCH equipment which will (in a modelled projection) fill gaps in supply, increase efficiency in the supply chain, and reduce the cost of procuring equipment. Phase one will involve assessing MNCH equipment availability and supply chain bottlenecks through a needs assessment; and short-listing and prototyping medical equipment for KNH. The second phase will involve clinical testing of MNCH equipment prototypes; and developing a business model for production and distribution. Conclusion: By engaging Makers, innovators, designers and MNCH practitioners through the Maker Hub, the project can develop a model for producing cost-effective and locally produced equipment to fill gaps in service provision. Additionally, each piece of equipment will potentially generate a business case and model for a social enterprise to be developed and scaled for further impact and sustainability. Increased availability of MNCH equipment will lead to an increase in the availability of life-saving MNCH procedures.

H.20	Assistive device to facilitate NG tube insertion
	Agyeya Dwivedi, *Stanford India Biodesign, India; Himanshu Gupta, Medha Tyagi, Neha Shetty, All India Institute of Medical Sciences, India* An accurate way of inserting nasogastric tube in neurological dysphagic patients Abstract: Although nasogastric tube (NGT) is a simple procedure, the blind placement of nasogastric feeding tubes is not without risks. It is estimated that more than 1.2 million small bore feeding tubes are used each year in the United States alone. Evidence accumulated over more than 25 years documents that between 1–2 percent of small bore feeding tubes that are placed blindly at the bedside enter the airway undetected, and a proportion of these misplacements result in pulmonary injury. Although the overall percentage of injury and death from blind feeding tube placement is relatively low, the large number of feeding tube placements results in unacceptable numbers of unnecessary harm to patients. Our product is a device based solution for above mentioned problem. The present invention is a low cost disposable assistive device which is used facilitates the insertion of NG tube into the esophagus and thus preventing it from entering into trachea. This is supposed to provide 19% more accuracy than existing solutions at same the price. The present invention is a handheld device designed in such a way that it is used to be inserted through the mouth of patient so that its one end get placed in Nasopharynx which is designed in such a way that when NG tube pass through it get direct the tube towards the posterior wall of pharynx. The basic look of our device is: • Like a scoop with extended handle • Top of the scoop has opening big enough to receive the NG tube coming nasal cavity • Lower opening is in a slant form • The anterior side of the scoop has a posterior curvature to direct the tube towards posterior wall of pharynx.
H.24	Low cost near infrared measurement of subcutaneous fat for newborn malnutrition
	Alistair Mcewan, *The University of Sydney, Australia; C Rosiak, P Jones, F Mustafa, S Bian, School of Electrical and Information Engineering, The University of Sydney, Australia; G Garguilo, Bioelectronics Neuroscience Lab, The University of Western Sydney, Australia; H Jeffery, School of Public Health, The University of Sydney, Australia* Low fat composition in newborns exposes them to an immediate risk of increased mortality and morbidity, and to an increased risk of developmental challenges and diseases later in life. Information about nutritional and dietary status of newborns can be accessed by measuring the amount of fat composition in the body. The functions of subcutaneous fat involve energy storage, thermo-insulation and a physical buffer. The examples of current technologies for newborn body fat monitoring are a device based on air displacement plethesmography (PeaPod), dual-energy X-ray, or underwater weighting. However these are bulky, expensive, immobile, and require technical expertise. Skin fold thickness would be ideal, however it presents operator variability even with extensive training. We propose measurement of in-vitro subcutaneous fat by diffuse reflectance measurement system. A low cost sensor, suitable for mass use in the developing world was developed. It consists of two LEDs (940nm and 1050nm) and a photodetector. These were chosen to be sensitive to fat at its 930nm peak and water at 1000nm, to remove hydration bias. Results on a porcine tissue model demonstrate differentiation as low as 2mm fat which is a relevant screening thickness to indicate low percentage body fat. There was up to 3 times less variation in repeated measurements compared to skin fold thickness.
H.28	Brazilian industrial and innovation complex in health: Non-invasive intracranial pressure measurement methods
	S Mascarenhas, *G H F Vilela, B Cabella, A C Cardim, C Wang, L Gomiero, M Vicentini, University of São Paulo, Brazil; Y M Mascarenhas, P R Mascarenhas, Brazil; D Cardim, Federal University of São Carlos, Brazil; M R SIgnori, P H D Antonino, E J V Oliveira, C A G Gadelha, Ministry of Health Brazil* Intracranial pressure (ICP) is an important neurological parameter in animals and humans. ICP is a function of the relationship among three contents into the cranium (brain parenchyma, cerebrospinal fluid and blood) and the skull volume. Nowadays, all methods to monitor the ICP are invasive, and physicians need to make a hole in the skull and insert the sensor in the intracranial space, which can cause to the patient several problems like haemorrhage, swelling and infection. The ICP STUDY GROUP developed - with Pan America Health Organization (PAHO), São Paulo Research Foundation (FAPESP), Brazilian Ministry of Health and Brazilian Ministry of Science Technology and Innovation support - new methods to monitor intracranial pressure through detection of the skull bone deformation. Two different sensors are in tests with humans and animals and the results of comparison between new methods and the invasive sensor showed a good statistic correlation (Pearson Correlation of 0.95) encouraging our group to continue with the development. The minimally invasive sensor was the first sensor designed and the sensor is glued on the skull bone. The next step was the development of the non-invasive sensor in which the sensor is positioned on the scalp without surgical incision and trichotomy. The technology of these sensors was developed with the objective of decreasing the risks to the patient and makes the sensor less expensive. The cost of an actual (invasive) sensor is a problem to countries in Latin America and Africa, for instance, in Brazil the ICP monitoring is done only in medical schools and private hospitals. Thus, access to these important neurological parameters is strict, and the population ends up suffering from lack of medical assistance. The expected final result of this project is the use of this new equipment in the Brazilian health system, a program that achieves 100 million people.
H.29	Mobile-connected Doppler analyzer for fetal health evaluation in low-resource settings
	Jeremy Wallis, *Council for Scientific and Industrial Research, South Africa; Rita van Rooyen, mHealth Inc., United States of America; Josef Mufenda, Stellenbosch University, South Africa* Innovative technologies in prenatal healthcare are needed to improve outcomes for the most vulnerable members of society – mothers and their babies. We identified the need for a solution for rapid and accurate risk assessment, referral, and management advice for intrauterine growth restriction (IUGR) by nurses and midwives in low-resource community settings. We believe that mobile and simple-to-use Doppler technology is able to harness existing resources to overcome the barriers in primary prenatal care in remote settings produced by lack of skills, distance to resources and availability of equipment. Our project thereby aims at providing easier access to better care with the view to improve pregnancy outcomes. Intrauterine Growth Restriction (IUGR) is responsible for a high number of perinatal morbidity and mortality. Obstetrics practices around the world include a proven and effective Doppler intervention to screen for placental incompetence and to address the conditions associated with IUGR. The prediction of adverse maternal outcomes in IUGR fetuses is based on symptoms and clinical signs including a small symphysis-fundal (SF) growth and a high resistance index in the blood velocity flow of the umbilical artery measured by Doppler technology. The current situation in most prenatal healthcare systems requires referral of any patient with poor SF growth to a higher level of care for a Doppler intervention in order to establish whether the fetus is at risk or just constitutionally small. Our technological solution integrates two separate previously successful innovations: The Doppler ultrasound and mobile telephony for a fully vertically integrated solution into the existing structure of any tiered healthcare system. We are currently working directly with nurses and midwives in Africa to study the socioeconomic impact and clinical significance of this mobile application, and to generate evidence-based information to determine how best to use existing scarce resources and uptake at the community level.

H.30	Postpartum uterus model
	Ingrid Lærdal, Ida Neuman, *Norway* The Postpartum Uterus Trainer is designed to be a highly affordable, portable and realistic training tool. It will help improve the capacity, competence and confidence of frontline health workers in providing postpartum care. The model is particularly helpful for training insertion of IUD and uterine balloon tamponade in the postpartum period.
H.31A	Innovative health technologies: Infant radiant warmer for neonatal thermoregulation
	Ashish Gupta, *India* Two of our submissions have been selected for the 2013 Compendium of Innovative health technologies: 1. LED Phototherapy for neonatal jaundice and 2. Infant radiant warmer. Both of these devices showcase innovation in healthcare technologies for neonatal care that enable access to therapy in low resource settings. The posters will highlight the current problem with neonatal jaundice & hypothermia, how it relates to MDG4, why current technology solutions current in the marketplace are inadequate to solve the problem in low resource settings, and why our technologies help address this problem successfully.
H.31	Innovative health technologies: Infant LED phototherapy for neonatal jaundice
	Ashish Gupta, *India*
H.32	Improving access for maternal and infant health through the use of compact portable ultrasound
	Gisela Abbam, *United Kingdom; Janeen Uzzell, Africa* Maternal wellbeing is of significant importance globally. Neonates whose mothers die during childbirth are more likely to die in their first year. The World Bank estimates that 74% of maternal deaths could be averted if all women had access to interventions that address complications of pregnancy and childbirth, especially emergency obstetric care. Portable ultrasound devices, combined with proper skills, knowledge, and quality-assurance, have the potential to change this scenario – provided they are acceptable, feasible, cost-effective, and scalable. They can contribute towards efforts to reduce maternal mortality and newborn deaths, and hasten the attainment of MDGs 4 and 5. Portable ultrasound can help healthcare workers to supply health care in low-resource settings, addressing delays in seeking care, delays in reaching care, and delays in care delivery. The limited availability of physicians in developing countries shifts the focus of healthcare delivery to the nurses and clinical officers who work with the physicians. These end-users can be licensed to deliver ultrasound scans. However, lack of resources affects the ability to support rural settings, where over 80% of women continue to give birth in unassisted environments. Providing portable, intuitive ultrasound technology has an immediate impact on care delivery, thus reducing maternal and neonatal mortality. Furthermore, it can help with the identification of high risk pregnancies that can be referred to appropriate health centres where better care can be provided by skilled birth. Therefore taking technology to the most remote corners of the world via handheld ultrasound coupled with purpose built solar chargers can help improve health outcomes especially for mothers and babies. The initial focus of the use of the portable compact ultrasound was on OB scanning and its impact on MDGs 4 and 5. This has shown good acceptance among communities in Bangladesh, Indonesia and Tanzania.
H.33	Tissue generator based on combined physical factors: Clinical effectiveness study in painful shoulder
	Maria Teresa Arista Rivera, *Hospital Nacional Dos de Mayo, Peru; L. Vilcahuamán, Pontifical Catholic University of Peru* Developed a prototype of medical device for combined electro-physical therapy and it was applied to a clinical case. Painful shoulder PS is a common condition that involves the rehabilitation field for its significance in the functionality of the people. This study was conducted at the “Dos de Mayo” National Hospital in Lima Peru. It was included PS traumatic and rheumatic with clinical or ultrasound diagnostic of biceps tendinitis, rotator cuff tendinitis and supraspinatus tendinitis. The clinical trial was conducted from September 2010 to September 2012. The target population consisted of 80 patients between 30 and 50 years who have applied before and after Scale Evolution of Global Function of UCLA. We evaluated the ability to: activities of daily living (ADL), work at home, sports and performing the current job. This population was selected for four types of treatment for every 20 persons which included the use of electro-physical agents. In group A: Ultrasound + TENS, group B: Laser + TENS, group C: Ultrasound + Laser, group D: magnetic fields + LED. The results demonstrated in the subjective rating scale that 90% of patients in group D were greatly improved by the end of treatment. According to the UCLA scale was reached full less pain and complete independence in ADL, and 85% improved amplitude joint range and muscle strength. We conclude that the Tissue Regenerator prototype based on combined physical factors is a viable option for physical therapy in developing countries and requires further study for application in other clinical cases.
H.35	Technological innovation in the diagnosis of enteroparasitosis
	Jose Carlos Lapenna, *Brazil* Parasitological infestations are the most common health problem that affects billions of people. To properly diagnosis the problem and treat the disease with the correct drug, it is a real issue. We developed a test that can be performed in any environment, without equipment, chemicals, water or electricity, and with no risk for the technician and for the ecosystem. The product is: Affordable, Accessible, Appropriate and is Available, for low and medium income countries.
H.36	The MRI cleaner
	Guillaume Metenier, Pascal Challande, Maria Vargas, *Hôpitaux universitaires de Genève (HUG), Switzerland* My Innovation: a simple solution to clean the interior of the shuttle of MRI. It is not-magnetic, it looks like a brush but this solution is very efficient : you can clean the MRI in 20 seconds. The extremity is flexible, which is why we can clean the shuttle
H.38	The Polypropylene Technology: An appropriate response to enable access to mobility devices
	Olivier Chappuis, *Switzerland*
H.39	Oxygen concentrator-driven baby bubble CPAP
	Robert Neighbour, *United Kingdom*
H.40	GNU Health: interfacing and interoperability
	Luis Falcon, *GNU Solidario, Spain*
H.41	A Universal Anaesthesia Machine: General anaesthesia for austere environments
	Paul Fenton, *United States of America*
H.43	Modulated Electro-Hyperthermia: Improving cancer treatments in low resource settings
	Carrie A Strauss, *South Africa*

H.50	Interoperability maturity roadmap for medical devices

Fred Hosea, *Kaiser Permanente*

Innovation in the healthcare domain is occurring at a pace and degree of complexity that is increasingly problematic to manage at organizational, enterprise, or national levels. As more medical devices become networked and extended into homes, rural and community settings, they need to behave as smart technological partners in complex IT and business environments that are very different from the "stand-alone" environments that medical devices have traditionally been designed for. This presents significant design challenges for device manufacturers and lifecycle management challenges for end users, requiring a fundamentally more consultative and targeted approach to medical device lifecycles and business models. This workshop focuses on conventional assumptions about business and medical device innovation that warrant fundamental re-examination under current global circumstances of economic and organizational austerity that severely constrain the design, marketability and adoption of medical devices across high, medium, and low-resource environments. "Purposive Innovation" is proposed as an innovation model that will leverage medical technology innovations more effectively to achieve a higher adoption rate of appropriate and interoperable technologies with less wastage of resources, less planned obsolescence, more universal coverage, and a more rational staging of medical infrastructures as economies and service models mature.

Key elements of the Purposive Innovation model are:

• Collaborative design forums to engage key stakeholders

•Nonprofit industry alliances to solve core technology challenges

•Stratified innovation goals to re-target manufacturing, facilities and workforces more equitably to low and medium resource markets •Strategic consultations with Ministries of Health to develop mid- to long-term infrastructure plans and capital budgets, within regional and multi-national planning and purchasing frameworks

•Academic partnerships to cultivate sustained, multi-disciplinary research and professional development programs aimed at integrated healthcare planning

•Regional/continental networks of innovation centers, to distribute the enormous workload of innovation design , assessment and planning

•Adoption of a common interoperability maturity roadmap

I. Medical imaging

I.02	Knowledge extraction of thoracic radiology reports using statistical natural language processing

Leandro Zerbinatti, Lincoln de Assis Moura Jr, *Universidade de São Paulo, Brazil*

This work promotes a study in health informatics technology which analyses reports of chest X-ray through statistical natural language processing methods for the purpose of supporting the interoperability between health systems. Two thousand radiology reports were used for the extraction of knowledge by identifying the words, n-grams and phrases of reports. Zipf's constant was studied and it was determined that few words make up the majority of the reports and that most of the words do not have statistical significance.The translation and comparison with exisiting standardized medical vocabulary with international terminology, called SNOMED-CT, was done based on the terms identified. The terms that had a complete and direct correlation with the translated terms were incorporated into the reference terms along with its class and the word identifier. Another 200 reports of chest x-rays were selected to perform the terms tagging experiment of with respect to the reference. The efficiency obtained, which is the percentage of labeling of the reports, was 45.55%. Subsequentely, articles, prepositions and pronouns were incorporated into the terms of reference under the linkage concept of class. It is important to note that these terms do not carry health knowledge to the text. Thus, the efficiency ratio was 73.23%, significantly increasing the efficiency obtained previously. The study was concluded with some forms of application of the reports tagged for system interoperability, using different ontologies, the HL7 CDA (Clinical Documents Architecture) and the archetypes at OpenEHR Foundation

I.03	Increasing access to diagnostic imaging in developing countries: The Asha Jyoti mobile clinic

Nandish Shah, Kathryn Everton, Anna Starikovsky Nordvig, Bianca Nguyen, Daniel Mollura, *RAD-AID International, United States of America; Niranjan Khandelwal, Postgraduate Institute of Medical Education and Research in Chandigarh, India*

Diagnostic imaging has changed the way physicians diagnose and manage patients. Unfortunately, as per the WHO, two-thirds of the world lack access to imaging technology. The WHO's "Baseline country survey on medical devices 2010" shows that disparity exists between developed and developing countries. However, disparity also exists within developing nations between the private and public sectors. The private sector has resources, but is inaccessible to many due to cost and urban location. For public-sector facilities in rural areas, the primary challenge lies in having the infrastructure to house and repair imaging technology. RAD-AID International has looked at the issue of access through its Radiology Readiness survey, which attempts to reveal the infrastructural, educational, financial, and clinical barriers surrounding access. In 2010, RAD-AID administered this survey in India, which led to the creation of the Asha Jyoti mobile clinic. This clinic focuses on a significant need found through the survey: women's health. Through a partnership with PGIMER in Chandigarh, India, the 2nd largest government hospital in India, Project HOPE, and Philips Healthcare, RAD-AID has deployed this mobile women's health clinic to provide for urban, rural, and slum residents of Chandigarh. It offers free screenings for disease: bone mineral density via x-ray imaging, cervical cancer via colposcopy, and breast cancer via mammography and ultrasound. In addition, through the PGI School of Public Health in Chandigarh, RAD-AID has conducted research and assessed the local impact of its work. This poster looks at the factors that define 'access' and details what diagnostic imaging technologies are essential in developing countries. It also discusses the Asha Jyoti clinic with an emphasis on data, impact, and future steps of the pilot phase of the mobile clinic in 2012. Through this, one can better understand the issue of access and the mechanisms of a possible solution.

I.04	The IOMP used equipment donation program
	Mohammed Kazmain Zaidi, *Idaho State University, United States of America* The objective of the Used Equipment Donation Program (UEDP) of the International Organization for Medical Physics (IOMP) is to help developing countries acquire used equipment in good working condition. The staff verifies as-far-as possible that it meets the need of the recipient country. The guidance in the 'WHO Guidelines for Healthcare Equipment Donations' (WHO 2000) are followed. The receiver of the donation pays for the handling and shipping. Some financial help is available in special cases. If the developing country needs help in installation or training of their personnel then assistance is provided at their expense. Donations are matched to requests from recipients in DC. Some of the UE donated in these years consists of Treatment Planning Systems, Imaging Systems – x-ray, scintillation camera and ultrasound machines, Dose calibrators, Beam analyzers, r-meters, RMI Scanners, Film scanners, TLD Readers, Densitometer, block cutters, electrometers, Radiotherapy attachments and an ambulance. The countries received equipment were Argentina, Bangladesh, Brazil, Egypt, India, Iran, Nigeria, Pakistan, Philippines and U.A.E. and the donors were Australia, Germany, Lebanon, United Kingdom and the United States of America. The program is a modest one and under review to ensure it meets current needs, regulations and guidance. Links, liaison and co-operation with other EDP of WHO are made to run a smooth program. The UEDP provides written instructions and copies of the technical manuals. Some physicists were generous enough to pay for shipping and handling cost. One group donated a simulator, ships it and had provided services in Bangladesh to install the machine and train the staff. So to say, the UEDP is a very good, well established program, and it had helped many DCs in past and will surely help many more in the time to come.
I.05	Acquisition of four digital imaging devices in Benin: Weaknesses of the project and a proposed solution
	Maliki Seidou Adjaratou, Pascal Soroheye, *Ministry of Health, Benin; Marcelin Oyedokoun, National University Hospital, Benin* Introduction: The Health Ministry in 2011 with three hospitals in Benin 04 digital X-ray apparatus: 02 for CNHU-HKM, the first reference center, and 02 for two Departmental Hospitals. This communication presents the problem of specifications development and actors training on this biomedical equipment acquisition project Objective: Assess the situation of four X-ray numerique machines Achievements: The observation of the case and conversation with users and equipment suppliers was the method used in this work. Results: The three recipient hospitals have agents for the equipment use (average four manipulators and two maintenance technicians for each center). Four days training at the manufacturer was given to two of four users and to only one technician. Five hours of training was given to technicians and users on site. The warranty period is one year, no maintenance contract is drawn up with the supplier. The level of maintenance is allowed 2. Frequent breakdowns are recorded throughout several months of downtime. Because some accessories are not included in the market contract, all devices function as analogical apparatus and it is not possible to perform image processing. The expected benefits of digital are not obtained (reduced time, consumables and dose, constants corrections, etc.) Conclusion: This project acquired by great expense and that is a first for the installation of numerique x-ray machines is a big loss for Benin. The key accessories absence of to accompany the equipment, insufficient actors training and the short warranty period didn't achieve the expected benefits of digital. This shows the weakness of medical devices acquisition and tracking policy in Benin. Outlook: It is urgent for Benin to review the policy of acquiring heavy biomedical equipment to optimize their use
I.06	Medical devices for screening and diagnosis
	Tekin Kaya, Isbara Alp Sezen, Hüseyin Altug, Osman Nacar, Ismet Köksal, Ali Sait Septioglu, *Turkish Medicine and Medical Devices Agency, Turkey* Medical equipment used in screening tests usually differ from equipment used in diagnostic tests as screening tests are used to indicate the likely presence or absence of a disease or condition in people not presenting symptoms; while diagnostic medical equipment is used to make quantitative physiological measurements to confirm and determine the progress of a suspected disease or condition. Medical screening equipment must be capable of fast processing of many cases, but may not need to be as precise as diagnostic equipment. Common screening where medical devices are used-Breast Cancer Screening: There are several approaches on this including molecular breast imaging, ultrasonography and magnetic resonance imaging. Molecular breast imaging uses a radioactive tracer that "lights up" any areas of cancer inside the breast. Medical ultrasonography is a diagnostic aid to mammography. Magnetic resonance imaging has been shown to detect cancers not visible on mammograms. - Fetal screening: Ultrasound scanning is used to detect down syndrome. Also electric fetal monitors are used to monitor fetal wellbeing. - Diabetic retinopathy: Fungus camera is used to detect this complication. -Dental caries: Dental radiographs are used to detect dental caries. -Colorectral cancer: Colonoscopy techniques are employed.
	J. Policies for medical devices
J.01	Brazilian industrial and innovation complex in health: Product development partnerships (PDP) to guarantee access to health technologies in Brazil
	Valeria Monteiro do Nascimento, Paulo Henrique Dantas Antonino, Eduardo Jorge Valadares Oliveira, Carlos Augusto Grabois Gadelha, *Ministry of Health, Brazil* In Brazil, the law ensures universal access and the integrality to health care what is a continuous challenged, as the country is the unique Member and Associate at World Health Organization to offer free national universal health system to over 190 million people. The Health Industrial Complex (HIC) aims to boost the domestic pharmaceutical, biotechnology and medical device industries to reduce the dependence of Brazil in relation to these products. Product Development Partnerships (PDPs) with Brazilian public and private companies as the leading strategy to incentive, to qualify and to regulate medical device sector. The PDPs provides an annual economy about US$1.5 billion to Brazilian Government; medical device is US$50 million. PDP started since 2009 with pharmaceutical area and tend to stabilized. Now the efforts will be in medical devices. Nowadays were established four medical devices PDP's: Intrauterine Device (IUD), Diagnostic Kit, Hearing Aid and Coils. The first one is IUD, the estimated economy is US$6 million, with the perspective of access grown providing a more women will be attended. Diagnostic Kit is a product including chips to detect multiple diseases; the expected economy is US$88 million. Hearing Aid devices take place in the program Health of People with Deficiency, and the economy estimate is US$29 million. The coils are critical product in neurology, as in 2011 Brazil had watchful of shortage of this product, a PDP was establish to ensure national technology and the supply. The expected economy is US$3,5 million PDPs provide many advantages to HIC, capacity building and incorporation of technology to public institutions; add value to domestic production; save costs; grown the access; ensure the supply to health programs; promote price regulation and avoid shortages and stock outs.

J.02	Brazilian industrial and innovation complex in health: Access to health technology, offsets, procurement and delivery in radiotherapy
	Silvia do Amaral Pereira, Paulo Henrique Dantas Antonino, Eduardo Jorge Valadares Oliveira, Carlos Augusto Grabois Gadelha, *Ministry of Health, Brazil* The Federal Government, through the Ministry of Health, aiming to expand the radiotherapy services on the Unified Health System (SUS), introduced the Radiotherapy Expanding Plan. The growth of services, will happen in 80 hospitals distributed in 58 cities and 20 states, representing an expansion of access to 32%, from 149,000 to 197,000 patients cared for years in the SUS. The initiative foresees the acquirement of 80 linear accelerators, high-tech equipment used in radiotherapy, considered nowadays as the biggest public acquisition in the global market of this equipment's, providing the utilisation of purchasing power to establish the Technology Transfer Agreement with the sector producer. For this purpose, will be invested just over US$ 250 million, of which about US$ 125 million will be for purchase of the 80 linear accelerators, included accessories and others medical devices. The modalities of this acquisition contemplate national policy guidelines, specially the Industrial Policy and the Innovation, Technology and Science Policy, once they articulate the development of the Health's Industrial Economic Complex, considered as strategic for the country.The equipment producer shall provide the Technological Compensation for Brazil by implementing a national production line of linear accelerators; qualifying national suppliers of parts, components, accessories and software; developing software and qualifying professionals.The incorporation of this technology and the stimulus of local production reflect on the reduction in both SUS's technological vulnerability and public resources for equipment maintenance, triggered by the dependence on importing their components and accessories. In conclusion, these actions are aligned with the strategic axes of industrial development and with the national interests formulated in its politics, valuing and articulating the regional development, competitiveness as well as a sustainable production.
J.03	Brazilian industrial and innovation complex in health: Strengthening the local industry using the government purchasing power
	Marcos Salomão, Paulo Henrique Dantas Antonino, Eduardo Jorge Valadares Oliveira, Carlos Augusto Grabois Gadelha, *Ministry of Health, Brazil* The Federal Government has adopted several measures to stimulate the internal domestic market, through tax exemption and public orders.Thus, the new wording given to the paragraphs 5, 6 and 9 of the Law 8666/93 established a new margin of preference.The Decree 7767/12 has regulated the margin of preference on Medical Devices according to the technological intensity. The high-intensity ones may win bids with prices up to 25% higher. The main objective is to stimulate the local production of those products which are benefited by the margin of preference, stimulating the domestic industries to internalise technologies.The use of the governmental purchasing power as an inductor tool of development, for instance of similar policies pursued by other countries such as United States and China, presents itself as strategic to encourage the technological autonomy of the Unified Health System (SUS) as well as to reduce the expressive trade deficit of the Health's Industrial Complex. The Brazilian government take into account the attendance of the Brazilian technical standards, job creation, effects on the tax collection, development and technological innovation and product's additional costs.The aim of this work is to analyse the impact of governmental policies in the public procurement realised by the Ministry of Health.The methodology is the exploratory research, bearing in mind the problem's characteristics and nature. The main sources of research are secondary data and information such as reports, dissertations, thesis, articles; and primary through research in the information system of government procurement.The analysis between, June 2012 to September 2013, has shown that, in the Ministry of Health, margin of preference were applied in 413 acquisitions, which corresponds to 29 million unities and foreign currency saving of US$ 104.5 million.
J.04	Clinical engineering experience in the National Cancer Institute
	Sandra Luz Rocha Nava, Abelardo Meneses Garcia, Angel Herrera Gomez, Patricia Volkow Fernandez, Yolanda Villaseñor Navarro, *Instituto Nacional De Cancerologia, Mexico* The National Cancer Institute is the governing body of cancer in Mexico, sets policy for care and treatment of cancer patients. It has contributed in many ways to establish care programs nationally and catastrophic program (Seguro Popular) for some neoplasms, mainly cervical, breast, testis, bone marrow transplant and is currently managing the incorporation of ovarian cancer. It has also generated and is coordinator of the network of 27 state policies and agreements establishing oncology for diagnosis, treatment, equipment procurement, maintenance cost criteria, etc. Similarly training drives specialist breast radiologists to increase the number of medical specialists across the country, also support remote reading mammography studies using telemedicine tools. Currently on Building a New Tower will enable us to increase the range of patients, mainly in surgery, hospitalization, medical and molecular imaging equipment incorporating PEM, PET and PET-MRI. Similarly looking resource for incorporating a cyclotron for production of drugs for the generation of studies, such as for research on new molecules. Biomedical Engineering and Clinical Engineering mainly participates fully in these programs, setting criteria for procurement of medical equipment and maintenance services, participation in project design and the new unit, as well as verification of construction, facilities and security. Generating risk mitigation plans for the movement or removal of existing areas, controlling the removal, relocation and reinstallation of imaging equipment. Establishing criteria and managing the technology for the project telemammography, among other activities.
J.05	Brazilian industrial complex and innovation in health: PAHO/WHO technical cooperation with the Ministry of Health of Brazil in the context of the WHA 60.29 resolution
	Flavia Poppe, Christophe Rerat, *Pan American Health Organization, Brazil; Paulo Henrique Dantas Antonino, Eduardo Jorge Valadares Oliveira, Carlos Augusto Grabois Gadelha, Ministry of Health, Brazil* The Brazilian government has put efforts in Health and Industrial Policies in order to increase overall access to health promote regional development and decrease the trade deficit in the Heath Industrial Complex sector. In order for that to be achieved, policies and instruments designed to promote technological innovation and competitiveness of the national medical devices industry has been put into effect. The Basic Production Process (BPP) in one of such instruments. The BPP, as defined by Law nº 8.387 of December 30, 1991, consists of describing the minimum necessary steps in fabrication so that a product can be considered Brazilian and was introduced by means. Interministerial Ordinances, signed by the Ministers of Development, Industry and Foreign Commerce (MDIC) and Science, Technology and Innovation (MCTI). The benefits granted by the Federal Government are fiscal benefits designed to the Free Economic Zone of Manaus and advantages found in the Law of Informatics, such as margin of preferences, and inclusion in the Unified Health System's (UHS) list of strategic products. Since the beginning of 2013, in the context of the Health Industrial Complex, the Health Ministry has been supporting the BPP, aiming at the development of resources of strategic relevance to the Unified Health System, in order to learn and incorporate technologies crucial to the manufacturing of medical devices. The first BPP aligned to this philosophy for medical devices was put into practice in 2013, and defined the Basic Production Process for Ultrasound with Spectral Doppler Analysis. Other BPP currently in phase of public consultation are: Digital Mobile X-Ray with "C" arc, Fixed X-Ray Machine with flat-panel digital detector image acquisition, and Positron Emission Computerized Tomography device

L. World Health Organization Medical Device Projects	
L.01	Compendium of innovative health technologies for low-resource settings
	Jennifer Barragan, Heike Hufnagel, Adriana Velazquez Berumen, *World Health Organization, Switzerland*
L.02	Global medical device pricing survey
	Olumurejiwa Fatunde, Adriana Velazquez Berumen, *World Health Organization, Switzerland*
L.03	Global Atlas of Medical Devices 2013
	Ricardo X. Martinez, Adriana Velazquez Berumen, *World Health Organization, Switzerland*
L.04	MEDEVIS: WHO Medical Device Information System
	Heike Hufnagel, Yukiko Nakatani, Laura Alejandra Velez Ruiz-Gaitan, Adriana Velazquez Berumen, *World Health Organization, Switzerland; Mladen Poluta, University of Cape Town, South Africa; Hans-Peter Dauben, German Institute of Medical Documentation and Information, Germany*
L.05	H4 Interagency List of Medical Devices for Essential Interventions (ILMDEI) for Reproductive, Maternal, Newborn and Childhood Health (RMNCH)
	Laura Alejandra Velez Ruiz-Gaitan, Yukiko Nakatani, Adriana Velazquez Berumen, *World Health Organization, Switzerland*
L.06	Priority medical devices for Noncommunicable Diseases (NCDs) and Ageing Population
	Yukiko Nakatani, Adriana Velazquez Berumen, *World Health Organization, Switzerland*
L.07	National Regulatory Authority (NRA) assessment tool for medical devices
	Yukiko Nakatani, Adriana Velazquez Berumen, *World Health Organization, Switzerland*
L.08	WHO Global Biomedical Engineering Education and Professional Database
	Jennifer Barragan, Adriana Velazquez Berumen, *World Health Organization, Switzerland*
L.09	United Nations Commission on Life-Saving Commodities
	Yukiko Nakatani, Laura Alejandra Velez Ruiz-Gaitan, Jennifer Barragan, Adriana Velazquez Berumen, *World Health Organization, Switzerland*
L.10	WHO technical specifications for medical devices
	Adriana Velazquez Berumen, Laura Alejandra Velez Ruiz Gaitan, Yukiko Nakatani, *World Health Organization, Switzerland; Andrew Gammie, United Kingdom; Mladen Poluta, South Africa; Peng Si, China; Roberto Ayala, Mexico; Niranjan Khambete, India; James Abbas, United States of America; Tom Nakazaki, Japan; Nicolas Pallikarakis, Greece; Didier Vallens, France; Kamel Abdul Rahim, Jordan; Firas Mustafa Abu-Dalou, Jordan*

Appendix 7

List of participants for the Second WHO Global Forum on Medical Devices

This list is divided into the following categories: government, intergovernmental organizations, professional associations and non-governmental organizations (NGOs), academia health professionals and independent participants. The list of participants contains the information submitted and authorized by each participant; should there be any specific request or change, please send a message to medicaldevices@who.int.

GOVERNMENT

African Region

Benin

Ms. Adjaratou MALIKI SEIDOU
Ministry of Health
seidadj@yahoo.fr

Mr. Charles Pascal SOROHEYE
Ministry of Health
soroyep@yahoo.fr

Burkina Faso

Mr. Bandiba Isidore LANKOANDE
AGEMAB Ministere de la Sante

Dr. Zida OUAMBI EMMANUEL
ezida2002@yahoo.fr

Mr. Rimdella Dominique TASSEMBEDO
Agence de l'Équipement et de la Maintenance Biomédicale (AGEMAB)/Ministère de la Santé
t.rimdella@gmail.com

Burundi

Mr. Ir NIYONKURU DEO

Central Africa Republic

Dr. Timothee MOBIMA
Ministry of Health
Central African Republic

Comoros

Dr. Said Fazul AHAMADA
Ministry of Health
sfazul@yahoo.fr

Côte d'Ivoire

Mr. Yrié Denis TRA BI
Ministère de la Santé et de la Lutte Contre le SIDA
denis.trabi@yahoo.fr

Ethiopia

Mr. Mekonnen BELAYNEH

Gambia

Mr. Andrew DEMBA
National Public Health Laboratories/Ministry of Health and Social Welfare
anthems81@yahoo.com

Ghana

Dr. Nicholas ADJABU
Ghana Health Service
adjabu95@yahoo.com

Ms. Akua AMARTEY
Food And Drugs Authority
akuamart@yahoo.com

Mr. Emmanuel NKRUMAH
Food and Drugs Authority
emmlnkrumah@hotmail.com

Mr. Kofi OPOKU
Ghana Health Service
Ghana
kopoku@gmail.com

Ms. Mabel Yayra Mawuena SEGBAFAH
Ghana Health Service - Policy Planning Monitoring and Evaluation Division

Guinea-Bissau

Mr. Fodé Carambá SANHÁ
Ministry of Health
focasa60@gmail.com

Kenya

Mr. Philip Amoko ANYANGO
Ministry of Health
anyangopa@gmail.com

Ms. Salome Wangari MWAURA

Ms. Beth W.Wanjohi NJARAMBA
Ministry of Health
bethnjaramba@yahoo.com

Mauritius

Dr. Maryam Timol TIMOLL
Ministry of Health and Quality of Life
mtimol@mail.gov.mu

Nigeria

Dr. Charity ILONZE
chyplusiyke@yahoo.com

Senegal

Dr. Jerome CLOUZEAU
Ministère De La Sante Et De L'action Sociale
Sénégal
jerome.clouzeau@gmail.com

Ms. Awa Ndiaye DIOUF
Direction des Infrastructures des Equipements et de la Maintenance (Diem)/Ministère de La Sante et de l'Action Sociale
awandiayediouf@yahoo.fr

Sierra Leone

Mr. Alusine Bobson KABIA
Ministry of Health
alusinebk@yahoo.com

South Africa

Prof. Shabir BANOO
Medicines Control Council
shabir.banoo@righttocare.org

Dr. Johanna GOUWS
Medicines Control Council
gouwsj@health.gov.za

Tanzania, United Republic of

Ms. Agnes Sitta KIJO
Tanzania Food and Drugs Authority
agnes.kijo@tfda.or.tz

Mr. Valentino MVANGA
Ministry of Health and Social Welfare
vmvanga@yahoo.com

Ms. Severing SHIRIMA
Ministry of Health and Social Welfare
shirimask@yahoo.com

Togo

Mr. Komlan EDOH-KOSSI
Ministère de la Santé
kedohkos@yahoo.fr

Uganda

Mr. Sam Steve Balayo WANDA

Zambia

Dr. Emmanuel MAKASA
Permanent Mission of Zambia to the UN
emmanuel.makasa@fulbrightmail.org

Zimbabwe

Dr. Christopher TAPFUMANEYI
Ministry of Health and Child Care
tapfu0man@gmail.com

Region of the Americas

Argentina

Mr. German Jose GILES
Municipality of General
Pueyrredon
germangiles@gmail.com

Brazil

Mr. Ricardo ALCOFORADO MARANHÃO SÁ
Secretaria De Estado Da Saúde De Goiás
ricardo_amsa@yahoo.com.br

Mr. Paulo Henrique Dantas ANTONINO
Ministério da Saúde do Brasil
paulo.antonino@saude.gov.br

Mr. Marcio BORSIO

Mr. Murilo CONTÓ
Ministry of Health
murilo.conto@saude.gov.br

Mr. Eduardo COURA ASSIS
Ministry of Health
courassis@ig.com.br

Ms. Rafael GOMES FERNANDES
ANVISA-Agência Nacional de Vigilância Sanitária
(Brazilian Health Surveillance Agency)

Mr. Marco NASCIMENTO
Ministry of Health
marco.carvalho@saude.gov.br

Mr. Joselito PEDROSA
ANVISA-Agência Nacional de Vigilância Sanitária
(Brazilian Health Surveillance Agency)
joselito.pedrosa@anvisa.gov.br

Mr. Lucas Vinicius SVERSUT

Dr. Mery Wilma TERAN CARREON
Unidad de Medicamentos y Tecnología en Salud
wilteranc@yahoo.es

Colombia

Ms. Andrea Rocio GARCIA IBARRA
ingenierandrea@gmail.com

Ms. Marleny MONTENEGRO
Ministerio de Saludy Protección Social de
mmontenegro@minsalud.gov.co

Cuba

Ms. Dulce María MARTÍNEZ PEREIRA
Centro de Control Estatal de Equipos y
Dispositivos Médicos (CECMED)
dulce@cceem.sld.cu

Ecuador

Mr. Luis ESPINOSA SALAS
Mission of Ecuador
LGESPINOSA@YAHOO.COM

Ms. Maria Dolores Ximena PINTO SERRANO
Ministerio de Salud Pública
mariad.pinto@msp.gob.ec

Dr. Ricardo SILVA
Secretaria Nacional de Educación Superior,
Ciencia y Tecnología (Senescyt)
rjsilvab@gmail.com

El Salvador

Dr. Igor Fabricio CASTRO RAMIRIOS
Ministerio de Salud
El Salvador
igorramirios.md@hotmail.com

Haiti

Mr. Roland PALME

Mexico

Mr. Roberto AYALA
Centro Nacional de Excelencia Tecnológica en
Salud (CENETEC)
rap6701@gmail.com

Ms. Verónica GALLEGOS
Centro Nacional de Excelencia Tecnológica en Salud (CENETEC)
veronica.gallegos@salud.gob.mx

Suriname

Mr. Gordon VOIGT
Ministry of Health
gvoigt@azp.sr

Trinidad and Tobago

Ms. Anesa ALI-RODRIGUEZ

United States of America

Mr. Richard PADDOCK
International Trade Administration

Ms. Kimberly TRAUTMAN
US Food and Drug Administration Center for Devices and Radiological Health

Uruguay

Dr. Ana Maria PEREZ GALAN
Ministerio de Salud de Uruguay
aperez@msp.gub.uy

Eastern Mediterranean

Lebanon

Ms. Sizar AKOUM
Ministry of Public Health
sizarak@gmail.com

Libya

Mr. Ezzeddin .S.Z DURAR
Libyan Ministry of Health
dura@yaho.com

Dr. Reida ELOAKLEY

Saudi Arabia

Dr. Saleh AL TAYYAR
Saudi Food and Drug Authority
stayyar@sfda.gov.sa

Dr. Mazen HASSANAIN
Ministry of Health of the Kingdom of Saudi Arabia
mHassanain@moh.gov.sa

Mr. Abdullah THABIT
Saudi Food and Drug Authority

Syrian Arab Republic

Dr. Raef YASSIN

Ms. Khawla YOUSSEF

Yemen

Mr. Faisal MUJAMAL
MOPHP-Yemen
eng-alfaisal@hotmail.com

European Region

Belgium

Ms. Fabienne Marie VAN SLOTEN
Permanent Representation of Belgium to the UN in Geneva
fabienne_vansloten@hotmail.com

Bosnia and Herzegovina

Ms. Natasa GRUBISA
Agency for Medicinal Products and Medical Devices of Bosnia and Herzegovina
n.grubisa@almbih.gov.ba

Mr. Zoran JOSIPOVIC
Agency for Medicinal Products and Medical Devices of Bosnia and Herzegovina
opp@almbih.gov.ba

Ms. Tanja SAVANOVIC
Agency for Medicinal Products and Medical Devices of Bosnia and Herzegovina
t.savanovic@almbih.gov.ba

Estonia

Ms. Tairi VÄLINURM
Ministry of Social Affairs
tairi.valinurm@sm.ee

Finland

Mr. Heikki MATTLAR VALVIRA
National Supervisory Authority for Welfare and Health

Germany

Dr. Hans-Peter DAUBEN
DIMDI
dauben@dimdi.de

Ms. Ute WORRINGEN
German Federal Institute for Drugs and Medical Devices
ute.worringen@bfarm.de

Greece

Mr. Dimitrios KRANIAS
dkranias@gmail.com

Israel

Dr. Osnat LUXENBURG
Ministry of Health
osnat.luxenburg@moh.health.gov.il

Italy

Ms. Luciana BALLINI
Agenzia Sanitaria e Sociale Regionale
luballini@regione.emilia-romagna.it

Dr. Marina CERBO AGENAS
cerbo@agenas.it

Dr. Gaddo FLEGO

Kyrgyzstan

Ms. Ainura ABALIEVA
Department of Drug Provision and Medical Equipment under Ministry of Health
abalieva-a@yandex.ru

Lithuania

Ms. Kristina AURUŠKEVICIENE
Ministry of Health
kristina.auruskeviciene@sam.lt

Prof. Juozas GALDIKAS
State Health Care Accreditation Agency Under the Ministry of Health
juozas.galdikas@vaspvt.gov.lt

Moldova, Republic of

Mr. Alexandru COMAN
Medicine and Medical Devices Agency
alexandru.coman@amed.md

Ms. Ludmila TOPCHIN
Ministry of Health
ludmila.topchin@ms.gov.md

Montenegro, Republic of

Dr. Erna SEHOVIC
Agency for Medicines and Medical Devices
erna.sehovic@calims.me

Netherlands

Ms. Josephina HANSEN
Dutch Healthcare Inspectorate

Dr. Hugo Reinier HURTS
Dutch Ministry of Health, Welfare and Sport
hr.hurts@minvws.nl

Mr. Johannes VAN GINNEKEN
Ministry of Health, Welfare and Sport
j.v.ginneken@minvws.nl

Norway

Dr. Helene ARENTZ-HANSEN
Norwegian Knowledge Centre for the Health Services (NOKC)
helene.arentz-hansen@kunnskapssenteret.no

Ms. Jorunn AUSTAD
Norwegian Directorate of Health

Dr. Katrine B. FRØNSDAL
Norwegian Knowledge Centre for the Health Services (NOKC)

Dr. Brynjar FURE
Norwegian Knowledge Centre for the Health Services (NOKC)
brynjar.fure@kunnskapssenteret.no

Mr. Dimitrios GOUGLAS
Norwegian Institute of Public Health
Dimitrios.Gouglas@fhi.no

Dr. Oyvind MELIEN
Norwegian Directorate of Health
Oyvind.melien@helsedir.no

Dr. Ellen NILSEN
Norwegian Directorate of Health
Ellen.Nilsen@helsedir.no

Ms. Sari Susanna ORMSTAD
Norwegian Knowledge Centre for the Health Services (NOKC)
sor@nokc.no

Ms. Anna Maria Helene ÖRTHAGEN
Norwegian Directorate of Health

Poland

Ms Lida Esther HILDEBRANDT PINEDO
Headquarter of Medicines Inputs and Drugs (DIGEMID), Department of Health
lhildebrandt@digemid.minsa.gob.pe

Ms. Agnieszka WLODARCZYK
Agency for Health Technology Assessment in Poland (AHTAPol)
a.wlodarczyk@aotm.gov.pl

Dr. Matusewicz WOJCIECH
Agencja Oceny Technologii Medycznych
(HTA Poland)

Portugal

Ms. Emilia ALVES DA SILVA
INFARMED – National Authority of Medicines and Health Products, IP

Ms. Mariana MADUREIRA

Russian Federation

Ms. Elena ASTAPENKO
Federal Service on Surveillance in Healthcare (Roszdravnadzor)

Ms. Irina BORZIK
Federal Service on Surveillance in Healthcare (Roszdravnadzor)

Slovakia

Dr. Branislav JADUD
Ministry of Health of the Slovak Republic
branislav.jadud@health.gov.sk

Spain

Ms. Margarita MARTÍN LÓPEZ
Agencia Española de Medicamentos y Productos Sanitarios (AEMPS)
mmartinl@aemps.es

Dr Teresa MOLINA-LOPEZ
Andalusian Health Technology Assessment Agency

Mr. Santiago VELEZ CASTILLO
Agencia Española de Medicamentos y Productos Sanitarios (AEMPS)
svelez@aemps.es

Sweden

Ms. Emelie HEINTZ
Swedish Council on Health Technology Assessment
heintz@sbu.se

Switzerland

Mr. Charles RAZAFINDRAZAKA
tianabe@gmail.com

Turkey

Mr. Ali Riza DEMIRBAS

Ms. Serian DOMA
Turkish Medicine and Medical Devices Agency
serian.doma@titck.gov.tr

Mr. Tekin KAYA
Turkish Medicine and Medical Devices Agency

Ms. Funda Guler OZDILER COPUR
Medicine and Medical Devices Agency

Mr. Alper TEZCAN
alpertezcan@hotmail.com

Ms. Zehra YAMAN

Ukraine

Mr. Ivan BAVYKIN
State Administration of Ukraine on Medicinal Products
ivan@bavykin.com

Mr. Ivan VOLKOV
State Administration of Ukraine on Medicinal Products
ivancito911@gmail.com

United Kingdom

Ms. Eleanor BAHA
British Embassy
eleanor.baha@fco.gov.uk

Ms. Dagmar LUETTEL
NHS England
dagmar.luettel@nhs.net

Uzbekistan

Mr. Javokhir NURMETOV
Permanent Mission of the Republic of Uzbekistan to the UN Office and other International Organizations in Geneva
uzbekistan@bluewin.ch

South-East Asia Region

Bangladesh

Dr. Abu Saleh Mohammad NAZMUL HUQ
Ministry of Health and Family Welfare
drnazmulhuq@yahoo.com

India

Dr. Ravi Kant SHARMA
National Health System Resource Centre
adcrks@gmail.com

Dr. Jitendar SHARMA
National Health System Resource Centre
jitendra9000@gmail.com

Ms. Aditi SHARMA
Center for Disease Dynamics, Economics and Policy, Public Health Foundation of India

Maldives

Ms. Iruthisham ADAM
Permanent Mission of Maldives to the UN

Ms. Rishfa RASHEED
Permanent Mission of Maldives to the UN

Myanmar

Prof. Lin TUN TUN
Yangon General Hospital, Ministry of Health
lyntun@gmail.com

Nepal

Mr. Deepak Raj BHATTA
Department of Health Services, Teku, Kathmandu
deepakbhatta43@yahoo.com

Sri Lanka

Dr. Gamini GALAPPATTHY
The National Hospital of Sri Lanka

Thailand

Ms. Yuwadee PATANAWONG
Food and Drug Administration

Dr. Sripen TANTIVESS
Health Intervention and Technology Assessment Program (HITAP)
sripen.t@hitap.net

Western Pacific Region

Cambodia

Dr. Sivuthy CHEU
cheusivuthy@gmail.com

China

Dr. Yung Yan Terence CHEUNG
Department of Health
terence_cheung@dh.gov.hk

Korea, Republic of

Ms. Yoon Jung CHOI
Health Insurance Review and Assessment Service
yneschoi@hiramail.net

Ms. Gyung Sook ROH
Health Insurance Review and Assessment Service
roh8527@hiramail.net

Lao People's Democratic Republic

Mr. Thanom INSAL
Medical Products Supply Center, Ministry of Health
mpsc@laotel.com

Malaysia

Mr. Zamane ABDUL RAHMAN
Medical Device Authority
zamane@mdb.gov.my

Philippines

Dr. Rafael BUNDOC
University of the Philippines/Philippine General Hospital

Ms. Agnette PERALTA
Food and Drug Administration, Department of Health
apperalta2004@yahoo.com

Singapore

Dr. Huiling Debbie KO
Health Sciences Authority
debbie_ko@hsa.gov.sg

INTERGOVERNMENTAL ORGANIZATION

European Commission

Dr. Isabelle DEMADE
Belgium
isabelle.demade@ec.europa.eu

OECD

Ms. Xuedan YUAN
France

UNESCO Chair of Telemedicine

Mr. Krasimir FERRER
Spain

Prof. Olga FERRER-ROCA
Spain
catai@teide.net

UNICEF Supply Division

Dr. Nagwa Abdel Tawab HASANIN
Denmark
nhasanin@unicef.org

Dr. Helene MOLLER
Denmark
hmoller@unicef.org

Mr. Ludo SCHEERLINCK
Denmark
lscheerlinck@unicef.org

UNOPS

Dr. Valerio DI VIRGILIO
Panama
valeriod@unops.org

World Bank

Dr. Andreas SEITER
United States of America
aseiter@worldbank.org

African Development Bank

Dr. Feng ZHAO
Tunisia

WORLD HEALTH ORGANIZATION

African Region

Dr. Florentine Sylvie MBERYO YAAH
WHO Central African Republic
mberyosy@who.int

Dr. Regina MBINDYO
WHO Kenya
mbindyor@who.int

Dr. Mujinga Anastasie MULUMBA
WHO Democratic Republic of the Congo

Dr. Jean-Bosco NDIHOKUBWAYO
WHO Regional Office for Africa
Congo
ndihokubwayoj@who.int

Region of the Americas

Dr. Pablo JIMENEZ
PAHO/WHO
United States of America
jimenezp@paho.org

Mr. Alexandre LEMGRUBER
PAHO/WHO
United States of America
lemgruba@paho.org

Dr. Christophe RERAT
WHO Brazil
reratchr@paho.org

Eastern Mediterranean Region

Dr. Adham ISMAIL
WHO Regional Office for Eastern Mediterranean
Egypt
ismaila@who.int

Ms. Meriem MEDDEB
WHO Tunisia
meddebm@who.int

Dr. Safiullah NADEEB
WHO Afghanistan
nadeebs@afg.emro.who.int

Dr. Ramzi OUHICHI
WHO Tunisia
ouhichir@tun.emro.who.int

European Region

Ms. Hanne BAK PEDERSEN
WHO Regional Office for Europe
Denmark
hba@euro.who.int

South-East Asia Region

Dr. Sunil SENANAYAKE
WHO Regional Office for South-East Asia
India

Western Pacific Region

Dr. Karen NAHAPETYAN
WHO, Regional Office for the Western Pacific
Fiji
nahapetyank@wpro.who.int

WHO HEADQUARTERS

Director-General Office Cluster

Ms. Suruchi KUMAR
Intern

Ms. Anna-Maria PAGKALOU

General Management Cluster

Mr. P P CHOPRA
WHO Malaysia
choprap@who.int

Family, Women's and Children's Health Cluster

Dr. Elizabeth MASON
Director

Dr. Mario Philip FESTIN
Human Reproduction
festinma@who.int

Ms. Clare LOFTHOUSE
Adolescents and at-Risk Populations
lofthousec@who.int

Dr. Lisa THOMAS
Adolescents and at-Risk Populations
thomasl@who.int

Health Security and Environment Cluster

Ms. Elaine FLETCHER
fletchere@who.int

Dr. Maria Del Rosario PEREZ
Interventions for Healthy Environments
perezm@who.int

HIV/AIDS, TB and Neglected Tropical Diseases Cluster

Ms. Julia SAMUELSON
Key Populations and Innovative Prevention
samuelsonj@who.int

Noncommunicable Diseases and Mental Health Cluster (NMH)

Dr. Shanthi MENDIS
Coordinator

NMH/ Violence and Injury Prevention

Ms. Belen VALLADARES VAQUERO
Intern
valladaresb@who.int

Polio, Emergencies and Country Collaboration Cluster

Dr. Rudi CONINX
Policy, Practice and Evaluation
coninxr@who.int

Health Systems and Innovation Cluster (HIS)

Dr. Marie-Paule KIENY
Assistant Director General
Health Systems and Innovation

HIS/Health Policy, Development and Services

Dr. Meena CHERIAN

Ms. Katharina HAGENKAMP
hagenkampk@who.int

Mr. Jackey CHENG
Intern
chengja@who.int

HIS/Service Delivery and Strengthening

Dr. Edward KELLEY
Coordinator/Acting Director

Prof. Benedetta ALLEGRANZI
Patient Safety Programme
allegranzib@who.int

HIS/Essential Medicines and Health Products (EMP)

Mr. Cornelis DE JONCHEERE
Director
Essential Medicines and Health Products

EMP/Public Health, Innovation and Intellectual Property

Dr. Francis MOUSSY
Technology Transfer Initiative
moussyf@who.int

EMP/Quality Assurance and Safety: Medicines

Ms. Theresa Sophia BURKARD
Intern

Mr. Frederik HAGELSTEIN

EMP/Regulation of Medicines and other Health Technologies Unit (RHT)

Ms. Helena ARDURA
ardurah@who.int

Mr.Lahouari BELGHARBI

Ms. Robyn MEURANT
meurantr@who.int

Ms. Seun OMOBO
nues18sp@yahoo.com

Dr. Alain PRAT

Ms. Irena PRAT
prati@who.int

EMP/Policy, Access and Use Unit (PAU)

Dr. Gilles FORTE
Coordinator
Policy, Access and Use
forteg@who.int

EMP/PAU/Medical devices

Ms. Jennifer BARRAGAN
Technical Officer
barraganj@who.int

Ms. Susanna CHEN
Intern
chensu@who.int

Ms. Suruchi KUMAR
Intern

Ms. Olumurejiwa FATUNDE
Intern
ofatunde@post.harvard.edu

Ms. Keiko FUKUTA
Intern
isojirou@aol.com

Dr. Heike HUFNAGEL
Consultant
hufnagelh@who.int

Ms. Panita LOOAREESUWAN
Intern

Dr. Ricardo MARTINEZ
Consultant
xmartin75@yahoo.com

Dr. Miriam MIKHAIL
Volunteer
mikmiri@hotmail.com

Dr. Yukiko NAKATANI
Technical Officer
nakataniy@who.int

Ms. Karina REYES MOYA
Administrative Assistant

Ms. Adriana VELAZQUEZ
Coordinator Medical Devices
velazquezberumena@who.int

Ms. Laura Alejandra VELEZ
Volunteer
la.velezrg@gmail.com

PROFESSIONAL ASSOCIATIONS / NGO's

Ms. Hanan AL-AWADHI
Kuwait Association for Biomedical Engineers/
Kuwait Society of Engineers
Kuwait
ipho99@alum.bu.edu

Ms. Sheila ANAZONWU
International Hospital Federation
Switzerland
sheila.anazonwu@ihf-fih.org

Dr. Philippe AUCLAIR
United States of America

Mr. Roger AYER
International Committee of the Red Cross (ICRC)
Switzerland
rayer@icrc.org

Dr. Wendy BABIDGE
INAHTA
Australia
wendy.babidge@surgeons.org

Ms. Cathy BLANC-GONNET
HUMATEM
France
cathy.blanc-gonnet@humatem.org

Ms. Amanda BOGG
Health First Europe
Belgium
amandabogg@healthfirsteurope.org

Dr. Caridad BORRÁS
IUPESM
United States of America
cariborras@starpower.net

Ms. Barbara BULC
Global Development
Switzerland
bbulc@gd-impact.com

Dr. Josephine BUNDOC
Physicians for Peace Philippines
Philippines

Mr. Clay BUTTEMERE
LinkAcross
The Former Yugoslav Republic of Macedonia
clay@linkacross.org

Mr. Mario CASTANEDA
ACCE
United States of America
mario@healthitek.com

Prof. Pierrette CAZEAU
Haiti Cholera Research Funding Foundation
United States of America

Dr. Kin Yin CHEUNG
International Organization for Medical Physics
(IOMP)
China
kycheung@hksh.com

Mr. Bruce COMPTON
Catholic Health Association of the United States
United States of America
bcompton@chausa.org

Ms. Barbara COMTE
HUMATEM
France
barbara.comte@humatem.org

Mr. Thang DAO
Switzerland

Dr. Yadin DAVID
IUPESM/Health Technology Task Group (HTTG)
United States of America
David@BiomedEng.com

Ms. Dessislava DIMITROVA
Results for Development Institute
Bulgaria
dessi.d.dimitrova@gmail.com

Ms. Monique DORY
Médecins Sans Frontières
Belgium
monique.dory@msf.org

Ms. Emilie DURAND
France

Mr. Luis FALCON
GNU Solidario
Spain
lfalcon@gnusolidario.org

Ms. Sarah FANTA
AAMI - Healthcare Technology Safety Institute
United States of America
sfanta@aami.org

Mr. Farell FOLLY
Hsoft-Africa, Ltd.
Morocco
farell@hsoft-africa.com

Prof. Mario FORJAZ SECCA
International Federation for Medical and Biological Engineering (IFMBE)
Portugal
mfs@fct.unl.pt

Dr. Paola FREDA
Ao Citta' Della Salute E Della Scienza Di Torino - Associazione Italiana Ingegneri Clinici Aiic
Italy
paolafreda@gmail.com

Mr. Pierre GAUTHIER
ICRC
Switzerland
pigauthier@icrc.org

Mr. William GENTLES
American College of Clinical Engineering (ACCE)
Canada

Prof. Robert GIULI
OESO (World Organization for Specialized Studies on Diseases of the Esophagus)
France
robert.giuli@oeso.org

Ms. Katherine HAGEN
Global Social Observatory
Switzerland
khagen@gsogeneva.ch

Mr. Nicholas HALLACK
Medisend International
United States of America
nick.hallack@medisend.org

Ms. Audrey HERNANDEZ
HUMATEM
France
contact@humatem.org

Dr. Ernesto IADANZA
Clinical Engineering Division/IFMBE
Italy
ernesto.iadanza@unifi.it

Mr. Yohei INOUE
Swaziland

Mr. Jigte JEAN MARIE
Care Help Cameroun
Cameroon
cg@carehelpcameroon.com

Ms. Aurelie JEANDRON
HUMATEM
France
contact@humatem.org

Mr. Andrew JONES
Tropical Health and Education Trust (THET)
United Kingdom
andrew@thet.org

Prof. Brendon KEARNEY
Euroscan
Australia
brendon.kearney@health.sa.gov.au

Ms. Bobbi KLETTKE
Health Action International
Netherlands
bobbi@haiglobal.org

Ms. Shweta KULKARNI
Belgium

Dr. Jan LABUSCAGNE
International Society of Radiology
Australia
jlabuscagne@isradiology.org

Prof. Alberto LAZZERO
ZOHE E-Health Open Zone
Italy
alberto.lazzero@zohe-ehealth.org

Ms. Annabel LAVIELLE
Global Heart Network Foundation
United States of America
annabel@globalheartnetwork.net

Mr. George LINZER
American Association for Clinical Chemistry
United States of America
glinzer@aacc.org

Dr. Carole LONGSON
NICE/HTAi
United Kingdom
Carole.Longson@nice.org.uk

Mr. Hans LUNDGREN
World Alliance of Wound and Lymphoedema Care (WAWLC)
Sweden
hans.lundgren@molnlycke.com

Prof. Ratko MAGJAREVIC
International Federation for Medical and Biological Engineering (IFMBE)
Croatia
ratko.magjarevic@fer.hr

Dr. Edwin Mbugua MAINA
Concern Worldwide Kenya
Kenya
edwin.maina@concern.net

Mr. Peter MATOKE
Association of Medical Engineering of Kenya (AMEK)
Kenya
chairman@amek.or.ke

Mr. Paul MERLEVEDE
IFHE
Belgium
paulmerlevede@hotmail.com

Mr. Hiroshi MISAWA
Japan

Ms. Shauna MULLALLY
Tropical Health and Education Trust (THET)
United Kingdom
shaunamullally@gmail.com

Mr. Troy MURRELL
Clinton Health Access Initiative (CHAI)
Tanzania, United Republic of

Mr. Jeremiah MWANGI
World Heart Federation
Switzerland
jeremiah.mwangi@heart.org

Ms. Nadia G NAAMAN
International Society for Pharmacoeconomics and Outcomes Research
United States of America
nnaaman@ispor.org

Prof. Dieter NUERNBERG
Germany
nuernbergdieter@gmx.de

Ms. Akpene Esther NYOMI
Switzerland

Mr. Maurice PAGE
HUMATEM
France
maurice-page@orange.fr

Mr. Robert PARSONS
Health Partners International
United Kingdom
rparsons@healthpartners-int.co.uk

Mr. Verhoustraeten PRINCE
Association Des Ingénieurs Et Techniciens Biomédicaux de la RD Congo (AITB)
Democratic Republic of the Congo
mumpafamily@yahoo.fr

Mr. Francesco RIBOLZI
Italian Association of Clinical Engineers (AIIC)
Italy
francesco.ribolzi@libero.it

Dr. Tanya ROBBINS
MCAI (Maternal and Child Health Advocacy International)
United Kingdom

Mr. Panu SAARISTO
International Federation of Red Cross and Red Crescent Societies
Switzerland
panu.saaristo@ifrc.org

Mr. Christopher SARGENT
Health Technology Assessment International (HTAi)
Canada
csargent@htai.org

Mr. Nandish SHAH
RAD-AID International
United States of America
nshah@rad-aid.org

Ms. Erin SINES
Donor
United States of America
esines@macfound.org

Mr. Sumeet SINGH
CADTH
Canada
sumeets@cadth.ca

Mr. Jered SINGLETON
United States of America

Dr. Mamadou SOW
Valoris Santé Services/Horizons-Sahel
Senegal
mamadousowdemat@yahoo.fr

Mr. Robert SSEKITOLEKO
Uganda Maternal And Newborn Hub
Uganda
rsseki@gmail.com

Mr. Yoichi SUGIURA
Japan Association for Clinical Engineering
Japan
ycedar@tymc.twmu.ac.jp

Ms. Yumi SUZUKI
Japan

Dr. Slavik TABAKOV
International Organization for Medical Physics (IOMP)
United Kingdom
slavik.tabakov@kcl.ac.uk

Ms. Deepti TANUKU
Jhpiego
United States of America
deepti.tanuku@jhpiego.org

Ms. Ruth Tsitsi TAPFUMANEYI
Secretarialink
Zimbabwe

Mr. Komi Agbeko TSOLENYANU
NGO ASMENE (Association for Maternal, Neonatal and Child Health)
Togo
tsolenyanuclement@yahoo.fr

Mr. Anthony VIOLA
D-REV
United States of America
aviola@d-rev.org

Mr. Duy VO
MSF
Switzerland

Mr. Rainer VOELKSEN
RAPS
United States of America

Prof. Herbert VOIGT
International Union for Physical and Engineering Sciences in Medicine (IUPESM) / Boston University
United States of America
hfv@bu.edu

Ms. Lori WARRENS
VisionLink
United States of America
warrens@visionlink.org

Mr. Mark WASMUTH
GMDN Agency
United Kingdom
mark.wasmuth@gmdnagency.org

Mr. Alfred WHITLEY
International Society of Radiographers and Radiological Technologists
United Kingdom
aswhitley@msn.com

Ms. Anna WORM
THET
Netherlands
anna@worm.nl

Mr. Marc ZLOT
Switzerland

ACADEMIA

Australia

Mr. Robert MORHARD
University of Sydney
robamorhard@gmail.com

Bangladesh

Prof. Khondkar Siddique-E RABBANI
University of Dhaka
rabbani@univdhaka.edu

Belgium

Prof. Nikos MANIADAKIS
ESC

Brazil

Prof. Saide CALIL

Prof. Renato GARCIA OJEDA
IEB-UFSC
renato@ieb.ufsc.br

Prof. Siomara Regina HAHN
Universidade de Passo Fundo
siomara@upf.br

Ms. Marcelo HAYASHIDE
IEB-UFSC

Prof. Sergio MUHLEN
University of Campinas (UNICAMP)
smuhlen@ceb.unicamp.br

Dr. Luiz Eduardo SCHARDONG SPALDING,
Universidade de Passo Fundo e Hospital São Vicente de Paulo
spalding@upf.br

Mr. Diego Schirmer SPALL

Prof. Leandro ZERBINATTI
Universidade de São Paulo
lzerbinatti@gmail.com

Canada

Ms. Beverly BRADLEY
University of Toronto
bev.bradley@mail.utoronto.ca

Mr. Anik PATEL
University of British Columbia
anikpatel10@gmail.com

Ms. Adriana Astrid POZOS BARCELATA
astridpozos@gmail.com

Ms. Dinsie WILLIAMS
University of Toronto

China

Prof. Jie CHEN
Fudan University
jchen@shmu.edu.cn

Dr. Xiaolian DUAN
Chongqing Academy of Science & Technology

Prof. Li YANG

Prof. Daidi ZHONG
Chongqing University
daidi.zhong@cqu.edu.cn

Colombia

Mr. Andres TORRES
EIA-Ces University
pfantor@eia.edu.co

Mr. Sebastian TORRES MONTOYA
Antioquia Engineering School(EIA)/CES University/IQ Interquirofanos
setomon@eia.edu.co

Czech Republic

Mr. Gleb DONIN
Czech Technical University in Prague
gleb.donin@fbmi.cvut.cz

Dr. Ilya IVLEV
Czech Technical University in Prague
ilya.ivlev@fbmi.cvut.cz

Ethiopia

Mr. Mideksa MULUGETA
AAU, HSC, Tikur Anbesa Specialized Hospital
mulugetamideksa@yahoo.com

France

Ms. Semiath Adenike alake MALIKI
Student
semiath.maliki@yahoo.fr

Germany

Ms Christine KRIZA

Dr. Konstantinos MITSAKAKIS
University of Freiburg, Department of Microsystems Engineering (IMTEK) & HSG-IMIT
konstantinos.mitsakakis@imtek.uni-freiburg.de

Dr. Rainer WIECHING
University Siegen

Greece

Mr. Panagiotis MALATARAS
Institute of Biomedical Technology (INBIT) Greece
malataras@inbit.gr

Prof. Nicolas PALLIKARAKIS

Dr. Kallirroi STAVRIANOU
University of Patras
roy@inbit.gr

Hungary

Prof. Mihaly SZACSKY
University Association For Natural And Sport Sciences
mtse02@gmail.com

India

Mr. Himanshu GUPTA
Stanford India Biodesign
himanshugupta91@hotmail.com

Dr. Niranjan D KHAMBETE

Mr. Neeraj KUMAR
Stanford India Biodesign
neeraj.jasmatiya@gmail.com

Dr. Joseph Lazar MATHEW
Postgraduate Institute of Medical Education and Research
dr.joseph.l.mathew@gmail.com

Mr. Balram SANKARAN
Sree Chitra Tirunal Institute For Medical Sciences And Technology
balrams@gmail.com

Indonesia

Dr. Kastam ASTAMI
School of Electric and Informatic, ITB, Bandung
kastam@sysapp.itb.ac.id

Dr. Ediana SUTJIREDJEKI
Politeknik Negeri Bandung
ediana_sutjiredjeki@yahoo.com

Italy

Dr. Paolo ARIANO
Istituto Italiano di Teconologia
paolo.ariano@iit.it

Mr. Patrizio ARMENI
Cergas Bocconi University
patrizio.armeni@unibocconi.it

Dr. Federico CABITZA
Università degli Studi di Milano-Bicocca
cabitza@disco.unimib.it

Prof. Americo CICCHETTI
Catholic University of Sacred Heart
americo69@me.com

Mr. Aureliano Paolo FINCH
University of Bologna
aureliano.finch@unibocconi.it

Prof. Rosanna TARRICONE
Cergas Bocconi University
rosanna.tarricone@unibocconi.it

Japan

Mr. Ludovico CIFERRI
International University of Japan/Istituto Superiore Mario Boella
lciferri@iuj.ac.jp

Ms. Atsumi FUKUDA
Dr. Yusuke FUKUDA
National Institute of Mental Health
yfukuda@ncnp.go.jp

Dr. Masamichi HANAZATO
Chiba University

Dr. Akira HATA
Chiba University

Ms. Akiko KITAMURA

Dr. Chisato MORI

Dr. Masato MUGITANI
Tokyo Medical University
Drmato@aol.com

Prof. Kiyokazu NAKAJIMA
Osaka University
knakajima@gesurg.med.osaka-u.ac.jp

Mr. Tomomichi NAKAZAKI
Tokyo Women's Medical University/Waseda University Joint Institution for Advanced Biomedical Sciences
t-nakazaki@ruri.waseda.jp

Dr. Emiko TODAKA

Lebanon

Dr. Sandy RIHANA
Holy Spirit University, Jounieh
sandyrihana@yahoo.com

Mexico

Ms. Rosa Itzel FLORES LUNA
Universidad Nacional Autónoma De México (UNAM)
iitzel.flores@comunidad.unam.mx

Dr. Jorge LETECHIPIA
Universidad Iberoamericana
jorge.letechipia@ibero.mx

Prof. José URRUSTI
Universidad Iberoamericana
jose.urrusti@ibero.mx

Netherlands

Dr. Henry David BANTA
University of Maastricht
hd.banta@orange.fr

Mr. Jochem VAN LEIJSEN

Ms. Ava WAGTER
Delft University of Technology
ava.wagter@live.nl

Mr. Vincent WESSELINK
TU Delft
v.g.wesselink@gmail.com

Peru

Dr. Carlos Jahel OJEDA DIAZ
Universidad de Piura
carlos.ojeda@udep.pe

Ms. Rossana RIVAS TARAZONA
Pontificia Universidad Católica del Perú
rivasperupucp@gmail.com

Prof. Luis VILCAHUAMAN
Pontifical Catholic University of Peru
lvilcah@pucp.edu.pe

Philippines

Ms. Anna Christine AMARRA
Ateneo de Manila University
camarra@ateneo.edu

Prof. Maria Regina Justina Esguerra ESTUAR
Ateneo de Manila University/Physicians for Peace/ SMART Communications
restuar@ateneo.edu

Dr. Marlene MANA
Ateneo ee Manila University
mmana@ateneo.edu

Prof. Jose Alvin MOJICA
University of the Philippines, Manila

Korea, Republic of

Prof. Jung Kyung KIM
Kookmin University
jkkim@kookmin.ac.kr

Singapore

Prof. James GOH
National University of Singapore
biegohj@nus.edu.sg

South Africa

Ms. Debjani MUELLER

Mr. Jean Marie Vianney NAMAHORO
Stellenbosch University
uwanamahoro@yahoo.fr

Mr. Mladen POLUTA (By Skype)
University of Cape Town
mladen.poluta@uct.ac.za

Switzerland

Dr. Emiliano ALBANESE
University of Geneva School of Medicine
emiliano.albanese@unige.ch

Ms. Agata Joana BEIRA CARREIRA CORREIA
Swiss Tropical and Public Health Institute
agata.correia@unibas.ch

Mr. Matthieu GANI
Ecole Polytechnique Fédérale de Lausanne
matthieu.gani@epfl.ch

Dr. Neema KASEJE
University Children's Hospital Geneva
nkaseje@gmail.com

Mr. Bertrand KLAIBER
EPFL
bertrand.klaiber@epfl.ch

Dr. Rostyslav KUZYAKIV
Geneva University Hospital - HUG
Rostyslav.Kuzyakiv@unige.ch

Ms. Vanessa LAVERSENNE
Ecole Polytechnique Fédérale de Lausanne
vanessa.laversenne@epfl.ch

Mr. Christophe PINGET
Lausanne University Hospital (CHUV)

Mr. Martin RAAB
Swiss Tropical and Public Health Institute

Prof. Dorria SALEM
Swiss Tropical Institute
dorriasalem@yahoo.com

Mr. Goncalo SALVADOR RIBEIRO E CASTRO
Swiss Tropical and Public Health Institute
goncalo.castro@unibas.ch

Dr. Klaus SCHÖNENBERGER
Swiss Federal Institute of Technology
klaus.schonenberger@epfl.ch

Mr. Reinhold WERLEIN
Swiss Tropical and Public Health Institute
reinhold.werlein@unibas.ch

Mr. Claudio Marco ZAUGG
Swiss Tropical and Public Health Institute
claudio.zaugg@unibas.ch

Dr. Ruxandra IANCU FERFOGLIA
Geneva University Hospital/Ecole Polytechnique Fédérale de Lausanne

Thailand

Dr. Suwit WIBULPOLPRASERT
suwit@health.moph.go.th

Uganda

Dr. Santorino DATA
Mbarara University of Science and Technology
boymukedata@gmail.com

United Kingdom

Dr. Hippolite AMADI
Imperial College London
h.amadi@imperial.ac.uk

Ms. Clara ARANDA JAN
University of Cambridge
clara.aranda@cantab.net

Ms. Mariana BENETTI TERRA CARDOSO
mariana.terra8@gmail.com

Dr. Maurice Paul David BURKE
Partner (University College London/University College Hospital London/Royal Berkshire Hospital Reading)
maurice.bukre@ucl.ac.uk

Ms. Samantha BURN
University of Birmingham
s.l.burn@bham.ac.uk

Dr. Amanda CHAPMAN

Ms. Karin-Daniela DIACONU
University of Birmingham
kdd217@bham.ac.uk

Mr. Gianpaolo FUSARI
Royal College of Art
gianpaolo.fusari@rca.ac.uk

Prof. Richard LILFORD

Dr. Semira MANASEKI-HOLLAND
University of Birmingham
s.manasekiholland@bham.ac.uk

Dr. Ruth MCNERNEY

Prof. Alan MURRAY
Newcastle University
alan.murray@ncl.ac.uk

Dr. Leandro PECCHIA
University of Warwick
l.pecchia@warwick.ac.uk

Mr. Felipe RETTORE ANDREIS
felipeandreis66@hotmail.com

Prof. Daniel STEENSTRA
Cranfield University
d.steenstra@cranfield.ac.uk

Ms. Lisa STROUX

Dr. David SWANN
University of Huddersfield
d.m.swann@hud.ac.uk

Mr. Jonathan WEST
West
jonathan.west@rca.ac.uk

United States of America

Prof. James ABBAS
Arizona State University
james.abbas@asu.edu

Ms. Elizabeth Andrea BUTRICK
University of California
ebutrick@globalhealth.ucsf.edu

Dr. Pauline M. CHOU
Ann and Robert Lurie Children's Hospital
pchou@luriechildrens.org

Mr. John Tobey CLARK
University of Vermont
tobey.clark@uvm.edu

Mr. Dane EMMERLING
Duke University
dane.emmerling@duke.edu

Dr. Barry FINETTE
University of Vermont
barry.finette@uvm.edu

Ms. Bonnie JONES
RTI International
bonniejones@rti.org

Ms. Kelley MAYNARD
Rice University
kmayn@rice.edu

Dr. Shankar MUTHU KRISHNAN
Wentworth Institute of Technology
smkrishnan@gmail.com

Ms. Delaram PEIMANI
delaram.peimani@gmail.com

Dr. Doris ROUSE
RTI International
rouse@rti.org

Mr. Amir SABET SARVESTANI
University of Michigan
asabet@umich.edu

Mr. Mohammed Kazmain ZAIDI
Idaho State University
zaidimk@gmail.com

Ms. Heidi FANTA
Case Western Reserve University
heidi.fanta@case.edu

Prof. Kathleen SIENKO

Prof. Fong-Chin SU

HEALTH PROFESSIONALS AND INDEPENDENT PARTICIPANTS

Ms. Omobayode ADISA
United Kingdom
bayodeadisa@aol.com

Dr. Biagio ALFANO
Elettronica Bio Medicale Srl
Italy
biagio.alfano@ebm.it

Ms. Lecoultre ANIKO
Dynamia, Aniko Lecoultre
Switzerland
aniko.lecoultre@dynamia.ch

Ms. Maria Teresa ARISTA RIVERA
Hospital Nacional Dos de Mayo
Peru
aristateresa@hotmail.com

Mr. Riad BAAZIA
Switzerland
baaziad@gmail.com

Ms. Evangelia BALANOU
United Kingdom
evangelia.balanou@gmail.com

Ms. Maria Teresa BAREIRO QUINONEZ
Hospital National Itaugua
France
mtb9@orange.fr

Dr. Alexandre BARNA
Assistance Publique-Hôpitaux de Paris
France

Mr. Timothy BERGIN
Canada
timbergin3@gmail.com

Ms. Deepti BHAGIA
Independent
India
deeptibhagia@gmail.com

Ms. Kristi BUCKLES OTTO
Guardit Technologies
United States of America
kotto@guardit.com

Ms. Tazeen Saeed BUKHARI
Shaukat Khanum Memorial Cancer Hospital &Research Centre
Pakistan
tazeen.bukhari89@gmail.com

Dr. Joost BUTENOP
Medical Mission institute-The Advisory Group for International Health
Germany
joost.butenop@medmissio.de

Ms. Aya CALDWELL
Massachusetts General Hospital
Switzerland
acaldwell1@partners.org

Ms. Claudia CARDENAS ALANIS
Mexico

Dr. Francesco CARDINALE
ASL 4 Chiavarese
Italy

Mr. Changsoon CHOI
EMB
Korea, Republic of
medeidos@gmail.com

Dr. Elliot COWAN
Partners in Diagnostics, LLC
United States of America
elliot.cowan@partnersindiagnostics.com

Ms. Mireille CRAUSAZ
Switzerland

Dr. K. Andre DEGUENON
Consultant
Benin
akdeguenon@yahoo.fr

Mr. Boris ENGELSON
Plurality Press
Switzerland
boris_engelson@hotmail.com

Dr. Seham EL-SAADANY
Egypt
sehamelsaadany@yahoo.com

Mr. Charles-Edouard ESCURAT
RESAH
France

Mr. Fabio ESPOSITO
TBS group
Italy
fabio.esposito@tbsgroup.com

Mr. Bjorn FAHLGREN
Assistance Publique-Hôpitaux de Paris
France

Dr. Tim FARLEY
Sigma3 Services SARL
Switzerland
Tim.Farley@Sigma3services.com

Dr. Richard FITTON
United Kingdom

Mr. Andrew GAMMIE
Fishtail Consulting, Ltd.
United Kingdom
agammie@fishtail.biz

Mr. Jean Pierre GARCIA PEREZ
Association
France
garciapjp@ymail.com

Dr. Francois GILARDONI
duMonde LLC, Global Advisory Services (GlobAS)
Switzerland
fgilardoni@dumonde.co

Ms. Surgul GONUL
United Kingdom
surgul.gonul@gmail.com

Dr. Anne-Chantal HERITIER BARRAS
Geneva University Hospitals
Switzerland

Dr. Patricia HERNANDEZ
Consultant
Switzerland
patricia.hernandez.consultancy@gmail.com

Dr. Fred HOSEA III
United States of America
tangofred@gmail.com

Ms. Salma HUSAIN
United Kingdom

Mr. Zahid Bashir JAMALI
Shuakat Khanum Memorial Cancer Hospital & Research Centre
Pakistan
zahidbme@gmail.com

Ms. Gabriela JIMENEZ MOYAO
Escala Biomedica SC
Mexico
gabriela.jimenez@escalabiomedica.com

Mr. Thomas JUDD
Kaiser Permanente
United States of America
tom.judd@kp.org

Ms. Linga KALINDE MANGACHI
Consultant
Switzerland
linga.kalinde@gmail.com

Mr. Krishan KHANDPUR
CCDEP
United States of America

Mr. Emmanuel KOUEMO TCHOKODJEU
St. Elizabeth Catholic General Hospital
Cameroon
kouemoema@yahoo.fr

Ms. Corinne LEBOURGEOIS
Switzerland

Dr. John MACKINNON
Chile

Mr. Takeshi MATSUO
JICA
Cambodia
chief_medem2@ezecom.com.kh

Mr. Claudio MEIROVICH
Meirovich Consulting
Spain

Mr. Farhat M'MADI
CHUV Hospital
Switzerland
farhat.mmadi@chuv.ch

Dr. Gita MODY
Brigham and Women's Hospital
United States of America
gmody@partners.org

Ms. Maria MORENO CARBAJAL
Mexico

Mr. Jean-Marie MOZZON
Switzerland

Mr. Didier MUKAMA
BMIT
Rwanda
didier.mukama@gmail.com

Mr. Vincent NGALEU TOKO
Cameroon
vngaleutoko@yahoo.fr

Mr. Bethel Jacques NOUYA
GENEX Consulting
Cameroon
nouya.bethel@yahoo.fr

Dr. Ling-Yen PAN
Independent
Switzerland

Mr. Julien PASQUIER
France
Biomed.Humanitaire@gmail.com

Mr. Hector Antonio PEYNETTI RUIZ
Switzerland

Dr. Miguel PRO QUINTANA
Independent
France
mproquintana@yahoo.fr

Prof. Emilio QUAIA
Department of Radiology
Italy
quaia@units.it

Dr. Clara RAMALHÃO
Hospital Pedro Hispano
Portugal
clararamalhao@gmail.com

Ms. Jossie Elenisse RIVERA LEYVA
EHESP
France
jossiele@hotmail.com

Ms. Sandra Luz ROCHA NAVA
Instituto Nacional De Cancerología
Mexico
srochan@yahoo.com

Ms. Gabriella SCAMPERLE
Italy
gabriellascamperle@gmail.com

Dr. Yoshiyuki TAENAKA
National Cerebral and Cardiovascular Center
Research Institute
Japan
bio@osaka.cci.or.jp

Mr. Ifuku TAKESHI
Japan
ifuku@st-mary-med.or.jp

Ms. Maxine Shelley TANG
Stellar Consulting Pty, Ltd.
Australia
shelley@stellarconsulting.net.au

Dr. Vince S. THOMAS
V.S. Thomas Global Health Strategy Consulting
Switzerland
vince@vsthomas.com

Ms. Aissatou TOURE SOW
France

Ms. Jeanette TWELL
AAQ Consulting
Switzerland
jeanette.twell@gmail.com

Dr. Lucy WATERFIELD
United Kingdom
lucywaterfield@me.com

Ms. Mira YOO
Canada

Prof. Habib ZAIDI
Geneva University Hospital
Switzerland
habib.zaidi@hcuge.ch

Ms. Vivian ZERBINATTI
Brazil
vivian.zerbinatti@gmail.com

MEDICAL DEVICES INDUSTRY

Ms. Gisela ABBAM
GE Healthcare
United Kingdom
Gisela.Abbam@ge.com

Mr. Md ABDUR RAZZAQ
Bangladesh

Dr. Claire ALLARDYCE
Medlight SA
Switzerland
claire.allardyce@medlight.com

Dr. Polycarp Reccy ASMAN
Mediwise International Company Limited
Ghana
polycarp.asman@mediwise.com.gh

Mr. Kalyan Ram BHIMAVARAM
India

Mr. John BOOMGARD
Intellectual Ventures - Global Good
United States of America
jboomgard@intven.com

Dr. Sudhir BORGONHA
Embrace Innovations
United States of America
sudhirborgonha@gmail.com

Ms. Jennifer BRANT
Innovation Insights
Switzerland
jbrant@innovationinsights.ch

Ms. Pascale BRASSEUR
Medtronic International
Switzerland
pascale.brasseur@medtronic.com

Mr. Robin Geoffrey BULLOCK
United Kingdom
Mr. Olivier CHAPPUIS
Switzerland

Ms. Jane CHEN
Embrace Innovations
United States of America
jchen@embraceinnovations.com

Ms. Hallie Sue CHO
OttoClave
United States of America
hscho@mit.edu

Dr. Laurent CHOPPE
Orsense, Ltd.
Israel

Dr. Sailesh CHUTANI
Mobisante, Inc.
United States of America
sailesh.chutani@mobisante.com

Ms. Alexandra CLYDE
Medtronic, Inc.
United States of America

Mr. Pavankumar DADLANI
Philips
Netherlands
pavan.dadlani@philips.com

Mr. Grzegorz DAJER
Medical Technology Transfer and Services, Ltd.
Viet Nam

Ms. Nicole DENJOY
DITTA
Belgium
denjoy@cocir.org

Dr. Juergen EBERLEIN
International Dental Manufacturers (IDM)
Germany
eberlein@eberleinconsult.de

Ms. Anett GÁLLNÉ VÁLYI
Oncotherm, Kft.
Hungary
gvanett@oncotherm.org

Ms. Lisa GIULIANI
Elettronica Bio Medicale - TBS Group
Italy
lisa.giuliani@ebm.it

Dr. Giulietta GRIOT
ZOHE E-Health Open Zone
Italy
g.griot@libero.it

Dr. Trevor GUNN
GMTA
United States of America
trevor.gunn@medtronic.com

Mr. Hans-Ole HEDEGAARD
Denmark

Dr. Markus HEIBACH
International Dental Manufacturers (IDM)
Germany
heibach@vddi.de

Mr. Ralph F. IVES
AdvaMed/GMTA
United States of America
RIves@advamed.org

Mr. Szego JOHN
Ortho-Trauma International LLP
United Kingdom
johnszego@aol.com

Ms. Kristy KAINRATH
Medxcel
United States of America

Mr. Carmi KATZ
GE Healthcare
France
luc.katz@med.ge.com

Ms. Naureen KHALID
Medipak Limited
Pakistan
naureenkhalid@gmail.com

Mr. Jacques Kinsbergen KINSBERGEN
Belgium

Dr. Denise KRUZIKAS
GE Healthcare
United States of America
denise.kruzikas@ge.com

Ms. Ingrid LÆRDAL
Laerdal Global Health
Norway
ingrid.laerdal@laerdal.no

Mr. Anthony LAKAVAGE
BD/GMTA
United States of America

Mr. Jose Carlos LAPENNA
DK Diagnostics
Brazil
jclapenna@gmail.com

Ms. Jan LAURSEN
Uruguay

Mr. Samuele LAZZERO
ZOHE E-Health Open Zone
Italy
firstbase@live.it

Mr. Jinsu LEE
Korea Health Industry Development Institute (KHIDI)
Korea, Republic of

Mr. Noel LINDSAY
Sleep Science Partners/The Pure Sleep Company
United States of America
noel@sspi.com

Dr. Jing-Jie LIU
Qiagen
China

Ms. Ako MAKIYAMA
Osaka Chamber of Commerce and Industry
Japan
bio@osaka.cci.or.jp

Ms. Sanziana MARCU LAPADAT
Belgium

Mr. Jordi MARTI GASCON
DBS Screening
Spain
j.marti@dbs-screening.org

Dr. Laurent Dominique Michel METZ
Johnson & Johnson
Singapore
lmetz@its.jnj.com

Mr. Aman MIDHA
BiosenseTechnologies Private Limited
India
aman@biosense.in

Ms. Tanya MOUNIER
Rabin Martin
Switzerland

Dr. Kie Bong NAHM
Boditech Med, Inc.
Korea, Republic of
kb9nahm@boditech.co.kr

Mr. Rajiv NATH
India

Mr. Robert NEIGHBOUR
United Kingdom

Ms. Lindsey OTTO
Inspire
United States of America

Ms. Anette PAP
Oncotherm, Kft.
Hungary
papanette@oncotherm.org

Mr. Anil Nanubhai PATEL
UL (Underwriters Laboratories)
United States of America
Anil.N.Patel@ul.com

Dr. Pankaj PATEL
UL (Underwriters Laboratories)
United Kingdom
peter.patel@nhs.net

Mr. Denver PHIRI
GE Healthcare
United Kingdom
denver.phiri@ge.com

Mr. Timothy PRESTERO
Design that Matters
United States of America
tim@designthatmatters.org

Ms. Marium QAISER
GlaxoSmithKline
United Kingdom
marium.6.qaiser@gsk.com

Dr. Michelle RIGOZZI
Australia
mkr28@cam.ac.uk

Mr. John SABOL
GE Healthcare
Uganda
john.sabol@med.ge.com

Mr. Amit SAFIR
Israel
amitsafir@mobileoct.com

Mr. Antonio Carlos SALLES
Brazil

Ms. Ludmilla SCHLAGETER
Belgium

Dr. Urs SCHNEIDER
Philips Healthcare
Switzerland
urs.schneider@philips.com

Mr. Hermann SCHULTHESS
IC Products SA
Switzerland
info@icproducts.ch

Dr. Krisztina SCHULTHESS-SZABO
IC Products SA
Switzerland
info@icproducts.ch

Prof. Michael SCRIPT
Guardit Technologies, Research & Development, LLC
United States of America
mscript@inspirelivinginc.com

Mr. Ryosuke SHIMIZU
Osaka Chamber of Commerce and Industry
Japan
bio@osaka.cci.or.jp

Mr. Nitin SISODIA
Sohum Innovation lab
India
nitin@sohumforall.com

Dr. Vince Shing-Wing SIU
Becton, Dickinson and Company
United States of America
Vince_S_Siu@BD.com

Mr. J. T. SURGENER
TriMedx
United States of America
jt.surgener@trimedx.com

Dr. Li TAO
Johnson & Johnson
China
Ltao@its.jnj.com

Mr. Abelardo TORRES
United States of America

Ms. Janeen UZZELL
Ghana

Mr. Sashikumar VALIYAVEETIL
Phoenix Medical Systems (P), Ltd.
India
sashi@pmsind.com

Mr. Zeger VERCOUTEREN
Belgium

Ms. Gina WENGER
m2Health
South Africa
gina_wenger@hotmail.com

Dr. Benjamin WILSON
Intellectual Ventures Laboratory
United States of America
bwilson@intven.com

Prof. Lung WONG
Singapore

Ms. Petra ZOELLNER
European Diagnostic Manufacturers Association (EDMA)
Belgium
p.zoellner@edma-ivd.eu

Dr. Danielle ZUROVCIK
WiCare
United States of America
drz@wicaresolutions.com

Appendix 8

Voting results

Please note that the wording is the original as submitted in the electronic conferencing device.
Every session has the 5 selected and the 2 most voted statements are shown in bold

Top 5	Top 2	
Healthcare Delivery and Healthcare Infrastructure		
Health Care Delivery		
1	x	**WHO should assist healthcare policy makers in various countries to standardize on the procedures to be carried out at the various healthcare levels and match those to the services to be rendered and then to the levels of devices to be selected, provided and used. This will help rationalize the HTA development and delivery.**
2	x	**Saudi model to be carried out by 3rd party**
3		I think we need to speak more about safety patient.
4		Healthcare guidelines should be developed by WHO
5		WHO to develop guidelines on delivering care in the community
Health Care Infrastructure		
1	x	**WHO should outline what are the characteristics of the future hospital infrastructure based on data**
2	x	**Countries should remember to consider the full life cycle cost of medical devices and technologies when selecting and introducing new products**
3		Energy sources should be considered as part of the product selection criteria
4		In the light of the post-MDG era, WHO should provide guidelines for energy-saving and renewable energy measures in Resource poor settings. (Remember the recent finding of only 34% oh health facilities in sub-Saharan Africa having reliable energy sources)
5		The infection control in the rebuilding facilities is mandatory for to avoid disease and problems with the patients.
How to Prioritize Medical Devices		
1	x	**Full scale HTAs are not going to become reality soon in low income settings. WHO and the member states should develop a mini HTA framework which would be obligatory for international projects.**
2	x	**WHO should unify the data base generation efforts.**
3		WHO should provide a set of tools for adapting their generic essential device lists to specific countries.
4		Academia & industry should collaborate with politicians to come up with feasible solutions for healthcare technology management
5		Industry should present transparent, reliable evidence so that full product life cycle cost can be considered when prioritizing medical devices.
Health technology Assessment (HTA)		
HTA : Networks and Societies around the Globe		
1	x	**Most if not all HTA producers face challenges in having their work used and used appropriately by decision makers. A significant focus of HTA networks and societies should be sharing of strategies, tactics, successes and challenges in gaining uptake by decision makers.**
2	x	**Consider filling the geographic gaps in HTA by collaborating with consultants to bring HTA to those regions rather than waiting for it to emerge in those resource-constrained environments**
3		RedETSA should implement a program in which representatives from countries with more experience in HTA would make technical visits to countries that want to start using HTA to support decision making
HTA		
1	x	**Could a common international platform for sharing quality HTAs carried out be develop? If so, could WHO be mandated to play a role - similar to the WHO lead prequalification initiative.**
2	x	**Open access HTA sharing should be promoted by WHO**
4		A web based international database especially designed for hospital based or mini-HTA.
5		Do we hare sufficiently well defined health outcomes for assessment of key high prices medical devices? WHO should play a role in consulting on defining clinically meaningful health outcomes that can be used for HTA

Top 5	Top 2	
Health Technology Management (HTM)		
HTM: Country Initiatives		
1	x	**Sharing HTM strategies and results across countries in and across regions to identify best practices**
2	x	**Importance of all the countries to have national HTM policy and plan in place**
3		Establish Innovation centers in countries
4		To encourage WHO country offices to support HTAs local initiatives. Sometimes it just technical assistance related to managing health technology
HTM: Country Initiatives		
1	x	**Biomedical engineers and MoH policy makers present in this forum to push for the MoH to establish a department/directorate in charge of health technology and medical devices including health infrastructure**
2	x	**Generate global map of HTM initiatives, past and present, with links to information**
3		For long term sustainability emphasize both involvement and training of staff at managerial level.
4		Commission study to learn from project failures and success.
5		Develop CMMS at maintenance service in Africa
6		Promote models of regional cooperation in HTM
Policies for Medical Devices		
1	x	**Conduct a study to determine best practice policies across the countries and develop international policy standards.**
2	x	**Clinical engineers must be included in National policy definition process, since sustainability is a major issue.**
3	x	**Medical technology policy availability to each country should be strongly advocated.**
4		Explore ways for WHO to work more effectively with industry, e.g. in policies and specs
5		Always try to integrate Health, Industry and Development policies in all procurement processes.
Technical Specifications		
1	x	**Accelerate development of WHO database of technical specifications**
2	x	**WHO efforts in defining essential devices and developing specifications need to be expanded.**
3		Affordability and accessibility of medical device is very imp. There should be a essential medical device list to make access able and affordable to poor patients
4		Use of GHTF guidelines for Medical devices used by regulatory authorities provide a foundation for generic use in establishing specifications for procurement.
5		Another important area is the tender and contract document. We need to consider that as well
Procurement of Medical Devices		
1	x	**WHO should develop equipment guides in order to train about medical devices and recommendations about the financial information and the right acquisition way. In short, WHO should pay more attention to medical device related issues.**
2	x	**Purchasers could think of medical devices procurement as an investment decision in which price at the time of purchase reflects both capital cost & operational costs**
3	x	**Recycling of medical devices should take in consideration in the development of innovation. It'll help not only to save the environment but also to help the poor country**
4		WHO should encourage member states to support FTA for med equipment and devices.
5		It's necessary to create a decision-support system for rational selection of large medical equipment.

Human Resources		
Human Resources in BME		
1	x	**Need for innovative biomed engineering education approaches, by fostering cross institutions collaboration, to enhance engineering capacities at low-resource settings and reduce brain drain.**
2	x	**Need for open source, open to share program details from academic institutions to foster collaborative innovation.**
3		Engage local engineering faculty and students when establishing clinical immersion experiences in low resource settings
4		Suggestion for WHO/IFMBE: 'advertise' to students more, get them involved early on. Getting a broader view is very educational
5		Promotion of innovation and entrepreneurship in medical devices in low resource settings

Top 5	Top 2	
Human Resources in Technology Life Cycle Management		
1	x	**Global efforts are needed to strength the role of medical physicists and clinical biomedical engineers as key health professionals to promote safety and quality in medical devices particularly in developing countries**
2	x	**WHO and transnational societies Promote single professional definition for each of roles described in this session**
3		WHO and transnational organizations Jointly prompt the collaborative roles of biomedical engineer Clinical engineer and Medical physics
4		Standardize professional definitions internationally
5		Engineers and physicists should work closer
Human Resources in Technology Life Cycle Management / Human Resources in Medical Physics		
1	x	**IOMP and IFMBE have to work closely with who in the field of patient safety**
2	x	**Medical physicists to be included in advisory committees on health technology needs assessment at country level**
3		To come up with concrete recommendations for the training on the maintenance of the BM devices
4		Medical physicists should all be certified
5		Global activities for patient safety in particular in developing countries (e g in Africa) have to include collaboration between professional organizations and who
Innovation		
Innovation in Medical Devices		
1	x	**Improve knowledge of medical doctors and health care workers of medical devices**
2	x	**Use close collaboration between technological universities and academic hospitals to address needs of doctors and patients**
3	x	**Health technology management based on evidence and a good analysis with an objective, we need data**
4		Innovative medical devices should target the major burdens of health care systems such as incontinence dementia and mobility problems
5		Firms need greater predictability of reimbursement, to make sure cost-effective, innovative designs are rewarded
Innovation in Medical Devices for Maternal and Child Health		
1	x	**Support innovation and design "hubs" in low-income countries for developing countries. (Most technologies presented were developed by people from high-income countries)**
2	x	**Create cross-sector collaborations to implement workshops to teach designers to develop technologies for low-resource settings**
3		Need for evidence based device design development to address infant and maternal health challenges
4		WHO should develop a methodological canvas to guide innovators
5		Expanding helping babies breathe or similar program to include training on CPAP using standardized protocol
Innovative Medical Devices for Low-Resource Settings		
1	x	**WHO and innovators should work closer to facilitate development and access to new technologies, of quality, adequate for resource limited settings**
2	x	**There is a mismatch between all the products and public health needs happen. Let's focus on value-based innovation and not fall into the same trap as the developed countries.**
3		WHO should facilitate a forum for patients or potential patients to tell manufacturers what they want
4		Detection of HIV, hepatitis B, hepatitis C, brucelosis and Chagas diseases in one single device.
5		Relevant stakeholders to provide innovators with knowledge eg training, guidance of regulatory requirements at early phase of R&D
Innovative Medical Devices for Low-Resource Settings		
1	x	**Employ manpower in these settings to research, manufacture and implement these devices. Empowering these populations will provide a holistic solution for these settings.**
2	x	**Partnerships with local entities are key.**
3	x	**Engineers should consider the value of their devices to those that will end up funding them. Early assessment and engagement will be important for this.**
4		Practices in middle income countries can be seen as champions for LRS.
5		There are few or no commercially available medical device products made for low income settings. In the pharma industry, this same problem is counterbalanced by PPPs and global initiatives. MD's should follow the same track.

Top 5	Top 2	
1	x	**The WHO should generate a list of minimum safety reqs for medical equipment in countries where no medical equipment regulations exist.**
2	x	**WHO should initiate collaborative platforms (online?) between interested parties (such as NGOs, innovators, manufacturers, clinicians) in production of med devices in low resource settings.**
3		WHO should have a policy to promote R&D and manufacture of medical devices in each LRC.
4		Medical device societies and international organizations should organize programs to promote entrepreneurship in low resource settings.
5		WHO should contact NGOs already installed in the regions to cooperate in putting local production forward
Medical Imaging		
1	x	**Tomosynthesis can cut cost & decrease radiation doses**
2	x	**Comprehensive site analysis is needed to analyze when digital radiography systems and ultrasound are of benefit.**
3		Somatoinfra can assist in detection of people in building collapses/earthquakes.
4		PACS & linked hospital databases are paramount; WHO can focus time & funds on this.
5		Digital imaging can help achieve greater service coverage per capita.
Regulation		
Regulation of Medical Devices		
1	x	**WHO to provide a platform for harmonization of taxonomy and nomenclature of safety reporting and Learning systems across different disciplines in health care (e.g. radiation safety, blood safety, technovigilance, etc.)**
3	x	**WHO and IMDRF build a/invest in a Solid PPP to far more comprehensively organize capacity building training services for regulators**
4	x	**Global bodies Develop and offer training for users about AE and near miss reporting**
2		Authoritarian (top-down) system for regulation will not work in third world because of corruption. WHO to explore alternative models.
5		Increase the list of international valid standards and promote them
Regulation of Medical Devices: Country Initiatives		
1	x	**WHO should assist low resource countries to establish effective systems for regulating medical devices**
2	x	**1) medical devices should not be regulated the way drugs are regulated for efficacy but for bringing a disciplined approach to manufacturing and for ensuring safe performance 2) transition period of 5 years should be minimal**
3		In order to best serve all developing countries the use of the GHTF guidelines would assist and give more than a foundation for any country without the relevant expertise in place to start a regulatory office for Medical Devices with some confidence
4		It is brilliant to see many countries establishing a medical devices regulatory framework, I hope from the outset emphasis is also placed on sharing information globally
Safety		
Safety of Medical Devices		
1	x	**All medical devices need to be controlled, whether manufactured in the country or imported, and safety should include design and use aspects**
2	x	**WHO should provide workshops or secondments to key people working in organizations or institutions in developing countries**
3		Countries to establish integrated reporting and learning systems including private sector too
4		Countries to ensure control of medical devices and software to prioritize safety over financial or commercial issues
5		Medical devices innovators should be encouraged to refurbish recycle and rethink in order to bring out the best and supplement the effects of medicinal treatments
6		Need a coordinated approach on DRLs ,with WHO working together with professional societies

Top 5	Top 2	
Patient safety / Medical Software		
1	x	**WHO must includes themes in safety devices, includes software. its mandatory because the problems in this type of systems have increased.**
2	x	**Building a strong safety culture in health care is essential for primary prevention of adverse events in medical settings**
3		Performance testing should be applied to medical equipment as much as electrical testing before market releasing (pre marketing evaluation)
4		Regulators of countries may be motivated to restrict availability of std disposable syringes and push usage of AD and RUP syringes in assisting national ministry of health to implement a safe injection policy
5		Provide appropriate syringes and box safety to the hospital. Training and education
6		Training and knowledge Of Healthcare workers is essential to reduce errors And maintain patients safety.

Appendix 9

List of statements of participants

Suggestions listed are as entered into the electronic conferencing device by the participants in the different session, only typo or spelling editing has been done.

Theme	Session Titles	All Suggestions
Health Care Delivery / Health Care Infrastructure	Health Care Delivery / Health Care Infrastructure	Healthcare guidelines should be developed by WHO
		Promovoir la production locale des equipement et dispositifs medicaux
		WHO should assist healthcare policy makers in various countries to standardize on the procedures to be carried out at the various healthcare levels and match those to the services to be rendered and then to the levels of devices to be selected, provided and used. This will help rationalize the HTA development and delivery.
		I think we need to speak more about safety patient.
		Determine objectives, very closed to the reality homologate is the first step.
		Saudi model to be carried out by 3rd party
		WHO to develop guidelines on delivering care in the community
		WHO should encourage member states to use models & simulations to support decision making in healthcare at clinical, leadership, political, promotional levels
		Perform a Burden of Illness study of problematic wounds in Saudi Who: world alliance of wound and lymphedema care
		Countries should remember to consider the full life cycle cost of medical devices and technologies when selecting and introducing new products
		The infection control in the rebuilding facilities is mandatory for to avoid disease and problems with the patients.
		Energy sources should be considered as part of the product selection criteria
		Energy in healthcare is expensive, we need to control the costs.
		Risk identification and assessment in use of health technologies is important - WHO to develop further appropriate risk assessment tools
		The UN agencies involved in health care programmes should jointly develop green policies for Healthcare infrastructure
		In the light of the post-MDG era, WHO should provide guidelines for energy-saving and renewable energy measures in Resource poor settings. (Remember the recent finding of only 34% oh health facilities in sub-Saharan Africa having reliable energy sources)
		WHO should outline what are the characteristics of the future hospital infrastructure based on data
		WHO should support green healthcare initiatives, both infrastructure & operations
		WHO should support local hygiene campaigns to encourage frequent hand washing, medical waste management, sterilization, etc
		Major domestic fridge manufacturers could be encouraged to improve system performance based on this study
		Neonatal EFS is a new idea that needs emphasis by WHO

Theme	Session Titles	All Suggestions
How to Prioritize Medical Devices	How to Prioritize Medical Devices	WHO should maintain a database of medical devices including physical infrastructure and human resource requirements.
		WHO should provide a set of tools for adapting their generic essential device lists to specific countries.
		WHO should produce tools to assist decision makers in integrating innovative technologies into current device lists.
		Industry should present transparent, reliable evidence so that full product life cycle cost can be considered when prioritizing medical devices.
		WHO should develop a methodology to prioritize medical devices and make a Model list of key essential medical devices - to be reviewed and updated at a regular basis
		Slovakia is amazing. Can we borrow some of their expertise??
		WHO should unify database generation efforts.
		WHO should review the different methods used for HTA & come up with a template for emerging economies that can be easily used & implemented
		Academia & industry should collaborate with politicians to come up with feasible solutions for healthcare technology management.
		An effort should be made to spread HTA based decision making, especially in countries shifting from low to middle income and in those facing severe economical crisis, also in order to address health inequalities through correct resource allocation.
		WHO & politicians should promote low-cost medical device industry
		Governments and health service should have Criteria to prioritize md. these should be public and transparent
		Full scale HTAs are not going to become reality soon in low income settings. WHO and the member states should develop a mini HTA framework which would be obligatory for international projects.
		WHO should fund development of software for devices similar to that used in Slovakia so it is open source for poorer countries
		WHO in collaboration w academia and stakeholders, to lead the development of a tool (or selecting an existing tool) for prioritizing and selecting medical devises.
		Manufacturers of medical devices must charge more because they must navigate the regulatory environment of each country. If you would like to see lower prices, why not simply adopt any device that has received clearance from recognized agencies such as the FDA?
		Governments should mandate harmonization among sub-national prioritization processes
		Health ministries should collaborate through an international forum to evaluate and prioritize medical devices.
		It is important a recognized independent body, to evaluate the new tools proposed for Assessment and Prioritization of MDs before they are used.
Health technology assessment (HTA)	HTA : Networks and Societies around the Globe	An effort should be made to spread the concept that HTA is a tool for countries at any level of income, especially those that are moving from low to middle.
		RedETSA should implement a program in which representatives from countries with more experience in HTA would make technical visits to countries that want to start using HTA to support decision making
		Most if not all HTA producers face challenges in having their work used and used appropriately by decision makers. A significant focus of HTA networks and societies should be sharing of strategies, tactics, successes and challenges in gaining uptake by decision makers.
		Consider filling the geographic gaps in HTA by collaborating with consultants to bring HTA to those regions rather than waiting for it to emerge in those resource-constrained environments
		Observation : several activities INAHTA globally. Question what are the plans, if any, to integrate and share the results and efforts globally? If not, this could be undertaken.by Dr Shankar Krishnan IFMBE.

Theme	Session Titles	All Suggestions
Assessment (HTA)	HTA	Could a common international platform for sharing quality HTAs carried out be develop? If so, could WHO be mandated to play a role - similar to the WHO lead prequalification initiative.
		Open access HTA sharing should be promoted by WHO
		A web based international database especially designed for hospital based or mini-HTA.
		Do we hare sufficiently well defined health outcomes for assessment of key high prices medical devices? WHO should play a role in consulting on defining clinically meaningful health outcomes that can be used for HTA
Health technology Management (HTM)	HTM	Sharing HTM strategies and results across countries in and across regions to identify best practices
		Share MCH HTM best practices
		To encourage WHO country offices to support HTAs local initiatives. Sometimes it just technical assistance related to managing health technology
		Zaugg HTM approach for Moldova excellent should be shared widely
		Importance for all the countries to have HTM policy and plan in place
		Essential to push in country manufactured devices
		Establish Innovation centers in countries
		Importance of all the countries to have national HTM policy and plan in place
	HTM: Country Initiatives	Generate global map of HTM initiatives, past and present, with links to information
		Aider le pays a produire son matériel et accessoires
		Promote models of regional cooperation in HTM
		There should be a collaboration on skills development between North and South.
		Develop CMMS at maintenance service in. Africa
		Establish and Strengthen maintenance workshops from the district hospitals level to the higher levels is of high important.
		Commission study to learn from project failures and success.
		La plus part des pays africains ont les mêmes problèmes en ce qui concerne la gestion des technologies de santé. Il y a d'abords un problème de formation et de mise à disposition des ingénieurs et techniciens biomédicaux auprès des hôpitaux puis une indisponibilité d'outils de gestion. Quelques belles initiatives sont mise en place même s'il n'y a. Pas assez de recul pour les évaluer. La mise en commun et le partage de ces initiatives importent.
		In each country let organize a meeting where biomed professionals and their healthcare structures directors will be invited and will finally have the opportunity to meet each other!!
		For long term sustainability emphasize both involvement and training of staff at managerial level.
		Biomedical engineers and MoH policy makers present in this forum to push for the MoH to establish a department/directorate in charge of health technology and medical devices including health infrastructure
		En raison de la faible volonté des états a faire de la maintenance un outil de gestion des formations sanitaires
		Vu la faible volonté des états a accorder l'importance qu il faut a la maintenance je propose que la OMS aide nos état en inscrivant dans les stratégies un program a lister des programs de vaccination pour les enfant de 0 a 5 ans que la maintenance soit recommande selon les équipements par niveau de soin
		When we said about the medical devices related the HT management we should be divided. MDs 4 categories : Medical consumable , Medical instrument , Medical furniture, Medical Equipment.

Theme	Session Titles	All Suggestions
Health technology Management (HTM)	Policies for Medical Devices / Technical Specifications	Clinical engineers must be included in National policy definition process, since sustainability is a major issue.
		Discussion of free trade agreements didn't seem balanced. US, EU and others use their power to negotiate agreements that are less public health oriented than the WTO, under the TRIPPS agreement. Specifically, such balances as compulsory licensing for public health is often not part of the agreements from US and EU.
		Conduct a study to determine best practice policies across the countries and develop international policy standards.
		Explore ways for WHO to work more effectively with industry, e.g. in policies and specs
		Always try to integrate Health, Industry and Development policies in all procurement processes.
		Medical technology policy availability to each country should be strongly advocated.
		It seems evident that every country needs a system for evaluation of all significant medical services, including medical devices, integrated into the health system. This should include, among others, to relations to procurement and payment, applying at least to the public system.
		Were the prices from industry or just the vendor?
		Medical devices for government institutions should be purchased directly from manufacturers and not by international competitive bidding this is to reduce cost and prevent fakes
		Affordability and accessibility of medical device is very imp. There should be a essential medical device list to make access able and affordable to poor patients
		Accelerate development of WHO database of technical specifications
		WHO efforts in defining essential devices and developing specifications need to be expanded.
		How do you ensure what was procured is what has been delivered?
		The publication of generic specs of various State Agencies is the right way forward because others can draw from the vast pool of knowledge and put together individually what is needed. Who can lobby for this? WHO?
		Use of GHTF guidelines for Medical devices used by regulatory authorities provide a foundation for generic use in establishing specifications for procurement.
		Another important area is the tender and contract document. We need to consider that as well
		I will participate in the procurement area.
		Establish regional certification system in Latin America and Asia similar to CE mark
		I will also be interested in being part of the working group. Akua AmarteyM Food and Drugs Authority Ghana
Health technology Management (HTM)	Procurement of Medical Devices	It's necessary to create a decision-support system for rational selection of large medical equipment.
		WHO should encourage member states to support FTA for med equipment and devices.
		As recommendations :the certifications are useful for a short terms, 2 years or 3 and it could be renewable. Trademarks are a legal protections to protect the products in the market for sales. But standarisations are elaborated by lawyers and we can take the opportunities to collaborate with I.S.O.thanks
		Countries signing med tech FTA agreements with each other should support inter-group purchasing organizations to secure high quality medical devices at competitive prices to gain economies of scale.
		Recycling of medical devices should take in consideration in the development of innovation. It will help not only to save the environment but also to help the poor country
		Purchasers could think of medical devices procurement as an investment decision in which price at the time of purchase reflects both capital cost & operational costs
		WHO should develop equipment guides in order to train about medical devices and recommendations about the financial information and the right acquisition way. In short, WHO should pay more attention to medical device related issues.
		Kenya to finalize, adopt and start implementing its national health technology management policy that is still a draft since some years now
		WHO should devote more attention to medical devices

Theme	Session Titles	All Suggestions
Human Resources	Human Resources in BME	Need for cross institution collaboration between developing and developed countries academic institutions for a sustainable collaboration.
		Engage local engineering faculty and students when establishing clinical immersion experiences in low resource settings
		Need for open source, open to share program details from academic institutions to foster collaborative innovation.
		Who in sub Saharan Africa should inventory the medical device and typical problem on maintenance or use, then organize with health authorities training session for use n maintenance for employed CLINICAL TECHNICIAN
		Perhaps you could talk a bit about a faster track program that gets BMETs back into the workforce sooner than 2 years. The US military has an Exemption 2 from the US BMET Board of Examiners and US Certification Commission. Medisend International has a certified 5 month program that has the US Military exemption.
		Establishing BSc programs in biomed engineering and medical physics is of increasing importance for healthcare.
		Go to www.infratechonline.net for instructions on how to join Infratech, as well as an archive of past discussions
		To have a common quality assurance off Biomedical training
		Need for innovative biomed engineering education approaches, by fostering cross institutions collaboration, to enhance engineering capacities at low-resource settings and reduce brain drain.
		Suggestion for WHO/IFMBE: 'advertise' to students more, get them involved early on. Getting a broader view is very educational
		WHO needs to develop and/or promote fellowship programs and technical training modules to Biomedical Engineers and medical physicists.
		Promotion of innovation and entrepreneurship in medical devices in low resource settings
		Everybody should join Infratech.
		Provide more biomedical training and equipment to low income countries
		Encourage North South collaboration in human resources development
		Uniformize formation programs
		WHO should incubate NGOs activities that aims for enhanced public health
		L'OMS devra aider les pays d'Afrique Subsaheliens a former des ressources humaines localement ou en collaboration avec les autres pays (Ghana...)
		WHO could facilitate visiting committees to academic units in developing countries to review their curriculum.
Human Resources	Human Resources in Technology Life Cycle Management / Human Resources in Medical Physics	WHO and transnational organizations Jointly prompt the collaborative roles of biomedical engineer Clinical engineer and Medical physic
		Engineers and physicists should work closer
		Standardize professional definitions internationally
		Global efforts are needed to strength the role of medical physicists and clinical biomedical engineers as key health professionals to promote safety and quality in medical devices particularly in developing countries
		Biomedical engineering to sort out its own nomenclature globally. (I suggest "Zebedee".)
		WHO and transnational societies Promote single professional definition for each of roles described in this session
		Medical physicists to be included in advisory committees on health technology needs assessment at country level
		How to make a cost effective training program on imaging tech for the dev countries
		Global activities for patient safety in particular in developing countries (e g in Africa) have to include collaboration between professional organizations and who
		To come up with concrete recommendations for the training on the maintenance of the BM devices
		IOMPand IFMBE have to work closely with who in the field of patient safety
		Medical physicists should all be certified

Theme	Session Titles	All Suggestions
Innovation	Innovation in Medical Devices	Improve knowledge of medical doctors and health care workers of medical devices
		Health technology management based on evidence and a good analysis with an objective, we need data
		Economic evaluation of HTA in Telemedicine is peculiar since benefits appear in a different point of the chain of care sometime quite far from the point implementation
		Make academia, industry and doctors to integrate engineers
		Design of medical devices for BYOD (bring your own device) philosophy. In other words software, or add on hardware to BYOD
		Use close collaboration between technological universities and academic hospitals to address needs of doctors and patients
		Innovative medical devices should target the major burdens of health care systems such as incontinence dementia and mobility problems
		Healthcare innovation is extremely complex. Identify and validate framework for whole system approach that includes factors such as politics, users, technology etc.
		Firms need greater predictability of reimbursement, to make sure cost-effective, innovative designs are rewarded
		Telemedicine economic evaluation of HTA might require specific tools not considered in the classical forms
		In the near future MD development will not be on the hands of engineering's but on users
		Innovative medical devices should target the major burdens of health care systems such as incontinence dementia and mobility problems
		One of the essential aspects on MD design is resiliency
		Create an open access forum and think space hosting health problem statements, mentors and stakeholders willing to be consulted including a space for funders to publish opportunities
	Innovation in Medical Devices for Maternal and Child Health	WHO should push philanthropic funders to support innovation with a business perspective
		Expanding helping babies breathe or similar program to include training on CPAP using standardized protocol
		Create cross-sector collaborations to implement workshops to teach designers to develop technologies for low-resource settings
		Need for evidence based device design development to address infant and maternal health challenges
		Need for identifying who we are designing for/ who is actual user before just starting the device design
		WHO should develop a methodological canvas to guide innovators
		Need for a centralized idea sharing and feedback network for med device designers and developers to learn for each other's success and challenges
		Support innovation and design "hubs" in low-income countries for developing countries. (Most technologies presented were developed by people from high-income countries)
		WHO should develop database of innovative technologies for low resource settings
		WHO should advocate countries to publish pricing information
		Need for task shifting medical devices to enable low trained health care provides to attend women and children more effectively
		Could WHO (or maybe WTO) devise new business models to market innovative devices, which would include service and training?
		Programs should be developed to facilitate scale up of promising programs
		A common theme that I'm interested in seeing followed up with is the idea of the innovative ecosystem and how we can work together to link the different companies, NGOs and universities thinking about these problems and solutions

Theme	Session Titles	All Suggestions
Innovation	Innovative Medical Devices for Low-Resource Settings	The idea that there should be local production of some medical devices like in African countries, is very welcome. This will make the dream of universal health coverage to come true. This will make devices a bit cheaper comparatively
		Relevant stakeholders to provide innovators with knowledge e.g. training, guidance of regulatory requirements at early phase of R&D
		Mailing list to keep audience updated on progress of presented innovative projects
		Detection of HIV, hepatitis B, hepatitis C, brucelosis and Chagas diseases in one single device.
		Incite clinicians to adopt new devices, even if they are not as "sexy" as those of well-known global brands
		WHO should facilitate a forum for patients or potential patients to tell manufacturers what they want
		There is a mismatch between all the products and public health needs happen. Let's focus on value-based innovation and not fall into the same trap as the developed countries.
		WHO and innovators should work closer to facilitate development and access to new technologies, of quality, adequate for resource limited settings
		I suggest that WHO should such a directory that countries can share the information on innovation of MD through that with other countries and WHO should facilitate to transfer the knowledge and skills to other countries
		The point of care diagnostics are appealing, especially the flexibility to customize them to specific regions
		Portable and affordable ultrasound is very exciting for low resources countries but one of the challenge of portable equipment is the theft of the devices
		Would like to hear more about the cost of PATH products and how they intend to scale up?
		Employ manpower in these settings to research, manufacture and implement these devices. Empowering these populations will provide a holistic solution for these settings.
		Partnerships with local entities are key.
		Engineers should consider the value of their devices to those that will end up funding them. Early assessment and engagement will be important for this.
		Practices in middle income countries can be seen as champions for LRS.
		There are few or no commercially available medical device products made for low income settings. In the pharma industry, this same problem is counterbalanced by PPPs and global initiatives. MD's should follow the same track.
Local Production	Local Production in Low-Resource Settings	WHO should contact NGOs already installed in the regions to cooperate in putting local production forward
		WHO should initiate collaborative platforms (online?) between interested parties (such as NGOs, innovators, manufacturers, clinicians) in production of med devices in low resource settings.
		Need for promotion of evidence based successful cases of local production through an online platform managed by WHO or academia.
		Innovators should consider using imported components when available and affordable in order to jumpstart entrepreneurial efforts.
		WHO should have a policy to promote R&D and manufacture of medical devices in each LRC.
		Medical device societies and international organizations should organize programs to promote entrepreneurship in low resource settings.
		To facilitate partnerships, the WHO can help to create collaborative platforms between people/ institutions such as manufacturers, innovators, clinicians, NGOs, etc.
		Medical devices must be emphasized in WHOs agenda to increase access and facilitate their local production in low-resource settings.
		The WHO should generate a list of minimum safety requisites for medical equipment in countries where no medical equipment regulations exist.

Theme	Session Titles	All Suggestions
Medical Imaging	Medical Imaging	Somatoinfra can assist in detection of people in building collapses/earthquakes.
		PACS & linked hospital databases are paramount; WHO can focus time & funds on this.
		Tomo-Synthesis generates a lot of interest. Is this going to replace all CT scanners? This may be the next tech!'
		Radiation safety guidelines necessary in third world countries
		Tomo-synthesis can cut cost & decrease radiation doses compared to CT
		Tomo-synthesis should be be standard on enabled DDR equipment
		Need more digital and smaller equipments
		Ultrasound is now most useful in emergencies
		Digital imaging can help achieve greater service coverage per capita.
		Comprehensive site analysis is needed to analyze when digital radiography systems and ultrasound are of benefit.
Regulation	Regulation of Medical Devices	Still a long way to become global.
		World bank to extend fund for harmonizing medicines in Africa to include IVD medical devices
		Allow regulation processes to acknowledge innovative devices (and not slow down their use unnecessarily). Ms Velez from WHO or Mr Gammie could be involved
		Reuse of Single use devices in dev countries. WHO
		Medical directors should be involved in regulation of medical devices.
		Harmonization bodies To include clinical engineers education on Adverse Event reporting
		How do you regulate upcoming m-Health technologies. Specially when mobile phones are evolving in a much faster pace than medical devices.
		WHO to map all regulatory steps (admin, time, cost) devices are submitted to when destined to be distributed to multiple markets and do an impact and value-added assessment
		Global bodies To add clinical engineering representatives to global harmonization efforts
		WHO should focus on helping countries with resource appropriate regulations and not on essential devices which are setting specific
		APEC is working on Good Reviewer Practice. It will be good to see more international or regional organization jointly work on this. To leverage resource and avoid duplication
		Re use of medical devices should not be permitted for safety issues. GHTF recommends reuse? There should also be PMS for in vitro diagnostic kits in order to identify poor sensitive and specific kits. The issue pertaining to post approval Changes should be flagged
		Need to add users to regulators and manufacturers discussion to close the loop on safe use and reporting
		WHO to explain its regulatory system and capacity building initiative in the Western Mediterranean Cluster
		WHO and IMDRF build a/invest in a Solid PPP to far more comprehensively organize capacity building training services for regulators
		Develop more relevant International standards for medical devices to expand current pool and promote its use far more authoritatively
		Global bodies develop and offer training for users about AE and near miss reporting
		Authoritarian (top-down) system for regulation will not work in third world because of corruption. WHO to explore alternative models.
		WHO to provide a platform for harmonization of taxonomy and nomenclature of safety reporting and Learning systems across different disciplines in health care (eg radiation safety, blood safety, techno-vigilance, etc.)
		Medical Devices Regulatory Agencies must have medical physicists on their staff
		Capacity building in countries
		Health Authorities to foster dialogue and coordination between relevant regulatory bodies at national level (e.g. medical devices and radiation protection authorities)
		Prioritize Empowerment of consumers through utilization of media, perhaps lead by regulatory authority if it is a reliable SRA.
		Increase the list of international valid standards and promote them
		What about not reused but using expired new products?

Theme	Session Titles	All Suggestions
Regulation	Regulation of Medical Devices: Country Initiatives	My country has no regulation of Medical devices so I want to share with another country how to develop it ?
		Conceive basic logiciel of maintenance easily used by south countries to improve HTM
		The representatives from Cuba, Peru, Saudi Arabia, Singapore, Nigeria Malaysia, South Africa and Tanzania described the current status of regulations of medical devices in their countries which were quite encouraging and proposed for more amendments in their legislations to ensure the safety, quality, effective, affordable &accessible of medical devices
		WHO should assist low resource countries to establish effective systems for regulating medical devices
		1) medical devices should not be regulated the way drugs are regulated for efficacy but for bringing a disciplined approach to manufacturing and for ensuring safe performance 2) transition period of 5 years should be minimal
		In order to best serve all developing countries the use of the GHTF guidelines would assist and give more than a foundation for any country without the relevant expertise in place to start a regulatory office for Medical Devices with some confidence
		Have WHO promote the harmonization of the Certification of Clinical Engineers.
		It is brilliant to see many countries establishing a medical devices regulatory framework, I hope from the outset emphasis is also placed on sharing information globally
		Why are Asian countries not harmonizing and pooling resources AHWP should be requested to take a lead
		3) the unlicensed and unregistered manufacturing activity should be considered illegal and possibly criminal but a licensed manufacturer of a developing country should be disciplined to follow a corrective action plan rather than being treated as a criminal
Safety	Safety of Medical Devices	Safety can only be achieved if we have properly trained experts, specially in poor countries like Malawi. This being the case WHO and other stakeholders should assist giving scholarships to young people in these countries who have shown interest in biomedical/clinical engineering.
		Could there be separate sessions for IVDs as aspects of their regulation are quite different from medical devices?
		Need a coordinated approach on DRLs ,with WHO working together with professional societies
		WHO should provide workshops or secondments to key people working in organisations or institutions in developing countries
		Medical devices innovators should be encouraged to refurbish recycle and rethink in order to bring out the best and supplement the effects of medicinal treatments
		Countries to ensure control of medical devices and software to prioritize safety over financial or commercial issues
		Countries to establish integrated reporting and learning systems including private sector too
		In house government MD generation are not capable to be controlled by anyone. Actions should be taken.
		Government in house made Medical Devices and software should be control by an external body.
		Safety of medical devices should include design and use aspects
		All medical devices need to be controlled, whether manufactured in the country or imported, and safety should include design and use aspects
		In house made MD should get also a CE mark before they are used into real world
		Hi, medical devices are the main component of the infections and safety systems in the hospitals. Safety of medical devices could be built by certifications and trademarks. thank you
	Patient safety / Medical Software	Training and knowledge Of Healthcare workers is essential to reduce errors And maintain patients safety.
		Where is TELEMEDICINE safety in the WHO delivery safety.
		Where is in WHO the pretraining for TELEMEDICINE Devices.
		Provide appropriate syringes and box safety to the hospital. Training and education
		Issuance of a simple one page policy advisory or for mandating the usage of AD and RUP syringes in geographical regions and countries where unsafe injection practices and reuse exist to assist political commitment to bring in a phased change over
		Stand alone medical software should go through postmarked approval in order to be approved as such. None approved software whould specifically be marked as such.

Theme	Session Titles	All Suggestions
Safety	Patient safety / Medical Software	Stand alone informational or educational health software should not be considered medical software nor undergo pre/post market approval.
		Regulators of countries may be motivated to restrict availability of standard disposable syringes and push usage of AD and RUP syringes in assisting national ministry of health to implement a safe injection policy
		Donors have been subsidizing usage of AD syringes for immunization - they may rather help to subsidize the price difference between standard and RUP/ AD syringes which will be less costly
		Performance testing should be applied to medical equipment as much as electrical testing before market releasing (pre marketing evaluation)
		WHO must includes themes in safety devices, includes software. its mandatory because the problems in this type of systems have increased.
		WHO should consider ethical issues related to medical an telemedical applications
		The use of Health technology assessment should be mandatory for medical devices to assure the daily life performance, patient safety and the quality of the product (hardware and software)
		Transnational societies Include technology providers and integrators in telemedicine training
		Primary prevention of adverse events has absolute priority and building a strong safety culture in health care is a major way to achieve this goal
		Technology providers Develop and disseminate testing protocols for end to end performance verification of Telemedicine system
		Building a strong safety culture in health care is essential for primary prevention of adverse events in medical settings
		TELEMEDICINE Training is essential for Healthcare workers in a structural manner
		Assess safety, reliability of telemedicine and mobile med apps
		WHO should make a recommendation of the regulation of medical software from the stand point of the potential users all over the world.

Appendix 10

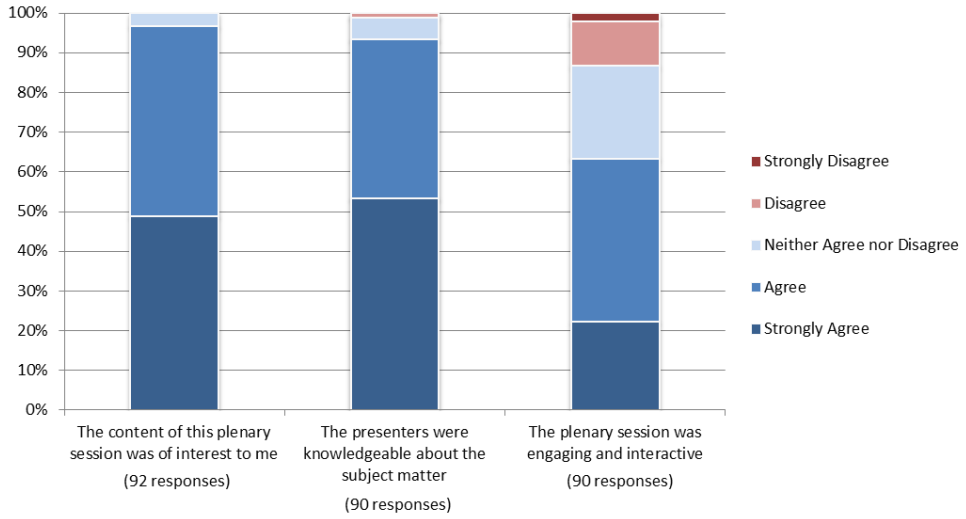
Participants evaluation survey results

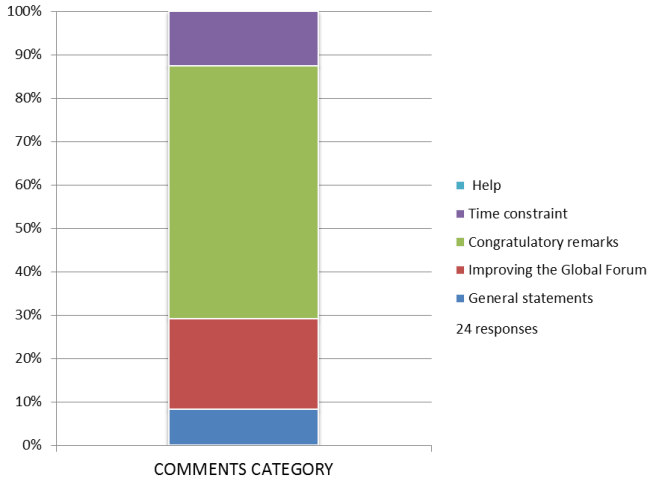
This appendix contains the participant's feedback received during each of the sessions of the forum in the electronic conferencing device that allowed voting and to submit comments. A total of 314 comments were received for the evaluation and some were selected.

Plenary Sessions

Plenary Saturday (morning)—Medical Devices for Universal Health Coverage

Comments and remarks





Selected comments from participants:

"There was no interactive dialogue with audience" – AS (Brazil)

"Thank you for bringing these important men and women on board" – BN (Kenya)

"*Not all talks were structured and visuals could be improved (where applicable)"* – CZ (Switzerland)

"L'OMS devra. Aider les pays a prioriser les dispositifs médicaux et a élaborer les politiques base sur des évidences (principales causes de mortalité)" – FMY (Central African Republic)

"*Projecting our/society's future health cost was brought up by Japan - the topic should get more focus in a next meeting"* – HP (Denmark)

"No Times for the discussion" – JC (Senegal)

"The plenary session this morning was fantastic! I liked it very much" – JN (Congo)

"Very important for political decisions. Thank you!" – LT (Republic of Moldova)

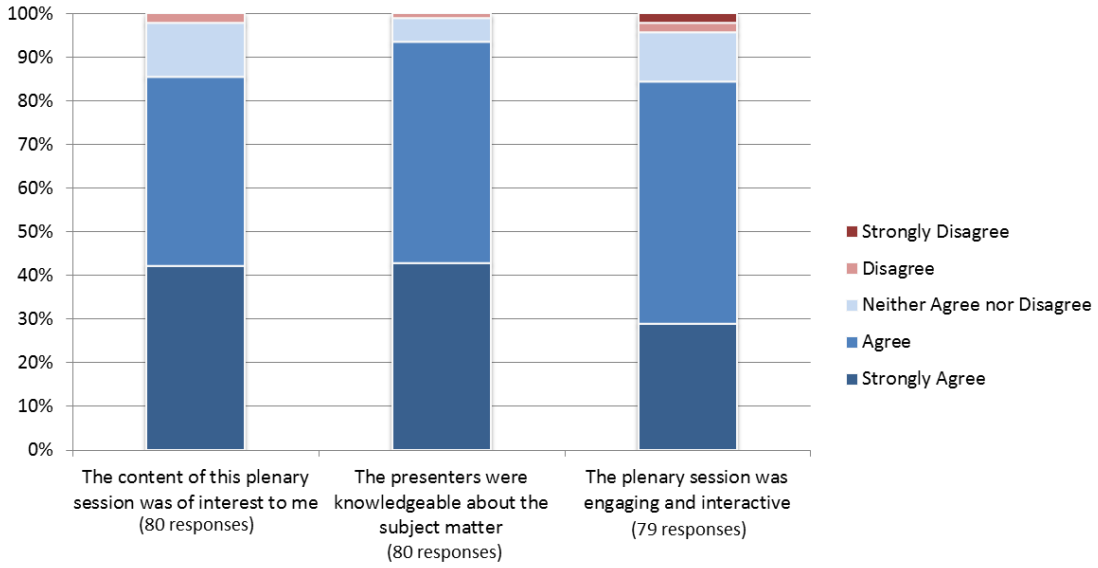
"Presentations were excellent! More time for interaction could have been built in" – PZ (Belgium)

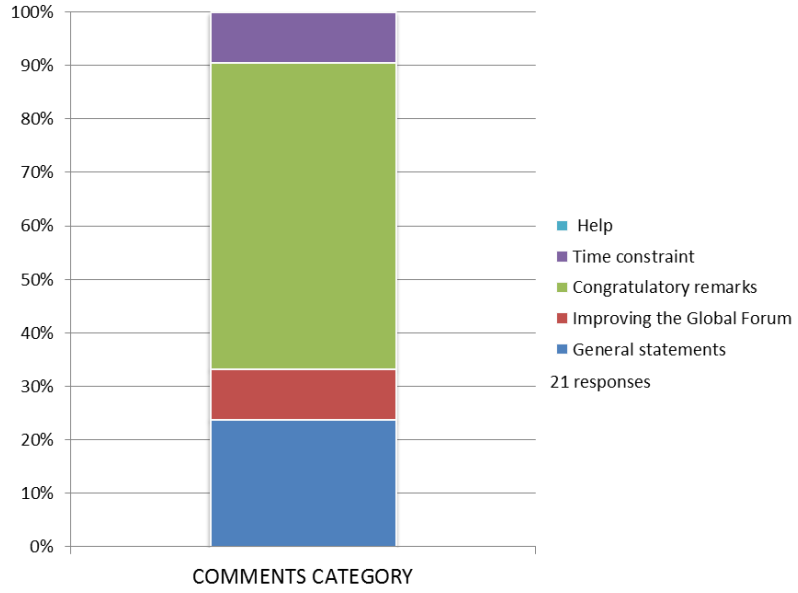
"Beside safety, high quality and affordable we need especially in developing countries SUSTAINABLE medical devices. In the sense of maintenance, training, and consumable provision" – VDV (Panama)

"Good section" – ZJ (Pakistan)

Plenary Saturday (afternoon)— The Unfinished Agenda: Medical Devices are Indispensable for Reaching The MDG Targets

Comments and remarks





Selected comments from participants:

"Great session. Opens up many important issues we should all collaborate to address them" – JU (Mexico)

"Excellent session with a broad range of perspectives" – WG (Canada)

"Having fewer panelists made this session more interactive and enjoyable. Very interesting presentations" – AB (Belgium)

"Is it possible to have a list of contacts for the panel persons ? They are very instrumental for reference" – BN (Kenya)

"Great session!!! Wrapped up Key points of the day. Seems there are interesting times ahead with private public collaboration, innovation and WHO once again in the driver's seat" – JB (Germany)

"It would have been longer for more interactivity" – BN (Cameroon)

"Please make the PPTs available on the website asap" – AAR (Trinidad and Tobago)

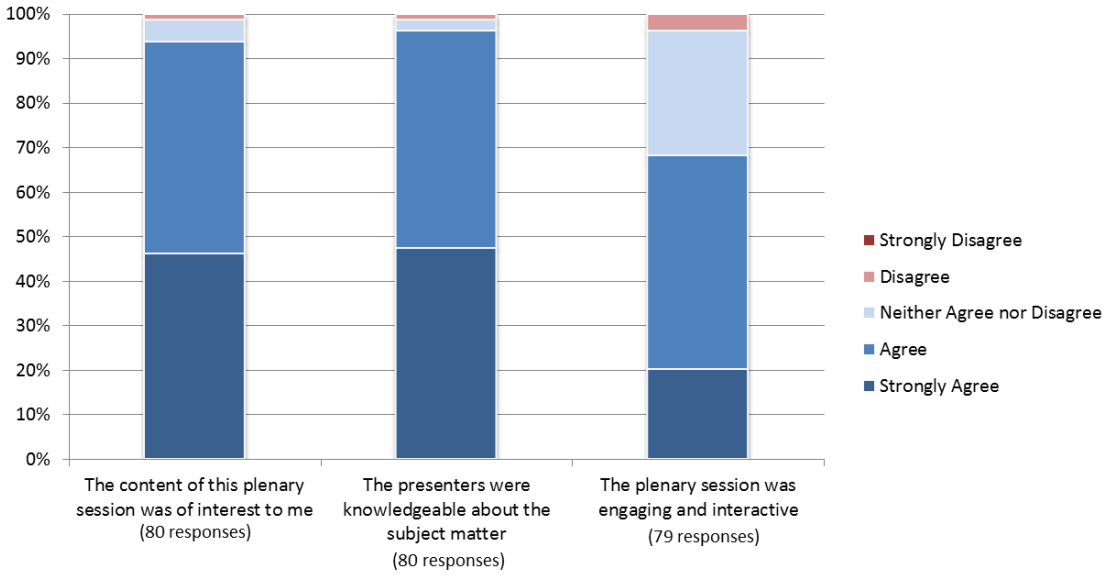
"More emphasis needs to be done on low resource settings to bring them up" – SM (Kenya)

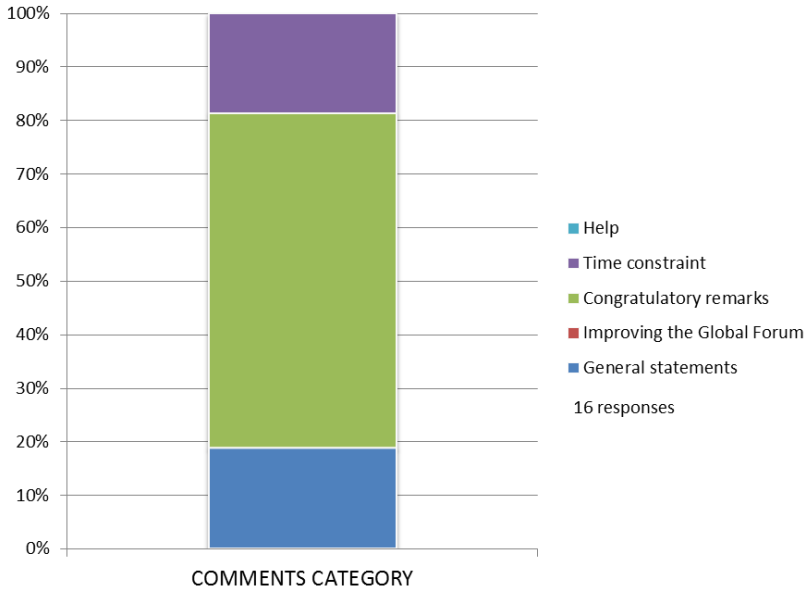
"Excellent" – LHP (Poland)

"I think to suggest that WHO should consider putting into decision-making position young people from poor countries who have shown interest in this issue of medical devices so as to expose them to real situation on the ground. I believe young people should be the leaders of today so as to make a better tomorrow" – VM (Malawi)

Plenary Sunday (morning)— Medical Devices for Non-Communicable Disease (NCD) agenda

Comments and remarks





Selected comments from participants:

"Excellent session - good speakers" – AW (United Kingdom)

"Too little time for discussions with the plenary, which is a pity given there were some hundred experts in the salle" – JB (Germany)

"Please post the PPTs online soon" – AAR (Switzerland)

"Merci pour la traduction de la session" – JC (Senegal)

"Recommendations should be sent to key decision makers in every country" – SM (Kenya)

"Really good discussion. I wish there was more time" – GA (United Kingdom)

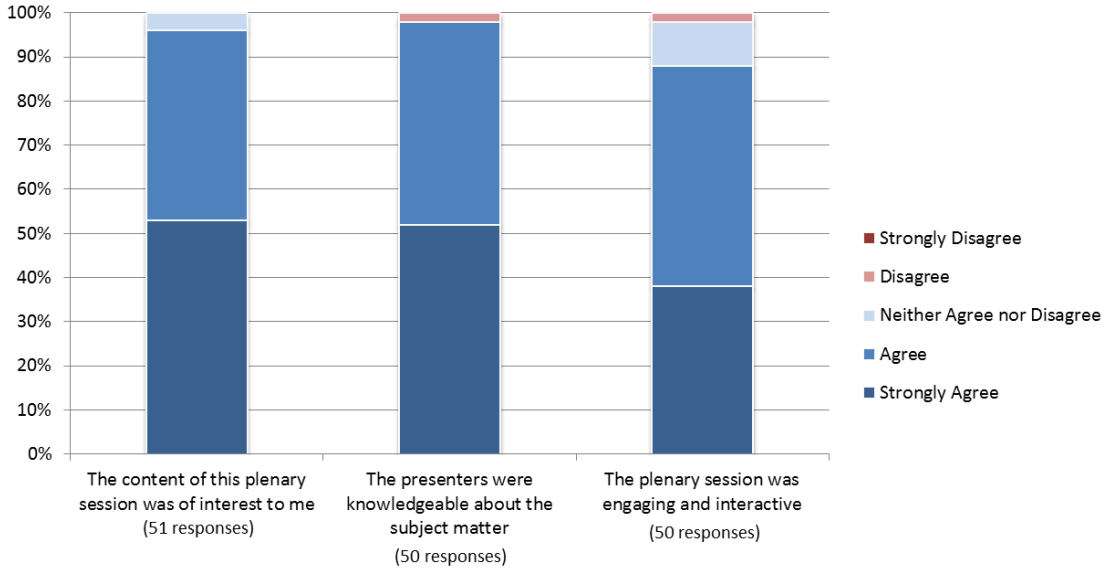
"Speakers gaged their talks to address issues that face resource rich countries and were irrelevant to countries with high mortality and morbidity and no internal regulations—BF (USA)

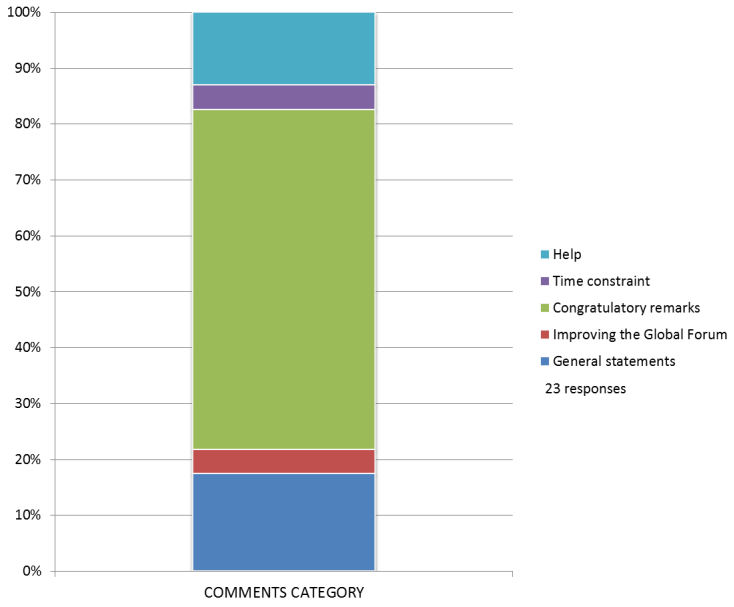
"Excellent presentations. Look forward to reading them in detail on the web" - RM (Kenya)

"Very informative presentations. Kindly make available the soft of copies of the same" – RS (India)

Plenary Sunday (afternoon)— Polices, Innovation, Regulation, Assessment, Management and Safe Use of Medical Devices for Increasing Access

Comments and remarks





Selected comments from participants:

"More of this forums (even online programs) should be encouraged for people to learn more" – SM (Kenya)

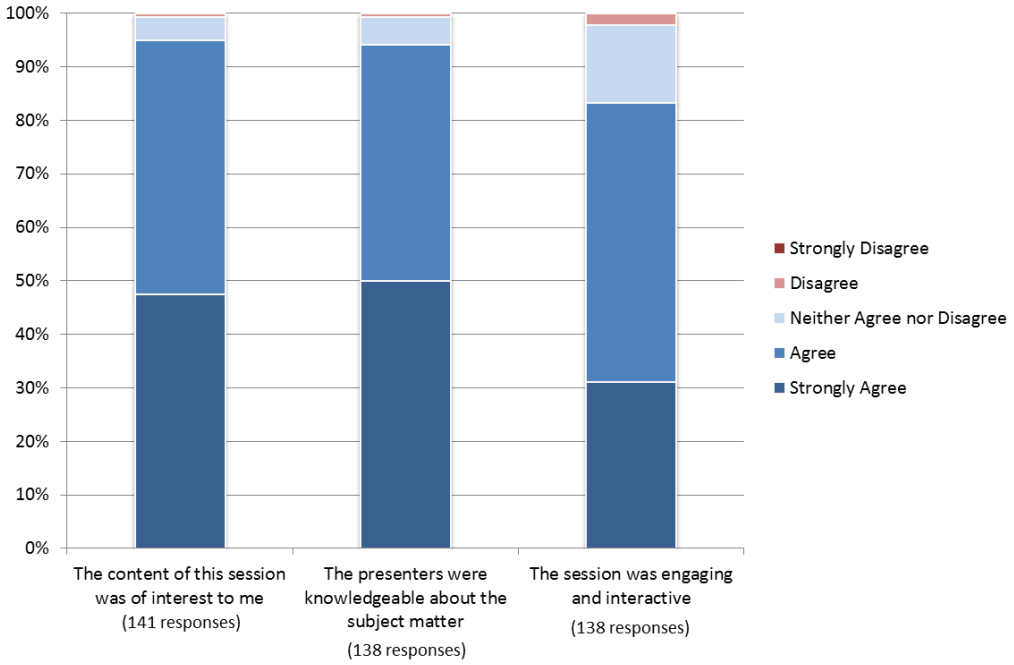
"I would like to contribute to the formation of the books" - PM (Kenya)

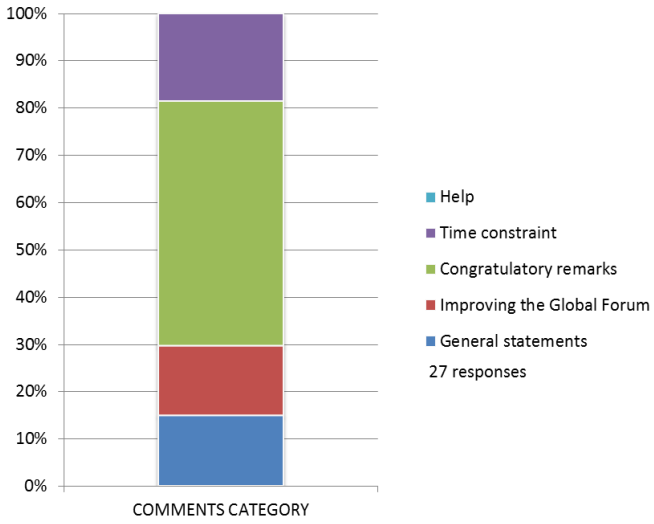
"Pour continuer : 1. développement de politiques relatives aux dispositifs médicaux; 2. développer in cursus de formation d ingénieurs et de techniciens" – YT (Cote d'Ivoire)

"Thank you for bringing everyone together. It was an excellent opportunity and very well executed. I got an idea in the last innovation session. I am interested in starting a crowd sourcing forum like quirky.com for matching needs with device design suggestions on a map, and running an enterprise that does the follow-through. Well done and thank you" – MR (Australia)

Parallel Sessions

Parallel Saturday (morning) - Comments and remarks from all parallel sessions on Saturday morning: 6 sessions





Selected comments from participants:

"This panel was very knowledgeable, and were respectful of the time slot allotted to them. I appreciate how the panel did not duplicate speeches, but rather talked about a unique angle about the subject. I was particularly interpreted in the ethnography discussion" – BJ (USA)

"Harmonization of standards & regulations is important for all medical devices stakeholders. IMDRF is one of the most important harmonization organizations, however, rather regulators (gov't)-oriented. So the door should be more opened to the other stakeholders" – CC (Republic of Korea)

"Some of the presentations were poor, others were in Spanish and the translators were only able to translate part of the presentation because the speaker spoke too fast and had too much info in Spanish" – CM (Spain)

"Reduce the number of the speaker to have a longer time slot for each speaker or make the session longer. The presentations were too short" – HA (Kuwait)

"Good occasion of sharing experiences" – AMS (Benin)

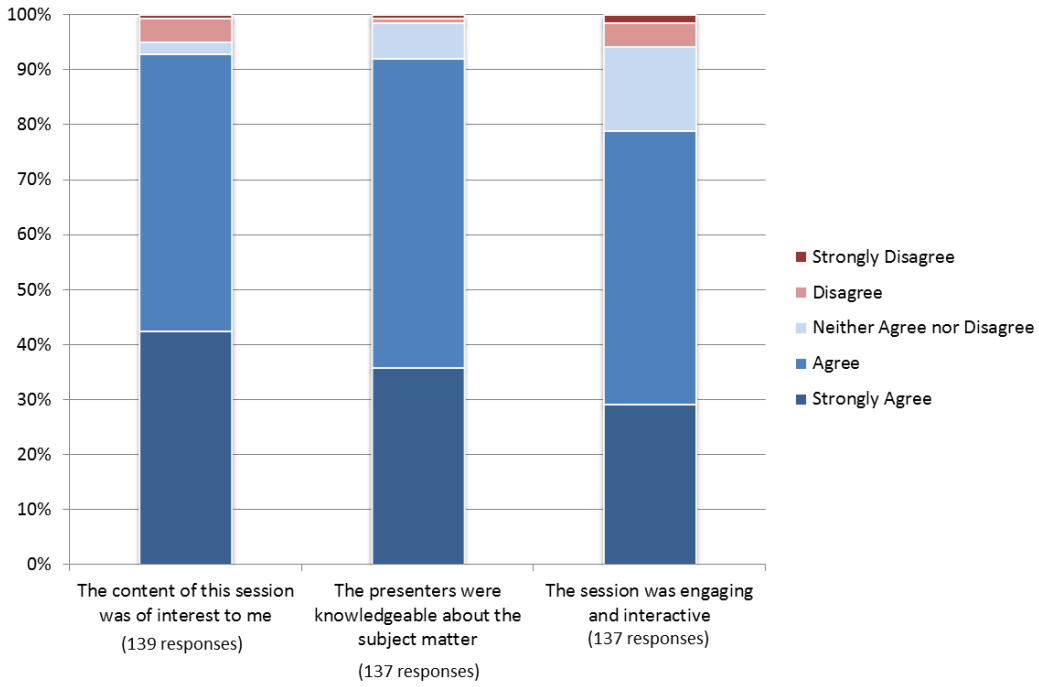
"Presentations too general. The basis on different topics is needed but presentations provided the roadmap where and what activities are done or are in process, so it is useful" – KA (Lithuania)

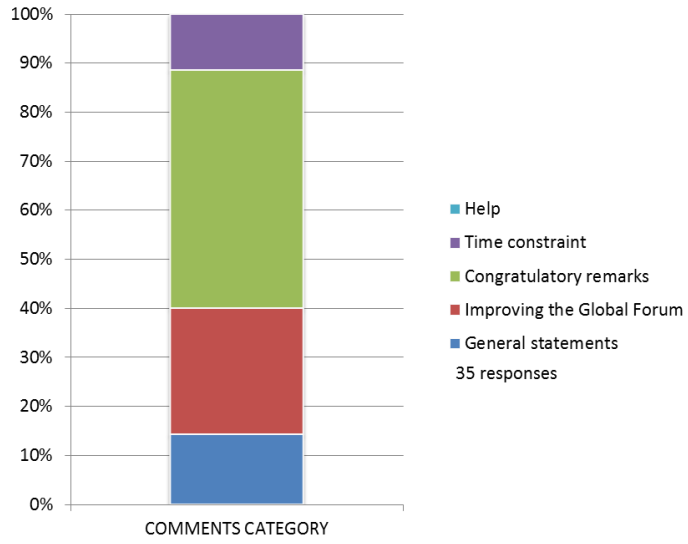
"It could be possible for the next time you will give us DVD about the event" – MAR (Peru)

"Congratulations in bringing together this groups of networks to link together" – MF (Switzerland)

"HTA is a growing concept globally, yet very little is being done in Africa, so opportunities abound. I would like to be part of the process of facilitating policy frameworks and institutional capacity for HTA in Africa. Thank you for the excellent work!" – RM (Kenya)

Parallel Saturday (afternoon) - Comments and remarks from all parallel sessions on Saturday afternoon: 5 sessions





Selected comments from participants:

"Too many presentations at the same time so presenters had to just run through their presentations" – AA (Ghana)

"I'd rather see WHO organize a session on the topic of how the many health ministries could work together collaboratively to develop a unified system for granting regulatory approval and prioritizing available medical devices. The current fragmented approach is a barrier which limits competition and necessitates higher prices to offset the high cost of working separately with each country" – NL (USA)

"I would have preferred fewer speakers with more time. Each speaker had only 5 min" – EB (USA)

"The session was well organized. All speakers gave clear presentation. One area which perhaps be useful to discuss is: challenges in the implementation of regulatory control" – JG (Singapore)

"I hope speakers get our comments given through electronic conferencing device and reply to them. Is that intended to happen?" – JU (Mexico)

"The presentation is good and it gives me knowledge" – MB (Ethiopia)

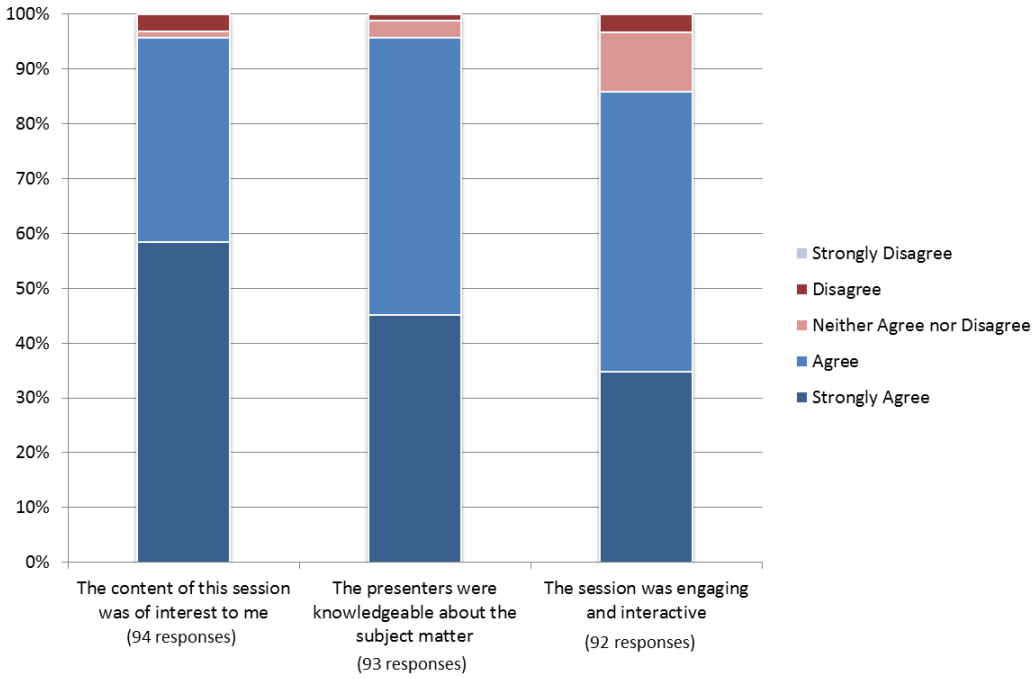
"Great forum for information exchange. I enjoyed it" – PA (Kenya)

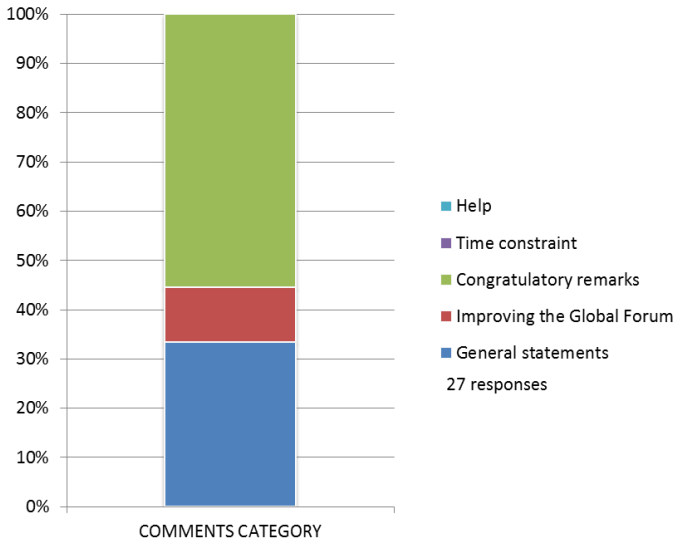
"The voting questions were not properly asked" – RA (Mexico)

"My comment is general: What is the recommendation for the improvement of this field in the developing countries" – SN (Afghanistan)

"I think it was ok. And it has potential to address the issues affecting women around the globe" – VM (Malawi)

Parallel Sunday (morning) - Comments and remarks from all parallel sessions on Sunday morning: 6 sessions





Selected comments from participants:

"Overall the presenters and presentations are very educative" – AK (Sierra Leone)

"Great session real topic. Future implications need guidance from WHO" – DP (United Kingdom)

"Better when there is other meeting especially in our region about the subject" – ED (Libya)

"L'experiance du Koweit a permis de voir comment on peut s'y prendre pour faire le plaidoyer et intéresser différents acteurs clefs" – FMY (Central African Republic)

"Industry speaker presented biased perspective on free trade agreements, ignoring how US and EU weaken the public health oriented IP provisions of the WTO to protect industry positions. Other speakers good. Gammie superb" – HB (France)

"I am satisfied of all presentation" - YT (Cote d'Ivoire)

"Useful information for future actions planning at national level" – KA (Lithuania)

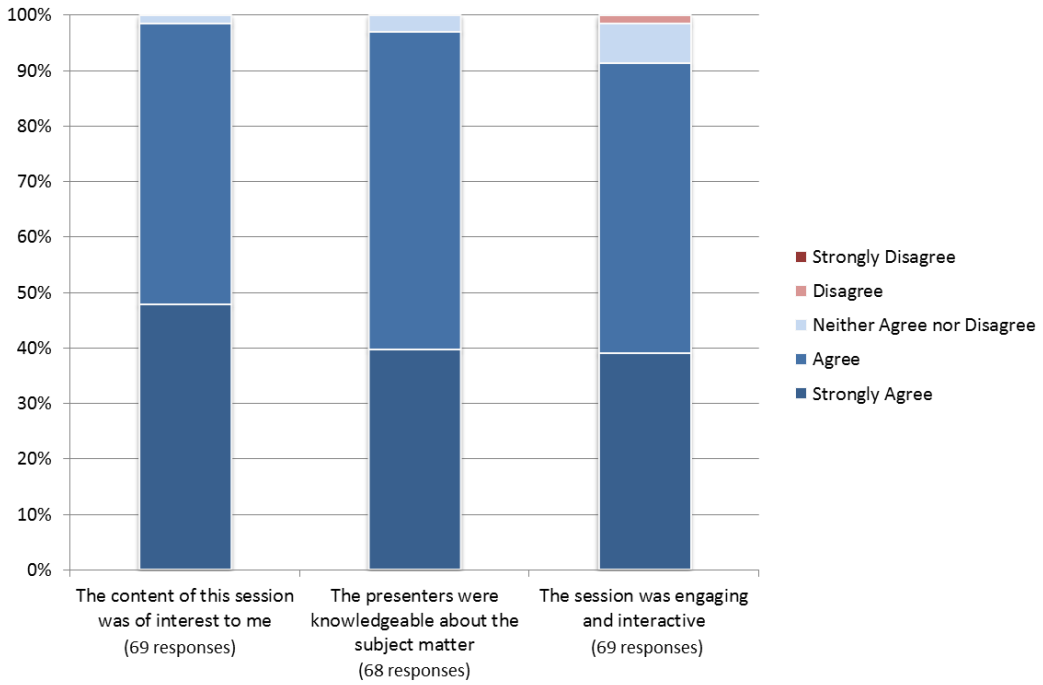
"All the topics have not being covered such as the "political" movements of BME in developing countries" – MP (France)

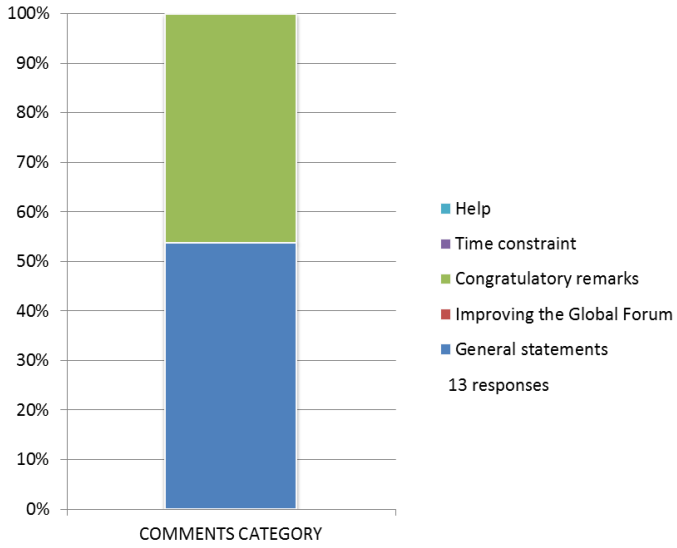
"'I am interested in' boxes should not be exclusive. I want to tick all four" – RP (United Kingdom)

"More information should be given on available options of training" – SM (Kenya)

"All the topics have not being covered such as the "political" movements of BME in developing countries" - MP (France)

Parallel Sunday (afternoon) - Comments and remarks from all parallel sessions on Sunday afternoon: 7 sessions





Selected comments from participants:

"A lot need to be harmonized when it comes to procurement" – BN (Kenya)

"L'experiance du Kenya peut etre superposable a mon pays la République Centrafricaine, sans aucune politique sur les dispositifs médicaux. Nous espérons que l'OMS aiderons par des ressources pour l évaluation et l'elaboration des politiques sur les Dispositifs Médicaux" – FMY (Central African Republic)

"There is an important need to harmonize the definitions regarding Bioengineering, clinical engineering, biomedical engineering, biological engineering, etc. this is a problem" – HV (USA)

"The collaboration and barrier breaking between MP and BME in developing countries is essential!" – MFS (Portugal)

"Nothing has been said on the problem of international tenders and the fact that they do not limit the number of models and manufacturers in a hospital" – MP (France)

"Great learning" - PC (USA)

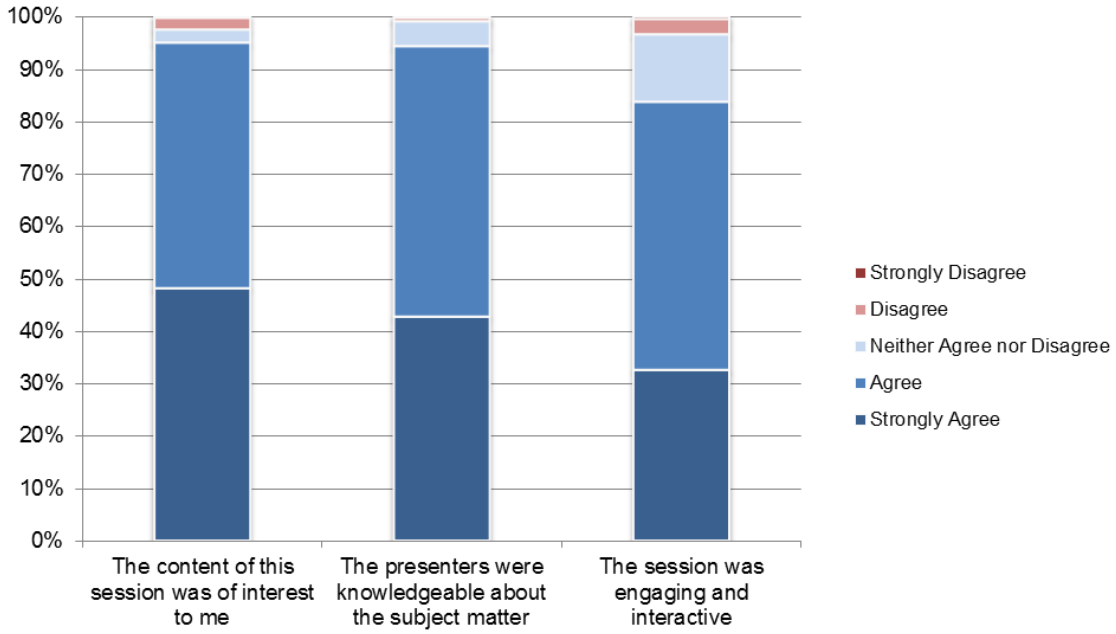
"WHO should work towards equipment regulations in those countries that do not have them yet" – SM (Kenya)

"Well presented" – VM (Malawi)

"Good section" – ZJ (Pakistan)

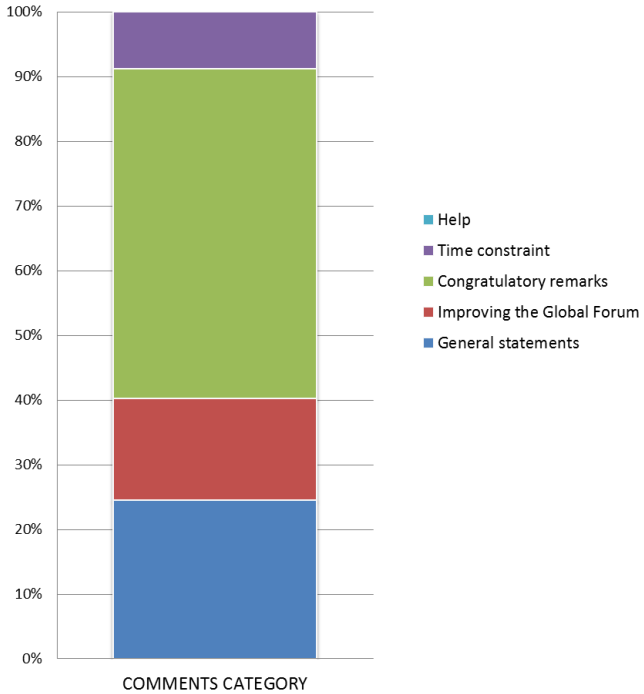
Overall Parallel

This section contains a general overview of 25 parallel sessions of 148 papers presented.



OVERALL	Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree	Total
The content of this session was of interest to me	214	207	11	10	1	443
The presenters were knowledgea-ble about the subject matter	187	224	21	3	1	436
The session was engaging and interactive	142	223	56	13	2	436
1315 Total responses						

Overall Parallel Comments

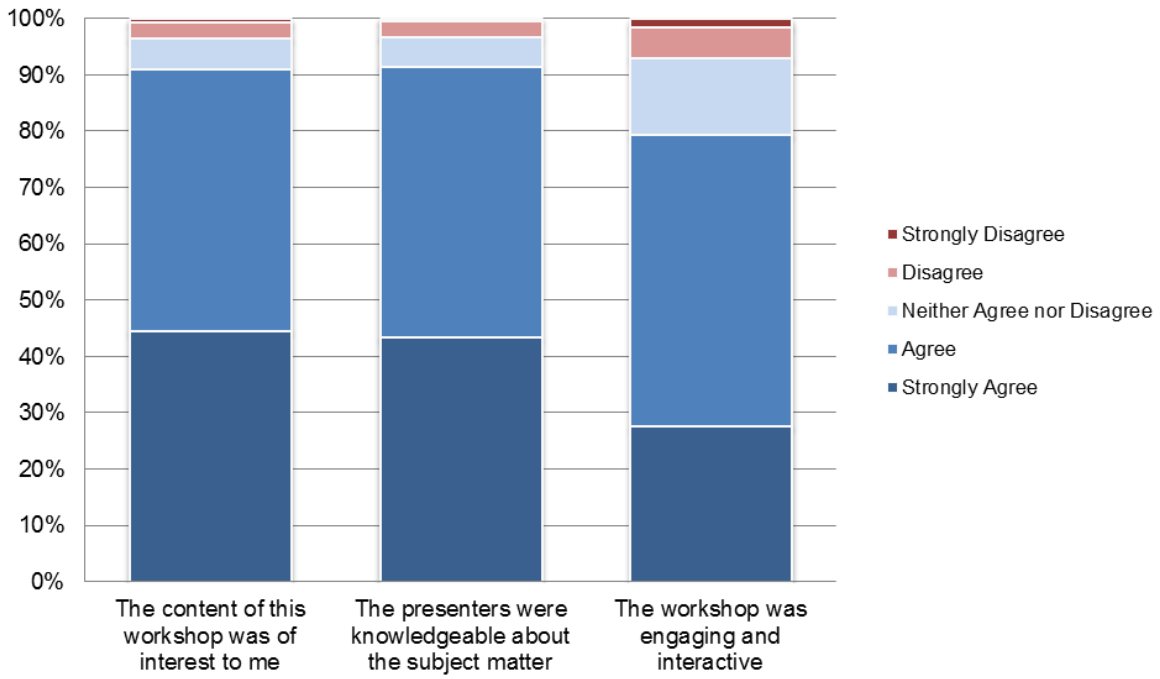


General statements	25
Improving the Global Forum	16
Congratulatory remarks	52
Time constraint	9
Help	0
Grand total	102

Workshops

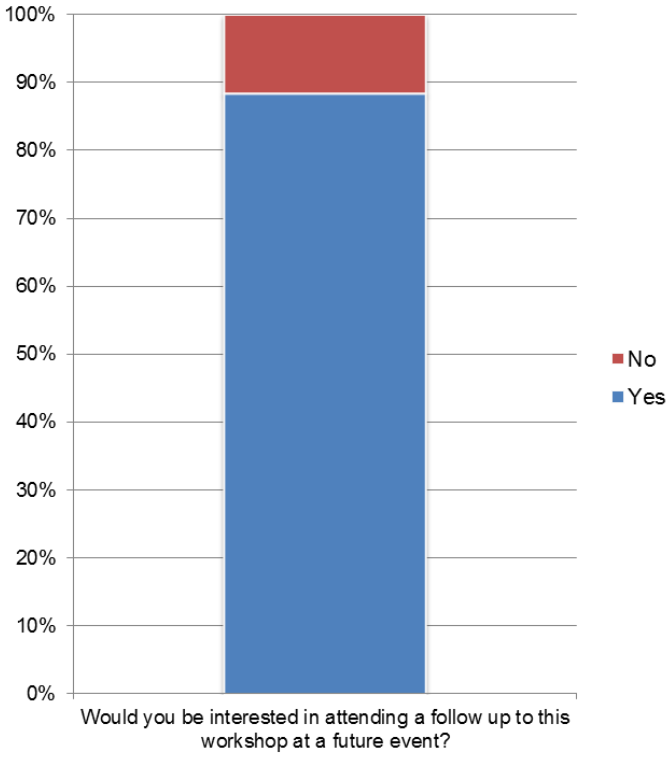
Workshop overall

There were 36 workshops and this graphic represents the input of comments received.



OVERALL	Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree	Total
The content of this workshop was of interest to me	125	131	15	8	2	281
The presenters were knowledgeable about the subject matter	117	130	14	8	1	270
The workshop was engaging and interactive	75	141	37	15	4	272

Would you be interested in attending a follow up to this workshop at a future events?



Workshop comments

Selected comments from participants:

"There was no global picture on the situation in Africa" – AK (Ghana)

"Important information and good presentation" – AC (Republic of Moldova)

"In the future, more time is need as the topic is wide. Kindly provide the soft copy of the presentation" – BN (Kenya)

"Learn to realize BME engineers' active participation in various fields is important and interoperability will change both hospital environments and the way we act" CC (Republic of Korea)

"Zimbabwe is currently pushing statutes on regulation of medical devices" – CT (Zimbabwe)

"Adverse events are a reality particularly in our part of the world where equipment is old obsolete and dubiously maintained" – CT (Zimbabwe)

"A group of experts from around the world is needed to support and continue the work" – CM (Spain)

"As no policies yet regulatory act for medical devices in my country so this session is fruitful in my context" – DB (Nepal)

"For overall conference: Presentations are generally engaging but there is hardly time to be interactive" – DW (Canada)

"The workshop was very informative and drew attendance from various backgrounds. It was also very engaging" – EM (Kenya)

"I note that lot of African experiences presented today (action for education in biomedical engineering, innovation...) were realized first in English spoken countries, is it a coincidence or in contrary it is a real choice from WHO and its partners because these countries are more advanced (than French spoken countries for e.g.) in the problematic related medical devices" – FM (Switzerland)

"Very informative and well conducted" – GG (Sri Lanka)

"Very few of the chapter coordinators were present. Few ideas were generated" – HV (USA)

"Excellent information that will use in my country" – IC (El Salvador)

"Weak attendance, likely due to broad range of subjects covered by the Conference. A smaller focused meeting needed" – JL (Australia)

"The presentation was not clear" – JN (South Africa)

"We wish a simultaneous translation" – JC (Senegal)

"The contributions were too long, and some of them too basic. But nevertheless a thrilling High Level panel, and good content!" – JB (Germany)

"Great sessions!" – JU (Mexico)

"Not worked timely and movement between sessions is not comfortable" – JK (Republic of Korea)

"As a presenter from a high income setting some presentations were not interesting and presenters not knowledgeable enough to respond to questions. Great presentations from Brazil Mexico and SA but no questions addressed to them" – KD (United Kingdom)

"Some problems still need to be addressed. An email forum could be useful" - KR (Bangladesh)

"Workshop was more orientated to producers not for public authorities like ministries of health. It would be interesting strategic planning of health innovations in order to meet needs of both sides public bodies and producers" – KA (Lithuania)

"More information on specification process and transparency would be appreciated" – KA (Lithuania)

"Very helpful" – LTT (Myanmar)

"Very interesting and important dates for countries authorities. Thank you a lot !" – LT (Republic of Moldova)

"I found the workshop very useful and profitable!" – MFS (Portugal)

"Good to know the current information and innovations to use it" – MB (Ethiopia)

"GMDN session was engaging and very interesting" – NH (Denmark)

"I DID not found any REFERENCE to reverse innovation devices" – OFR (Spain)

"I request that the ACCE consider bringing together all Biomedical Engineering/Clinical Engineering Associations in all countries and provide leadership on the international level" – PM (Kenya)

"Developing countries should collaborate with developing countries on capacity development especially Africa" – PA (Kenya)

"A great session for sharing information. Please make it annual event" – PA (Kenya)

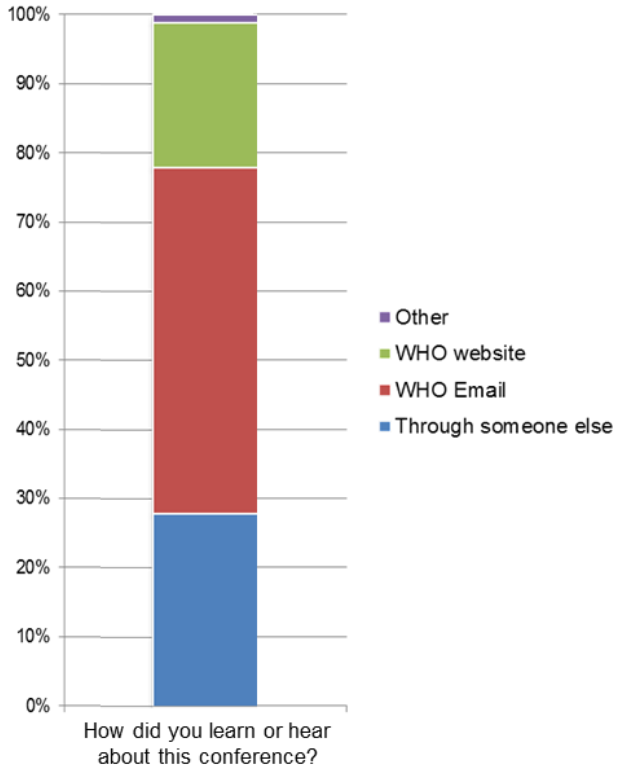
"Harmonization of medical devices regulations required in developing countries" – RS (India)

"Hope we will have soft copies of presentations" – SM (Kenya)

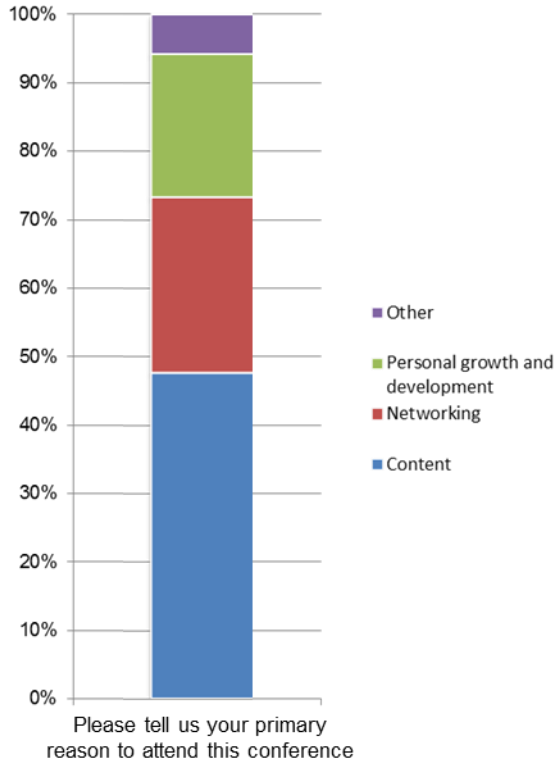
"The content is very important" – TM (Central African Republic)

Overall Event Evaluation

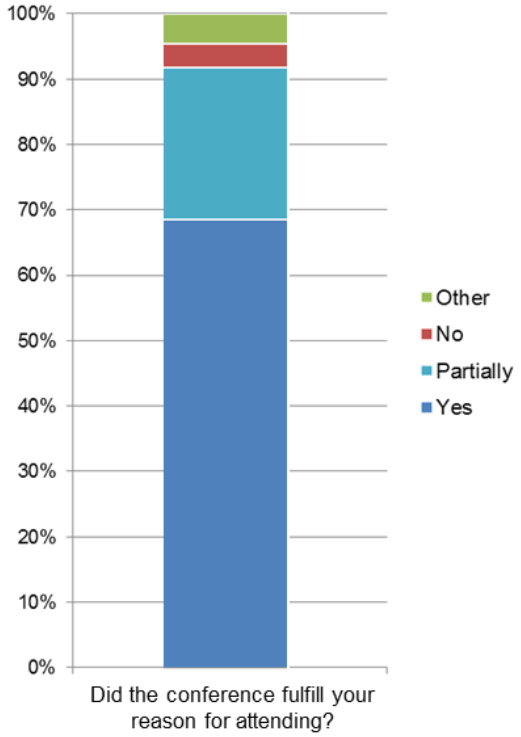
How did you learn or hear about this conference?



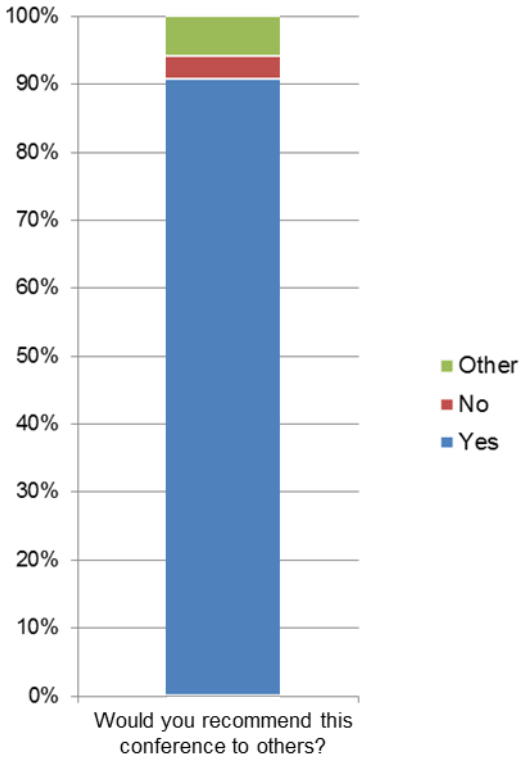
Please tell us your primary reason to attend this conference?



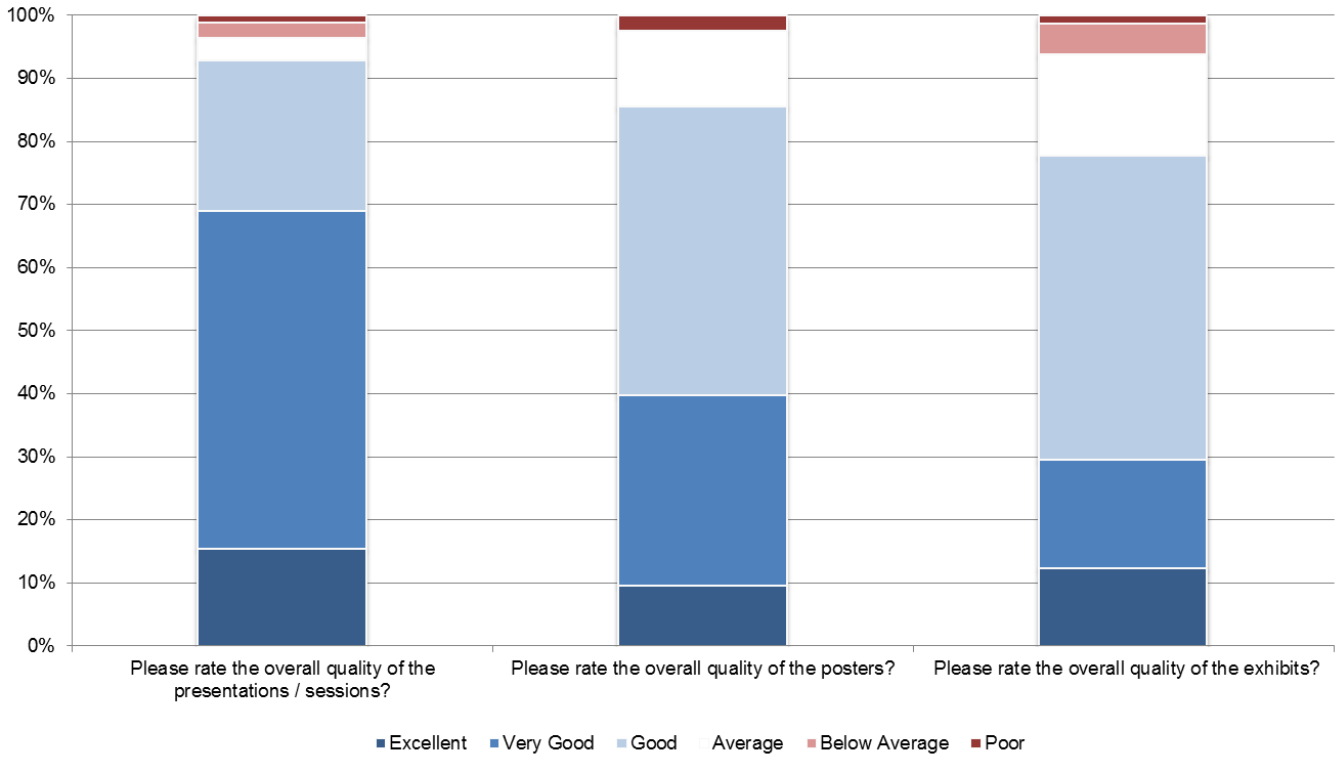
Did the conference fulfill your reason for attending?



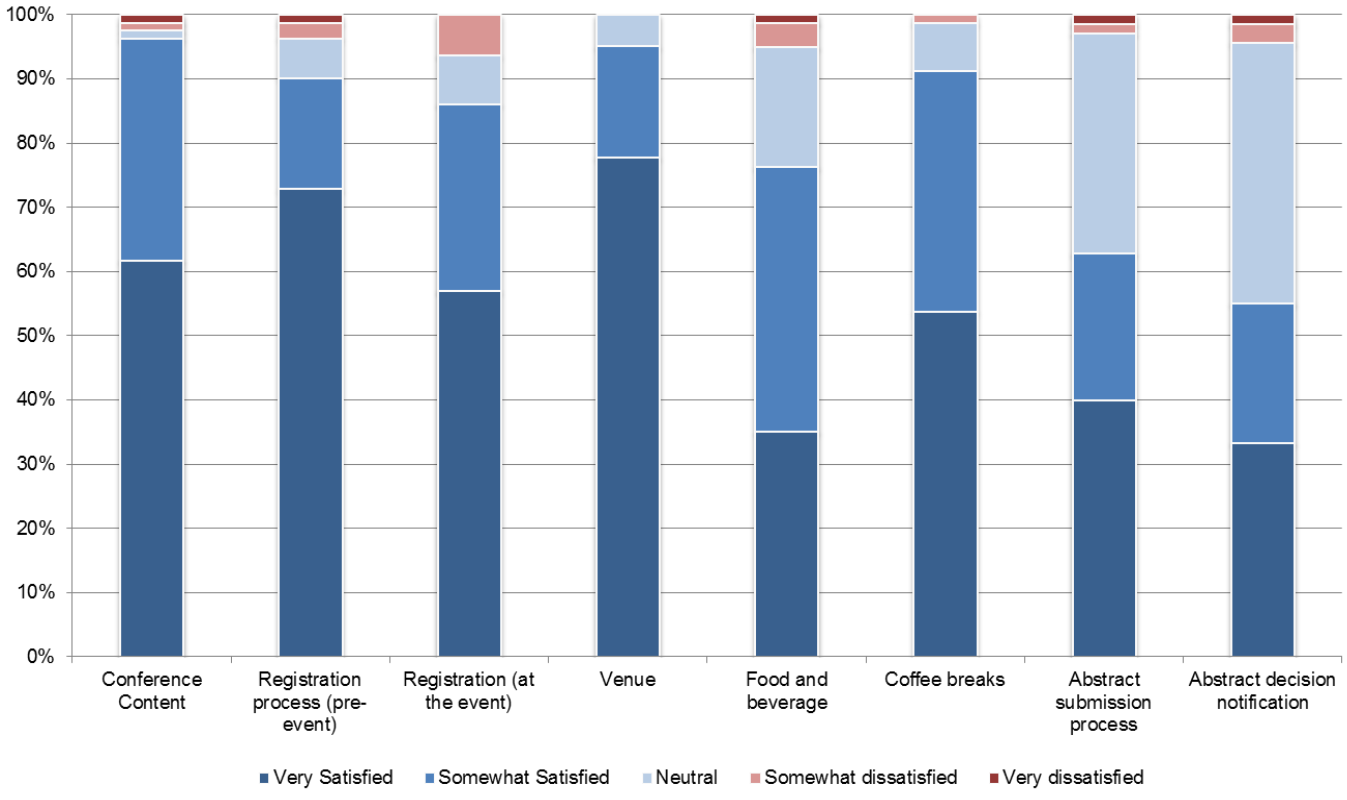
Would you recommend this conference to others?



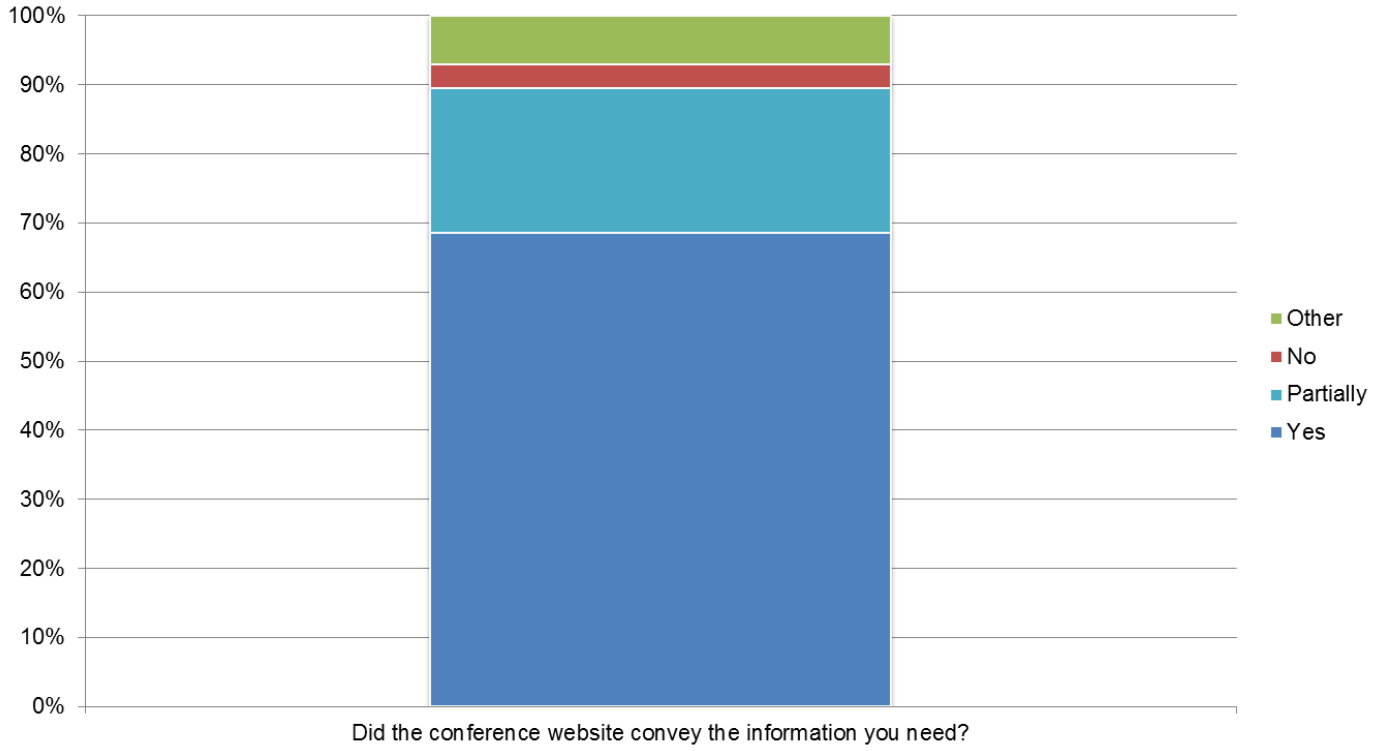
Overall feedback



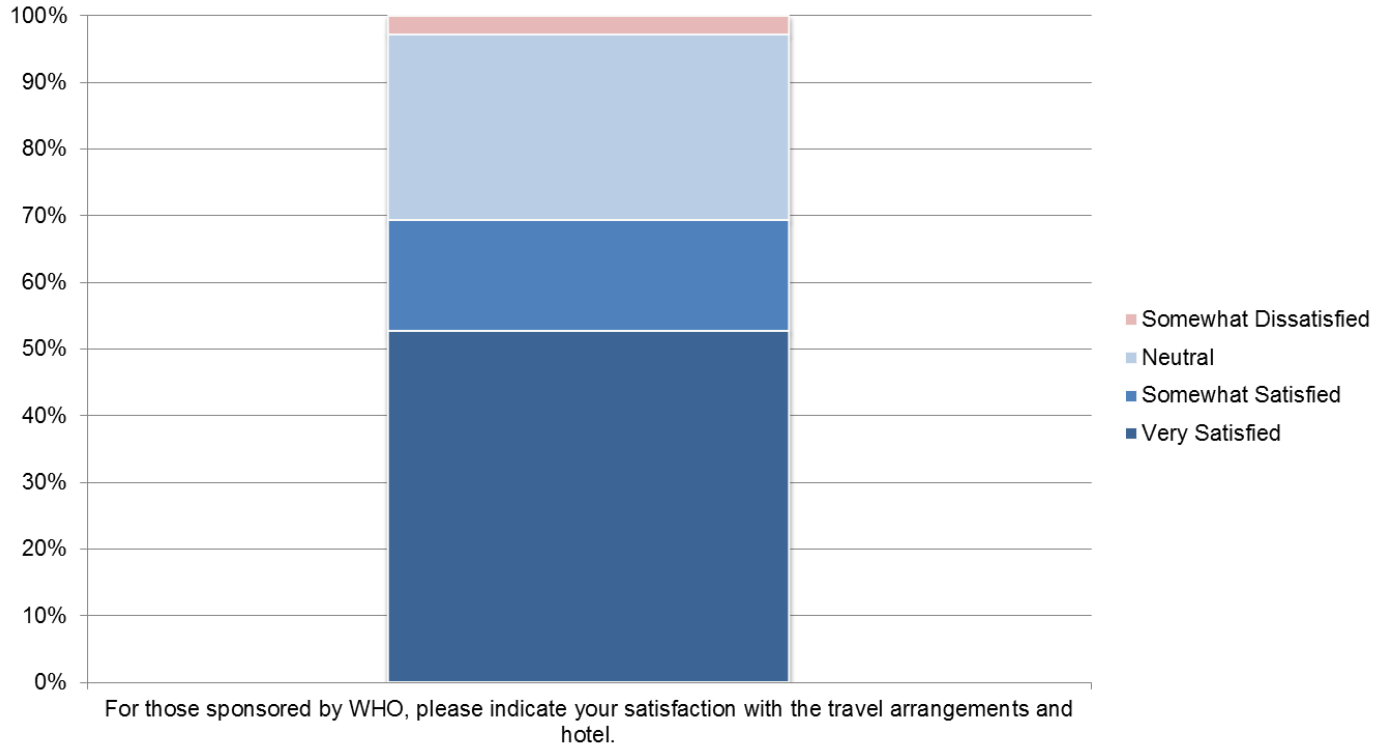
Overall feedback



Did the conference website convey the information you need?



For the sponsored by WHO, please indicate your satisfaction with the travel arrangements and hotel



Appendix 11

World Health Assembly Resolution WHA67.20

Regulatory System Strengthening for Medical Products

The Sixty-seventh World Health Assembly,

Having considered the report on regulatory system strengthening; [1]

Welcoming the efforts of the Director-General, and recognizing the pivotal role that WHO plays in supporting countries in strengthening their regulatory systems of medical products for human use,[2] and in promoting equitable access to quality, safe, efficacious, and affordable medical products;

Recalling the Constitution of the World Health Organization, which affirms that the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition;

Recalling also United Nations General Assembly resolution 67/81 on global health and foreign policy, which, inter alia, recognized the importance of universal coverage in national health systems, especially through primary health care and social protection mechanisms, in the provision of access to health services for all, in particular for the poorest segments of the population;

Recalling further resolutions WHA45.17, WHA47.17, WHA52.19, WHA54.11, WHA59.24, WHA63.12, and WHA65.19, all of which encompass aspects of the need to promote the quality, safety, efficaciousness and affordability of medicines, including blood products;

Reaffirming resolution WHA65.19 on substandard/spurious/falsely-labelled/falsified/counterfeit medical products, which establishes a new Member State mechanism for international collaboration, from a public health perspective, excluding trade and intellectual property considerations, to prevent and control substandard/spurious/falsely-labelled/falsified/counterfeit medical products and to promote access to affordable, safe and quality medical products;

Recognizing that effective regulatory systems are an essential component of health system strengthening and contribute to better public health outcomes, that regulators are an essential part of the health workforce, and that inefficient regulatory systems themselves can be a barrier to access to safe, effective and quality medical products;

Recognizing also that effective regulatory systems are necessary for implementing universal health coverage, responding to the dual burden of infectious and noncommunicable diseases, and achieving Millennium Development Goal 4 (Reduce child mortality), Goal 5 (Improve maternal health) and Goal 6 (Combat HIV/AIDS, malaria and other diseases);

Aware that health systems need to promote access to essential medical products and that, in order to ensure universal access to health care, rational use of medicines and the sustainability of health systems, urgent action is needed by the international community, Member States and relevant actors in health systems;

[1] Document A67/32.

[2] For the purpose of this resolution, medical products include medicines, vaccines, diagnostics and medical devices.

Very concerned by the impact on patients of medical products of compromised quality, safety and efficacy, in terms of poisoning, inadequate or no treatment, contributions to drug resistance, the related economic burden, and erosion of public trust in the health system;

Aware of the regulatory challenges presented by the ever-increasing complexities of medical product supply chains and welcoming the work plan of the Member State mechanism on substandard/ spurious/ falsely-labelled/falsified/counterfeit medical products;

Emphasizing WHO's role in strengthening regulatory systems for medical products from a public health perspective, and in supporting national drug regulatory authorities and relevant regional bodies in this area, and in particular in developing countries;

Recalling WHO's Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, in particular element three, which calls for establishing and strengthening regulatory capacity in developing countries as one effective policy for building and improving innovative capacity, and element six, which promotes establishing and strengthening mechanisms to improve ethical review and regulate the quality, safety and efficacy of health products and medical devices;

Noting with appreciation the many existing national and regional efforts to strengthen regulatory capacity (including through a variety of models), improve regulatory coherence and convergence among regulatory authorities, and enhance good governance, including transparency in decision-making, leading to the improved availability of quality, safe, efficacious and affordable medical products, such as the European Union regulatory framework for medical products, work under way in PAHO following the adoption by its Directing Council in 2010 of resolution CD50.R9 on strengthening national regulatory authorities for medicines and biologicals, the African Medicines Regulatory Harmonization Initiative, and the regulatory harmonization and cooperation work in ASEAN;

Noting the ongoing collaboration between national and regional regulatory authorities in promoting cooperation among regulatory authorities at the regional and global levels;

Recognizing the significant investments made in the procurement of medicines through national health budgets and global health initiatives;

Also recognizing the essential role of WHO's prequalification programme in facilitating procurement of medical products with assured quality, safety and efficacy;

Stressing that the strengthening of regulatory systems should complement the efforts of the Secretariat and Member States to promote access to affordable medical products with assured quality, safety and efficacy;

Recalling the WHO good clinical practices that focus on the protection of human research subjects;

Recalling also WHO's ongoing reform agenda and welcoming in this regard the establishment in November 2012 of the Health Systems and Innovation cluster,

1. URGES Member States:[1]

(1) to strengthen national regulatory systems, including – as appropriate and voluntarily – by:

(a) undergoing self-evaluations, including with WHO support, to identify the strengths and opportunities for improvement in regulatory system functions, as a first step towards formulating plans for regulatory system strengthening, including through WHO-coordinated institutional development plans;

(b) collecting data on regulatory system performance to enable analysis and benchmarking for improved systems in the future;

(c) developing strong legal foundations and political leadership to underpin a regulatory system with a clear focus on patient safety and transparency in decision-making;

(d) identifying and developing a core set of regulatory functions to meet country and/or regional needs, such as market control and postmarket surveillance;

(e) developing needed competencies as an integral part of, although not limited to, the health workforce, and encouraging the development of the regulatory field as a profession;

(f) facilitating the use of relevant guidance and science-based outputs of WHO expert committees and good regulatory practices at the national, regional and international levels;

(g) devising and implementing strategies to address the increasing complexities of supply chains;

(2) to engage in global, regional and subregional networks of national regulatory authorities, as appropriate, recognizing the importance of collaboration to pool regulatory capacities to promote greater access to quality, safe, efficacious and affordable medical products;

(3) to promote international cooperation, as appropriate, for collaboration and information sharing, including through electronic platforms;

(4) to support regulatory systems for medical products with appropriate funding as an essential component of the health system;

(5) to support regulatory system strengthening as an essential component of the development or expansion of local or regional production of quality, safe and efficacious medical products;

(6) to achieve access to and rational use of quality, safe, efficacious and affordable essential medicines, noting the growing emergence of resistance, and as a foundation for achieving broader access to quality, safe, efficacious and affordable medical products;

(7) to support WHO's institutional capacity relating to promoting access to and rational use of quality, safe, efficacious and affordable medical products in the context of universal health coverage;

(8) to strengthen the national and regional initiatives of regulatory authorities to improve regulatory capacities for review of medical products, promoting WHO's long-term objective of supporting the strengthening of national regulatory authority capacity among Member States;

(9) to support WHO's prequalification programme, including exploring modalities in consultation with Member States[2] for improved sustainability of this critical programme;

(10) to identify the need to strengthen regulatory system capacity, collaboration and cooperation in the technically complex areas where substantial gaps may still exist, such as the regulation of biotherapeutic products, blood products, and in vitro diagnostics;

[1,2] And, where applicable, regional economic integration organizations.

2. REQUESTS the Director-General:

(1) to continue to support Member States upon their request in the area of regulatory system strengthening, including, as appropriate, by continuing to:

(a) evaluate national regulatory systems;

(b) apply WHO evaluation tools;

(c) generate and analyse evidence of regulatory system performance;

(d) facilitate the formulation and implementation of institutional development plans; and

(e) provide technical support to national regulatory authorities and governments;

(2) to continue to develop appropriate norms, standards and guidelines, including taking into account national, regional and international needs and initiatives, in accordance with WHO principles;

(3) to ensure that all relevant parts of the Organization, at all levels, are actively engaged and coordinated in the carrying out of WHO's mandate pertaining to regulatory system strengthening as an integrated part of health system development, recognizing that WHO's support in this critical area, particularly for developing countries, may be required, as appropriate, well into the future;

(4) to prioritize support for establishing and strengthening regional and subregional networks of regulatory authorities, as appropriate, including strengthening areas of regulation of health products that are the least developed, such as regulation of medical devices, including diagnostics;

(5) to promote the greater participation of Member States in existing international and regional initiatives for collaboration and cooperation in accordance with WHO principles and guidelines;

(6) to strengthen WHO's prequalification programme, including its integration and coherence, taking into account the needs and capacities of national and regional regulatory systems to assist in ensuring a supply of quality, safe, efficacious and affordable medical products;

(7) to support the building-up of effective national and regional regulatory bodies and networks;

(8) to increase support for and recognition of the significant role of the International Conference of Drug Regulatory Authorities in promoting the exchange of information and collaborative approaches among drug regulatory authorities, and as a resource to facilitate further development of regulatory cooperation and coherence;

(9) to raise awareness of the importance of effective regulatory systems within the health system context;

(10) to increase support and guidance for strengthening the capacity to regulate increasingly complex biological products with the focus on biotherapeutic products, blood products and associated in vitro diagnostics, and, where appropriate, on new medicines for human use based on gene therapy, somatic-cell therapy and tissue engineering;

(11) to ensure that any activity carried out under this resolution does not duplicate or circumvent the work plan and mandate of the Member States mechanism on substandard/ spurious/falsely-labelled/falsified/ counterfeit medical products;

(12) to report to the Seventieth and Seventy-second World Health Assemblies on progress in the implementation of this resolution.

Ninth plenary meeting, 24 May 2014

A67/VR/9

Appendix 12

World Health Assembly Resolution 67.23

Health Intervention and Technology Assessment in Support of Universal Health Coverage

The Sixty-seventh World Health Assembly,

Having considered the report on health intervention and technology assessment in support of universal health coverage;[1]

Recalling resolutions WHA52.19 on the revised drug strategy, WHA58.33 on sustainable health financing, universal coverage and social health insurance, WHA60.16 on progress in the rational use of medicines, WHA60.29 on health technologies, WHA63.21 on WHO's role and responsibilities in health research, and WHA64.9 on sustainable health financing structures and universal coverage;

Recognizing the importance of evidence-based policy development and decision-making in health systems, including decisions on resource allocation, service system designs and translation of policies into practice, as well as reaffirming WHO's roles and responsibilities in provision of support to strengthen information systems and health research capacity, and their utilization in Member States;

Noting that the efficient use of resources is a crucial factor in the sustainability of health systems' performance, especially when significant increases in access to essential medicines, including generic medicines, to medical devices and procedures, and to other health care interventions for promotion, prevention, diagnosis and treatment, rehabilitation and palliative care are pursued by Member States, as they move towards universal health coverage;

Noting that *The world health report 2010*[2] indicates that as much as 40% of spending on health is being wasted and that there is, therefore, an urgent need for systematic, effective solutions to reduce such inefficiencies and to enhance the rational use of health technology;

Acknowledging the critical role of independent health intervention and technology assessment, as multidisciplinary policy research, in generating evidence to inform prioritization, selection, introduction, distribution, and management of interventions for health promotion, disease prevention, diagnosis and treatment, and rehabilitation and palliation;

Emphasizing that with rigorous and structured research methodology and transparent and inclusive processes, assessment of medicines, vaccines, medical devices and equipment, and health procedures, including preventive intervention, could help to address the demand for reliable information on the safety, efficacy, quality, appropriateness, cost–effectiveness and efficiency dimensions of such technologies to determine if and when they are integrated into particular health interventions and systems;

[1] Document A67/33.

[2] The world health report 2010. Health systems financing: the path to universal coverage. Geneva: World Health Organization; 2010.

Concerned that the capacity to assess, research and document the public health, economic, organizational, social, legal and ethical implications of health interventions and technologies is inadequate in most developing countries, resulting in inadequate information to guide rational policy, and professional decisions and practices;

Recognizing the importance of strengthened national capacity, regional and international networking, and collaboration on health intervention and technology assessment to promote evidence-based health policy,

1. URGES Member States:[1]

(1) to consider establishing national systems of health intervention and technology assessment, encouraging the systematic utilization of independent health intervention and technology assessment in support of universal health coverage to inform policy decisions, including priority-setting, selection, procurement supply system management and use of health interventions and/or technologies, as well as the formulation of sustainable financing benefit packages, medicines, benefits management including pharmaceutical formularies, clinical practice guidelines and protocols for public health programmes;

(2) to strengthen the link between health technology assessment and regulation and management, as appropriate;

(3) to consider, in addition to the use of established and widely agreed methods, developing, as appropriate, national methodological and process guidelines and monitoring systems for health intervention and technology assessment in order to ensure the transparency, quality and policy relevance of related assessments and research;

(4) to further consolidate and promote health intervention and technology assessment within national frameworks, such as those for health system research, health professional education, health system strengthening and universal health coverage;

(5) to consider strengthening national capacity for regional and international networking, developing national know-how, avoiding duplication of efforts and achieving better use of resources;

(6) to consider also collaborating with other Member States' health organizations, academic institutions, professional associations and other key stakeholders in the country or region in order to collect and share information and lessons learnt so as to formulate and implement national strategic plans concerning capacity-building for and introduction of health intervention and technology assessment, and summarizing best practices in transparent, evidence-informed health policy and decision-making;

(7) to identify gaps with regard to promoting and implementing evidence-based health policy, as well as improving related information systems and research capacity, and considering seeking technical support and exchanging information and sharing experiences with other Member States, regional networks and international entities, including WHO;

(8) to develop and improve the collection of data on health intervention and technology assessment, training relevant professionals, as appropriate, so as to improve assessment capacity;

2. REQUESTS the Director-General:

(1) to assess the status of health intervention and technology assessment in Member States in terms of methodology, human resources and institutional capacity, governance, linkage between health intervention and technology assessment units and/or networks with policy authorities, utilization of assessment results, and interest in and impediments to strengthening capacity;

[1]And, where applicable, regional economic integration organizations.

(2) to raise awareness, foster knowledge and encourage the practice of health intervention and technology assessment and its uses in evidence-based decision-making among national policy-makers and other stakeholders, by drawing best practices from the operation, performance and contribution of competent research institutes and health intervention and technology assessment agencies and programmes, and sharing such experiences with Member States through appropriate channels and activities, including global and regional networks and academic institutions;

(3) to integrate health intervention and technology assessment concepts and principles into the relevant strategies and areas of work of WHO, including, but not limited to, those on universal health coverage, including health financing, access to and rational use of quality-assured medicines, vaccines and other health technologies, the prevention and management of noncommunicable and communicable diseases, mother and child care, and the formulation of evidence-based health policy;

(4) to provide technical support to Member States, especially low-income countries, relevant intergovernmental organizations and global health partners, in order to strengthen capacity for health intervention and technology assessment, including, when appropriate, the development and use of global guidance on methods and processes based on internationally agreed practices;

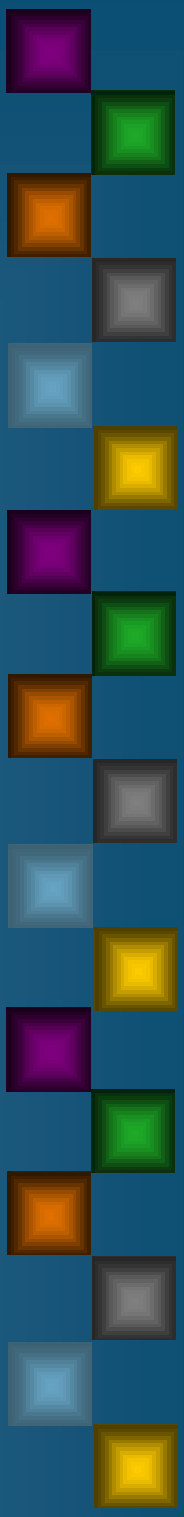
(5) to ensure adequate capacity at all levels of WHO, utilizing its networks of experts and collaborating centres, as well as other regional and international networks, in order to address the demand for support to facilitate evidence-based policy decisions in Member States;

(6) to support the exchange of information, sharing of experiences and capacity-building in health intervention and technology assessment through collaborative mechanisms and networks at global, regional and country levels, as well as ensuring that these partnerships are active, effective and sustainable;

(7) to report on progress in the implementation of this resolution to the Sixty-ninth World Health Assembly.

Ninth plenary meeting, 24 May 2014

A67/VR/9



Medical Devices
Department of Essential Medicines and Health Products
Health Systems and Innovation Cluster
World Health Organization
20 Avenue Appia
CH-1211 Geneva 27
Switzerland
Tel: +41 22 791 1239
E-mail: medicaldevices@who.int
Http://www.who.int/medical_devices/en