# 2nd WHO Global Forum on Medical Devices
## Workshop Programme (as of 18 November 2013)

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<tr>
<td>09:00-09:10</td>
<td>WHO/UN Tools to Improve Healthcare Delivery</td>
<td>Health Technology Assessment</td>
<td>Nomenclature, Standards and Regulations</td>
<td>Health Tech Management / Clinical Engineering</td>
<td>Medical Imaging and Radiation Safety</td>
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<td>09:15-10:00</td>
<td>Supporting integrated national strategic health planning, costing and health impact analysis: the GovemCmHealth tool (GMBHS, UNeoP, WHO, UNCT, UNICEF, the Futures Institute)</td>
<td>GMM - a requirement for Unique Device Identification (GMM Agency)</td>
<td>Healthcare Technology Management (HTM); ACEE advanced clinical engineering workshops (ACCE)</td>
<td>Role of medical physics in promoting radiation safety culture in health care (ICOMP)</td>
<td>Innovation Sandboxes Workshop: engaging medical entrepreneurs to improve health in low- and middle-income countries through the power of co-creation (GAMIS, Min. General Hospital)</td>
<td>MANDATE: priority setting for medical devices to reduce maternal, fetal and neonatal mortality (RTI International)</td>
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<td>10:00-10:45</td>
<td>Service Availability and Readiness Assessment (SUMA) tool for health system planning and management (WHO)</td>
<td>Creating synergies between national HTA and regional HTA agencies and hospitals in the assessment of medical devices (HTA)</td>
<td>Partnership on regulatory harmonisation (AHWP, APEC)</td>
<td>Improving data quality and technology management with mobile devices (Health Partners International)</td>
<td>Medical imaging education in developing countries (JHPIEGO, WHO)</td>
<td>Medical device introduction: adding the Non-gynaecological Antenatal Care (NAGS) for obstetric haemorrhage to programs and policies (UKM)</td>
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<td>10:45-11:10</td>
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<td>11:10-12:00</td>
<td>Crucial role of medical devices in emergency &amp; essential surgical care (WHO)</td>
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<td>12:00-13:30</td>
<td>Lunch / WHO visit</td>
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<td>13:00-14:20</td>
<td>WHO/UN Tools to Improve Healthcare Delivery</td>
<td>Health Technology Assessment</td>
<td>Nomenclature, Standards and Regulations</td>
<td>Health Tech Management / Clinical Engineering</td>
<td>Biomedical Engineering</td>
<td>Innovation</td>
<td>Approaches to improving Healthcare Delivery</td>
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<td>13:00-14:20</td>
<td>Life for humanitarian health response (WHO/UNFPA/UNICEF)</td>
<td>How to set up an HTA agency (INHATA)</td>
<td>International standards – state of play and future trends in the medical domain (IDMed)</td>
<td>Computed Tomography Management Systems (CMRS); essential features and pitfalls to avoid (ACCE)</td>
<td>Human resources for medical devices: the role of the Biomedical Engineer (WHO)</td>
<td>Training for local innovation of affordable and appropriate medical devices in developing countries; learning from the Stanford India Biodesign Experience (All India Inst. of Medical Sciences)</td>
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<td>14:10-15:20</td>
<td>Medical software – regulatory and legal trends (IFDTA)</td>
<td>WHO template for technical specifications of medical equipment (WHO)</td>
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<td>Améliorer les pratiques des projets d'accès à l’équipement medical linguist des docteurs (Prof. BREMET)</td>
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<td>15:20-16:00</td>
<td>Health break</td>
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<td>16:00-16:50</td>
<td>Interagency list of medical devices for reproductive, maternal, newborn and child health (WHO/UNFPA/UNICEF)</td>
<td>Information retrieval for HTA (INHATA)</td>
<td>National Regulatory Assessment tool (WHO)</td>
<td>A new generation web-based medical technology management system (BMST; U. Patras)</td>
<td>Harmonization of biomedical engineering education: states and challenges (IPMRE)</td>
<td>Local production of medical devices in Africa: characterizing the landscape and assessing feasibility (WHO)</td>
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<td>17:00-17:50</td>
<td>WHO Medical Device Information System (WHO)</td>
<td>Digital hospital 21st century: you certainly can’t manage it if you don’t understand it (WCMH/WHO)</td>
<td>Medical equipment donations: a toolkit for UK – developing country partnerships (THET)</td>
<td>Medical equipment education through innovation partnerships (NUS, Univ. of Singapore)</td>
<td>Enhancing biomedical engineering education through innovation partnerships (NUS, Univ. of Singapore)</td>
<td>Optimizing the WHO Compendium of Innovative Health Technologies for low-resource settings (WHO)</td>
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<td>17:50-18:00</td>
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<td>Disaster preparedness for health technology managers (LIFESP)</td>
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### 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 Kalliirroi Stavrianou, INBIT (Greece)

**Medical equipment donations: a toolkit for UK – developing country partnerships**
## 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, IFMBE (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)
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)

The OneHealth tool is the first of its kind and was developed as a multi-agency initiative with widespread international support. It is a software application developed to support countries in estimating the resource requirements for a comprehensive and integrated national health strategic plan. The tool allows users to project health sector needs for years into the future, plan budgets, plan for specific numbers of health care providers, plan the quantity and unit costs of pharmaceuticals that will be needed, identify where bottlenecks are likely to occur in the projection and planning, and assess the likely health impact (mortality and morbidity) that the planned provision of health interventions will result in. This workshop will provide key information on how to initiate and operate this 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)

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 will present the overview of this tool and as well as a few country reports.

Back
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.

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 will inform 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.

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.

This workshop will 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 will use 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)

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 is 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.

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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)

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 aims 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. We also welcome the opportunity for workshop participants to share examples of using a database on medical devices at the country level.

Back
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

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

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 overall impact, prompting 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 effective and efficient care in a resource-poor setting.

Conducting HTA requires specialized skills which vary from country to country and also within a single 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, which currently has members across all continents, has used certain criteria to formally recognize HTA agencies. This provides some form of a standard for establishing and maintaining a HTA agency.

This workshop will focus on the criteria used by INAHTA for recognition of an HTA agency and take a stepwise approach to guide the participants through a process of establishing HTA agencies in their own setting. HTA agencies from 4 different countries and from different backgrounds will share their perspectives on setting up an agency. Two of the agencies have been in existence for a number of years and are well established, while the other two agencies are new. These agencies will share their experiences with establishing an HTA agency and maintaining their affiliation with INAHTA.

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)

Health care decisions should be based on the best available evidence. To provide decision-makers with an unbiased evidence base, HTA agencies need to have skills in searching and familiarity with the various aspects of information retrieval for HTA. In addition, it is important for agencies to facilitate services, resources, and processes that are needed for information retrieval for HTA. This workshop will alert participants to key issues regarding literature searching for HTA, as well as to services, resources and competencies that are needed for information retrieval for HTA. The workshop will focus on important aspects 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.
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)

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 is 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 will explain the features and benefits of the GMDN and its relationship to UDI. Examples of the use of UDI will be presented. Opportunities will be available for the audience to ask questions on access and implementation of the GMDN.
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

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.

Back
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)

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 is 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 will also be 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 will give 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.

Back
Medical software – regulatory and legal trends

Time: 14:30-15:20, Friday 22 November 2013
Organizers: DITTA
Ms Nicole Denjoy (denjoy@cocir.org)

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 will provide clarity and build awareness of the regulatory framework for Medical Apps and other stand-alone software and will also identify 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 will then be 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)

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 aims 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.
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: Center 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 - Center 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

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 will demonstrate the CE Role through national and global case studies of the USA (Meaningful Use, IHE, FDA, ONC/TJC), Saudi Arabia, Colombia, and Macedonia.

Back
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

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 will provide concise background on these ACEWs and focus 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.

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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)

The first part of this workshop will provide 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 of the workshop participants will 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 the Planning and Management of Assets in Health Services (PLAMAHS) programme, 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.

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)

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 will give 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 will be discussed. The session will end with an open discussion of audience experiences with implementing CMMS. Topics to be covered in the workshop will include: 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.
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)

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 is to share and provide feedback regarding the content, process and application of technical specifications at the country level. We will also share the experience of developing technical specifications in the UN.

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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 Efmarfia Adamidi, University of Patras

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 minimized cost, 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 workshop 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 previously 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 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.

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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

The Tropical Health and Education Trust (THET) is a UK-based specialist global health organization 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. This workshop will serve as a forum in which to share the toolkit. We will 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.
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

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 behaviour 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”.

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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) ([labuscagne@isradiology.org])
Dr Dieter Nuernberg (WFUMB)
Mr Stewart Whitney (ISRRT)

Introduction

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 will outline the various international organizations' current programs and material for education.
2. This will be followed by opportunity for participants to give information about their situations and needs.
3. Discussion about possible actions.
**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)

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 current contents of the book will be discussed and debated with the goal of producing an effective and useful publication. The authors of each chapter will present their section of the book, after which participants will discuss and make 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)

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 is the intention here to describe a method to establish the minimum core of competencies for Clinical Engineering. We will then consider 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 will present 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

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 will address these items and try to propose 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)

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 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.

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.

Our 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 from its existing network. Each entrepreneur will present his/her 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). 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.

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.

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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

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 will educate potential innovators about the fundamentals and philosophy of local innovation of affordable medical devices. It will also educate policymakers from low-income countries about the working of a successful innovation process and program. The session will feature 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.
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

“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, will include 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 will be 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

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 will discuss the issues surrounding the annual call for technologies, the method of evaluation of the submissions, and the dissemination of the publication. Furthermore, the workshop will address how to improve the publication’s utility. It will be an open discussion moderated by WHO staff.
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

This workshop will provide 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 will provide participants with an overview of the framework for MANDATE and instruct them on its use by running the model with workshop participants to develop case studies. Following the workshop, participants will be 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

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 will lead 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 will lead 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 will then share 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 will introduce participants to our online NASG Toolkit of resources they can use to support the introduction/implementation process.

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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*

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<td>Organizers: HUMATEM</td>
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<tr>
<td>Ms Cathy Blanc-Gonnet, HUMATEM  (<a href="mailto:cathy.blancgonnet@humatem.org">cathy.blancgonnet@humatem.org</a>)</td>
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<td>Ms Aurélie Jeandron, HUMATEM, Ms Barbara Comte, HUMATEM, Mr Maurice Page, HUMATEM</td>
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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 obsolesces). 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/ Istituto Superiore Mario Boella
Mr Ludovico Ciferri, International University of Japan/ISMB (lciferri@iuj.ac.jp)
Dr Emiliano Albanese, Université de Genève
Dr Paolo Ariano, Istituto italiano di tecnologia
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)

Increases in life expectancy and reduction of communicable diseases are resulting in an unprecedented epidemic of chronic diseases. Amongst these, demographic projections show that the prevalence of dementia and that 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. This workshop will introduce 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. The 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 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.
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
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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 will provide 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 will be presented by experts from the clinical engineering and medical physicist’s communities and will offer solutions that can improve the safety of hospitals in disaster events.