

Affordability

Safety
Equity

Effective









Improving access to safe, effective and innovative quality medical devices











Second WHO Global Forum

on Medical Devices:

Priority Medical Devices for Universal Health Coverage

Centre International de Conférences Genève (CICG) Geneva, Switzerland 22–24 November 2013



Acknowledgements

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The Ministry of Health, Welfare and Sport, Netherlands

The European Commission

The members of the Programme Committee and the Local Organizing Committee.

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Welcome

Distinguished ladies and gentlemen:

On behalf of the World Health Organization, we welcome you to Geneva, Switzerland for The Second WHO Global Forum on Medical Devices: Priority Medical Devices for Universal Health Coverage, providing the global public health community an opportunity for unprecedented collaboration to increase access to high-quality, safe, and appropriate-priority medical devices. Our global health initiative aims to impact all aspects of healthcare delivery, from diagnosis to treatment, and further enable those from academia, international organizations, industry, and NGOs to exchange their own experiences and challenges in our common endeavour to provide more equitable access to medical devices, particularly in limited-resource settings.

We thank you for your enthusiastic response to the call for abstracts, which has enabled us to organize a 3-day program that includes 28 workshops, 159 oral presentations in parallel sessions, 144 posters, and 8 films. You will join approximately 700 of your colleagues from 108 countries in 4 plenary sessions that will address the key issues facing the medical device community in 2013.

Thank you very kindly for your attendance and participation,

The Local Organizing Committee



Contact information:

Medical Devices, Policy Access and Use, Essential Medicines and Health Products Department World Health Organization

http://www.who.int/medical_devices/en/

20 Avenue Appia, 1211, Geneva 27, Switzerland medicaldevices@who.int

Meeting Objectives

- 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.

Background

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. Medical devices involve those health technologies that are critical to delivery within health systems. However, attention to issues of equity, quality and access is insufficient, and often the most essential medical devices are not available.

The 1st Global Forum on Medical Devices took place in Bangkok in September 2010, with participants coming from 107 Member States. The event raised awareness and served as a forum to share ideas on how to increase access to safe and effective medical devices.

Now, 3 years later, the 2nd Global Forum on Medical Devices will address the development of lists of medical devices by clinical intervention and disseminate information about innovative, appropriate, and affordable devices for low-resource settings in accordance with the WHA 60.29 resolution.

2nd WHO Global Forum on Medical Devices

22-24 NOVEMBER 2013 CICG, GENEVA, SWITZERLAND

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 Radiation Safety / Biomedical Engineering Innovation	Salle 1 Salle 18 Salle 3 Salle 2 Salle 5/6 Salle 4
	Reproductive, Maternal, Newborn and Child Health / Approaches to Improving Healthcare Delivery	Salle 15

Saturday 23 November 2013

09:00-10:00	PLENARY SESSION 1 "Medical devices for Universal Health Coverage"		Salle 1
10:30—12:00	PARALLEL SESSIONS Health Technology Assessment: Networks and Socie Health Technology Management: Country Initiative Regulation of Medical Devices Innovation in Medical Devices Health Care Delivery / Health Care Infrastructure		Salle 4 Salle 2 Salle 3 Salle 1 Salle 5/6
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 Initiative Regulation of Medical Devices: Country Initiatives Innovation in Medical Devices for Maternal and Chi Medical Imaging	* Spanish translation available *	Salle 4 Salle 2 Salle 3 Salle 1 Salle 5/6
16:00-17:00	PLENARY SESSION 2 "The unifinished agenda: medical devices are indis	pensable for reaching the MDG targets"	Salle 1
17:00-19:00	Film viewing	Social networking / poster viewing	Salle 2

Sunday 24 November 2013

09:00-10:00	PLENARY SESSION 3 "Medical devices for the Non-Communicable Diseases (NCD) agenda"	Salle 1
10:30-12:00	PARALLEL SESSIONS Health Technology Assessment Policies for Medical Devices / Technical Specifications Safety of Medical Devices Innovative Medical Devices for Low-Resource Settings Human Resources in BME * French translation available *	Salle 4 Salle 2 Salle 3 Salle 1 Salle 5/6
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 Patient safety / Medical Software Innovative Medical Devices for Low-Resource Settings Human Resources for Technology Life Cycle Management / Human Resources in Medical Physics	Salle 4 Salle 2 Salle 3 Salle 1 Salle 5/6
16:00-16:45	PLENARY SESSION 4 "Policies, innovation, regulation, assessment, management and safe use of medical devices for increasing access"	Salle 1
16:45-17:00	CLOSING SESSION Summary of recommendations from parallel sessions and closure of Forum	Salle 1
17:00	ADJOURN	

 $^{^{\}ast}$ All plenary sessions will have French and Spanish translation available *

WORKSHOP PROGRAMME (AS OF 18 NOVEMBER 2013) FRIDAY 22 NOVEMBER

09:00-09:10	PLENARY / WELCOME / LOGISTICS						
	Salle 1	Salle 18	Salle 3	Salle 2	Salle 5/6	Salle 4	Salle 15
	WHO/UN Tools to Improve Healthcare Delivery	Health Technology Assessment	Nomenclature, Standards and Regulations	Health Tech Management / Clinical Engineering	Medical Imaging and Radiation Safety	Innovation	Reproductive, Maternal, Newborn and Child Health
09:15–10:00	Supporting integrated national strategic health planning, costing and health impact analysis: the OneHealth Tool (UNAIDS, UNDP, WHO, WB, UNFPA, UNICEF, the Futures Institute)	Creating synergies	GMDN - a requirement for Unique Device Identification (GMDN Agency)	Healthcare Technology Management (HTM): ACCE advanced clinical engineering workshops (ACCE)	Role of medical physics in promoting radiation safety culture in health care	Innovation Sandbox Workshop: engaging medtech	MANDATE: priority setting for medical devices to reduce maternal, fetal and neonatal mortality
10:00–10:45	Service Availability and Readiness Assessment (SARA) tool for health system planning and management (WHO)	between national HTA and regional HTA agencies and hospitals in the assessment of medical devices (HTAi)			(IOMP)	entrepreneurs to improve health in low- and middle-income countries through the power of co-creation (CAMTech,	(RTI International)
10:45-11:10	Health break		Health break	Health break	Health break	Mass. General Hospital)	Health break
11:10–12:00	Crucial role of medical devices in emergency & essential surgical care (WHO)		Partnership on regulatory harmonization (AHWP, APEC)	Improving data quality and technology management with mobile devices (Health Partners International)	Medical imaging education in developing countries (ISR, WFUMB, ISRRT)	позрны	Medical device introduction: adding the Non-pneumatic Anti Shock Garment (NASG) for obstetric haemorrhage to programs and policies (UCSF)
12:00-13:30				Lunch / WHO visit			
	WHO/UN Tools to Improve Healthcare Delivery	Health Technology Assessment	Nomenclature, Standards and Regulations	Health Tech Management / Clinical Engineering	Biomedical Engineering	Innovation	Approaches to Improving Healthcare Delivery
13:30–14:20	Kits for humanitarian health response	How to set up an HTA agency	International standards — state of play and future trends in the medical domain (DITTA)	Computerized Maintenance Management Systems (CMMS): essential features and pitfalls to avoid (ACCE)	Human resources for medical devices: the role of the Biomedical Engineer (WHO)	Training for local innovation of affordable and appropriate medical devices in developing countries: learning	Améliorer les pratiques des projets d'appui à l'équipement médical intégrant des dons (Improving practices in medical equipment
14:30–15:20	(WHO/UNFPA/ UNICEF)	(IÑAHTA)	Medical software — regulatory and legal trends (DITTA)	WHO template for technical specifications of medical equipment (WHO)	How to define the basic academic curriculum to train clinical engineers (CED/IFMBE)	from the Stanford India Biodesign Experience (All India Inst. of Medical Sciences)	support projects which include donations) (HUMATEM) * in French and English, not translated *
15:20-16:00				Health break			
16:00–16:50	Interagency list of medical devices for reproductive, maternal, newborn and child health (WHO/UNFPA/ UNICEF)	Information retrieval	National Regulatory Assessment tool (WHO)	A new generation web-based medical technology management system (INBIT, U. Patras)	Harmonization of biomedical engineering education: status and challenges (IFMBE)	Local production of medical devices in Africa: characterizing the landscape and assessing feasibility (WHO)	A tool for prevention and early diagnosis of neuro-degenerative diseases (Intl. U. of Japan)
17:00–17:50	for HTA (NOKC) WHO Medical Device Information System (WHO)		Digital hospital 21st century: you certainly can't manage it if you don't understand it [YCCMIYDUI] (CHIRP)	Medical equipment donations: a toolkit for UK — developing country partnerships (THET)	Enhancing biomedical engineering education through innovation experiences (Nat. Univ. of Singapore)	Optimizing the WHO Compendium of Innovative Health Technologies for Low- Resource Settings (WHO)	Disaster preparedness for health technology managers (IUPESM)

Useful information

Forum venue

Centre International de Conférences Genève Rue de Varembé 17 1211 Geneva

Internet

WiFi login: OMS Password: WHO



For SpotMe updates

Username: WHO13 Password: geneva13

Transportation to the CICG: Near all pre-booked hotels (except Ibis Nations), tram 15 can take you in the direction of the CICG terminus stop *Nations*. From Ibis Nations, bus 8 can transport you to the CICG stop *UIT* in the direction OMS/Appia.

Food at the venue

CICG restaurant in the venue offers reasonably priced meals (around 10-20 CHF).

Currency

Local currency is Swiss Francs (CHF) not Euros. Exchange rate is around US \$ 0.93.

Geneva tourism sites:

http://www.geneve-tourisme.ch http://myswitzerland.com http://www.geneva.com http://search.ch.com

Geneva transportation:

Geneva bus and tram information: http://www.tpg.ch/

Swiss train information: http://www.sbb.ch/ticketshop

Taxi stands are at almost all main squares. The Forum venue (CICG) is about 10 minutes from the airport (25-30 CHF). A taxi from the airport to the town centre costs 35–50 CHF.

Taxi-phone SA Geneva: +41 22 33 141 33 www.taxi-phone.ch AA Genève Central Taxi: +41 22 3 202 202 www.geneve-taxi.ch

Presenter guidelines

Speakers

- Speakers should deliver their slides to conference organizers the day before the presentation or before the start of the plenary session the morning of their talk.
- Speakers should arrive 15 minutes prior to the session start.
- To allow sufficient time for panel discussion, time limits will be strictly enforced.
- Speakers are expected to be present for the duration of the session.

Posters

- Posters should be set up before 08:00 on Saturday 23 November.
- Posters must be removed between 17:00 and 19:00 on 24 November.
- Poster presenters should be at the designated poster area at least 10 minutes before their assigned poster session begins and, if possible, during the lunch hour and coffee breaks.

Films

- Film presenters should arrive 15 minutes prior to the start of the film viewing.
- Each presenter may give a brief (1 minute or less) introduction before his/her video.
- After all films are completed, film presenters will participate in panel discussion.

Collaborating organizations

UN agencies







Non-governmental organizations in official relations with WHO

International Federation for Medical and Biological Engineering



International Federation of Hospital Engineering



International Society of Radiology



International Society of Radiographers & Radiological Technologists



International Union of Architects



World Federation for Ultrasound in Medicine and Biology



Organizations with memoranda of understanding with WHO

International Information Network on New and Emerging Health Technologies



Health Technology Assessment International



International Network of Agencies for Health Technology Assessment



Organization of Medical Physics



Other collaborating organizations

American College of Clinical Engineering



Diagnostic Imaging, Healthcare IT & Radiation Therapy Trade Association



Global Medical Technology Alliance





Institute of Biomedical Technology



International Union for Physical and Engineering Sciences in Medicine







	2 nd WHO Global Forum on Medical Devices Plenary Sessions	
Time	Plenary session 1 - Saturday 23 rd November 2013	Room
	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 2 nd WHO Global Forum on Medical Devices	
	Dr. Margaret Chan, Director General, WHO (video message) Challenges in Universal Health Coverage a Japanese perspective	
	Challenges in Universal Health Coverage, a Japanese perspective Dr. Masato Mugitani, Ex-chair, Global Health Workforce Alliance	
Sat.	Health Technology Assessment to select priority interventions, HITAP perspective	
9:00 - 10:00	Dr. Suwit Wibulpolprasert, Health Intervention and Technology Assessment Program (HITAP), Thailand	Salle 1
	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. Cicala Abbam. Clobal Medical Technology Alliance	
	Ms. Gisela Abbam, Global Medical Technology Alliance	
	Plenary session 2 - Saturday 23 rd November 2013	
	The unfinished agenda: medical devices are indispensable for reaching the MDG targets Chair De Flizabeth Man Macon Dispensable 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	
Sat.	Supply of appropriate medical devices for women and children's' health	
16:00 - 17:00	Dr. Helen Moller, United Nations Children's Fund (UNICEF)	Salle 1
	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 24 th November 2013	
	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	
Sun. 9:00 - 10:00	Dr. Ian Labuscagne, President, International Society of Radiology	Salle 1
J.00 - 10.00	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 24 th November 2013	
	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)	
Sun.	The way forward to educate the next generation of biomedical engineers	
16:00 - 17:00	Dr. Ratko Magjarevic, International Federation for Medical and Biological Engineering (IFMBE)	Salle 1
	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	
	Ms. Adriana Velazquez Berumen, WHO Closing remarks	
	Mr. Kees de Joncheere, Director, Essential Medicines and Health Products, WHO	
	ADJOURN	

Time	Parallel sessions - Saturday 23rd November 2013	Room
	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)	
Sat. 10:30- 12:00	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	Salle 18
	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?	Salle 2
	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	

Time	Parallel sessions - Saturday 23rd November 2013	Room
	Regulation of Medical Devices	
	Session Chair: Ms. Kimberly Trautman	
	Session Co-Chair: Ms. Robyn Meurant	
Sat. 10:30- 12:00	Harmonization and in-country implementation of regulations	
	Shelley Tang, Australia	
	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	
Sat.	IMDRF review of the NCAR exchange program: challenges and opportunities	
	Dr Isabelle Demade, European Commission, Belgium	Salle
	Best international PMS practice and in-country implementation of PMS systems	21,22
	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	
	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	
Sat.	America	
10:30-	Partnership in medical technology innovation: avoiding the prototype graveyard	Salle 1
12:00	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	

Time	Parallel sessions - Saturday 23rd November 2013	Room
	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	
Sat.	Should we train users in equipment care?	
10:30-	Mr. Andrew Gammie, Fishtail Consulting Ltd, United Kingdom	Salle 5/6
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	
	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	

Time	Parallel sessions - Saturday 23rd November 2013	Room
	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	
Sat.	Prof. Richard Lilford, Samantha Burn-Harris, Karin Diaconu, Semira Manaseki-Holland, Carole Cummins, University of	
14:00-	Birmingham, United Kingdom	Salle 18
15:30	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 Conté, Clarico Potromalo Mania Caputo, Erlan Cosar Dango, Marcio Luis Borsio, Darcio Cuados Junior	
	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	
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Time	Parallel sessions - Saturday 23rd November 2013	Room
	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	
Sat.	Connaught Government Hospital in Freetown, Sierra Leone	
14:00-	Mr. Alusine Bobson Kabia, Dr. Oliver Johnson, Ministry of Health of Sierra Leone	Salle 2
15:30	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 equiment 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	
	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,	
Sat.	Peru Post market surveillance in Saudi Arabia	
14:00-		Salle
15:30	Dr. Saleh Al Tayyar, Saudi Food and Drug Authority, Abdullah Thabit, Medical Devices Sector of Saudi Food and Drug Authority, Saudi Arabia	21,22
13.30	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	

Time	Parallel sessions - Saturday 23rd November 2013	Room
	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	Salle 1
	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	
Sat.	Mr. Grzegorz Dajer, Medical Technology Transfer and Services Ltd., Vietnam	
14:00-	Ventouse delivery in a low resource setting - A innovative device	Salle 1
15:30	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 taskshifting 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	
	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	
Sat.	Prof. Emilio Quaia, Guido Grisi, Elisa Baratella, Roberto Cuttin, Gabriele Poillucci, Sara Kus, Maria Assunta Cova,	Salle 1
14:00-	Department of Radiology, University of Trieste, Italy	Salle 5/6
15:30	Experience review on digital imaging, PACS and tele-radiology from a middle income country	Suite 5, 6
25.50	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. Sailoch Chutani, Mobicanto Inc., United States of America.	
	Dr. Sailesh Chutani, Mobisante Inc., United States of America	
	Is digital imaging helping to achieve service coverage? Experience review from a middle income country Mr. Martin Bash, Swiss Tropical and Bublic Health Institute, Basel, Switzerland, Dr. Tarek Badr, Dr. Dorria Salem, Dr.	
	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	
	Jenam Elsaavany, Directorate General of Kaulology of Millistry of Health and Population, Egypt	

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Time	Parallel session - Sunday 24th November 2013	Room
	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	
Sun.	Prof. Alan Murray, Newcastle University, United Kingdom	Salle
10:30-	Assessment of adverse events related to the use of the computed tomography equipment	1
12:00	Mr. Ricardo Alcoforado Maranhão Sá, Secretaria De Estado Da Saúde De Goiás, Brazil; Walter Vieira Mendes Júnior,	21,22
	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	
	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	
Sun.	A behaviour changing syringe: Making invisible risk, visible to deter the reuse of syringes in a curative context	
10:30-	Dr. David Swann, University of Huddersfield, United Kingdom	Salle 1
12:00	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, AllMS, 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	
	Disruptive innovation for sustainable healthcare - Enabling technologies for portable ultrasound devices	
	Prof. Daniel Steenstra, Dr. John Ahmet Erkoyuncu, Cranfield University, United Kingdom	

Time	Parallel session - Sunday 24th November 2013	Room
Sun. 10:30- 12:00	Human Resources in BME 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	Salle 5/6
	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	

Time	Parallel session - Sunday 24th November 2013	Room
	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	1
	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	
Sun.	Dr. Ruth McNerney, London School of Hygiene & Tropical Medicine, United Kingdom	Calla 10
14:00- 15:30	Assessing feasibility of local production of medical devices in Sub-Saharan Africa to improve access to quality medical care	Salle 18
15.50	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	
	Procurement of Medical Devices (French translation available)	
	Session Chair: Mr. Andreas Seiter	
	Session Co-Chair: Mr. Prem Prakash Chopra	1
	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	
Sun.	Dr. Maurice Paul David Burke, Abiodun Adeyemi, Paula Horne, Kate Ricketts, Royal Berkshire Hospital, James	C-11- 2
14:00-	Annkah, Ivan Rosenberg, Gary Royle, University College London, Shauna Mullally, Tropical Health and Education	Salle 2
15:30	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	1
	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	
	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	1
	Prof. Benedetta Allegranzi, WHO, Switzerland	
	Lessons learned and challenges in implementation planning for injection safety initiatives	1
	Prof. Benedetta Allegranzi, WHO, Switzerland	1
Sun. 14:00-	Perspectives of a new WHO injection safety initiative focusing on therapeutic services	
	Dr. Edward Kelley, WHO, Switzerland	Salle
	Medical Software Session Chair: Dr. Edward Kelley	21,22
15:30	Session Co-Chair: Ms. Helena Ardura-Garcia	′
	Medical software: are clinical engineers ready to face the challenge?	1
	Dr. Ernesto ladanza, 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	1
	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	

Time	Parallel session - Sunday 24th November 2013	Room
Sun. 14:00- 15:30	Innovative Medical Devices for Low-Resource Settings 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	Salle 1
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 Human Resources in Medical Physics Session Chair: Dr. Kin Yin Cheung Session Co-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; Raymond Wu, IOMP and Barrow Neurological Institute, United States of America	Salle 5/6

	Second WHO Global Forum on Medical Devices	
	Posters	
	A. Economics of medical devices	
A.01	Atrial septal defect (ASD) device closure using a device sizing formula without balloon sizing or invasive	
A.01	echocardiography is safe, cost effective and increases access to treatment	
	Gamini Galappatthy, Ruvan Ekanayaka, <i>The National Hospital of Sri Lanka, Sri Lanka</i>	
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, <i>Turkey;</i> Funda Özdiler, Ismet Köksal, Osman Nacar, Ercan Simsek, <i>Turkish Medicine and</i>	
4.07	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, <i>University of British Columbia, Canada</i> ; Scott Braithwaite, <i>New York University, United States of America</i> ; Mia Van Der Kop, <i>Karolinska Institutet, Sweden</i>	
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	

	Posters
	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, <i>University of the Philippines, Manila</i>
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, <i>Center for Preventive Medical Science</i> ,
	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, <i>Benin</i>

	Posters
	D. Healthcare Technology Management (HTM) (Clinical Engineering)
D.01	A new validation method proposal for electrical performance in electroscalpels using finite element
0.01	analysis (FEA)
	Sebastian Torres Montoya, Yesid Montoya Goez, Claudia E. Echeverri Cuartas, <i>Antioquia Engineering</i>
	School, CES University; Lina María Tapias, IO Interquirofanos, Colombia Immediate impacts of an inventory on the procurement, donations, maintenance and use of medical
D.02	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, <i>University of Vermont, United States of America</i> ; Yadin David, <i>United States of America</i>
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, <i>Turkish</i>
	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
D 15	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
D.16	BMET support
	Beverly Bradley, Samantha Chow, Yu-Ling Cheng, <i>University of Toronto, Canada</i> ; Ebrima Nyassi, <i>Biomedical</i>
	Engineering Unit, Medical Research Council, The Gambia; David Peel, United Kingdom; Stephen RC Howie,
5.47	Child Survival, Medical Research Council
D.17	The problem of acquisition and maintenance of biomedical equipment in Burkina Faso
D.18	Zida Ouambi Emmanuel, <i>Ministry of Health, Burkina Faso</i> Ubiquitous management methodology for medical equipment
D.16	William Alberto Cruz Castañeda, Renato Garcia Ojeda, <i>Biomedical Engineering Institute, Federal University</i>
	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

	Posters
	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, <i>National Health Systems Resource Centre, India</i>
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
5.04	Improving medical devices management in the hospitals by introducing a health technology lecture in the
F.01	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
1.02	biomedical engineering
	Elsie Effah Kaufmann, <i>University of Ghana, Ghana;</i> 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, <i>University of Michigan, United States of America</i>
F.04	Multinational undergraduate engineering student clinical immersion experience in obstetrics
	Kathleen Sienko, Amir Sabet Sarvestani, <i>University of Michigan, United States of America</i> ; 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
1.07	Marcelo Hayashide, Priscila Sousa de Avelar, Renan Feltrin, Renato Zaniboni, Renato Garcia Ojeda, <i>Institute</i>
	of Biomedical Engineering, Federal University of Santa Catarina, Brazil
	Brazilian industrial complex and innovation in health: Biomedical engineering training in Brazil,
F.08	achievements and challenges
	Sergio Santos Mühlen, <i>Universidade Estadual de Campinas, Brazil;</i> Paulo Henrique Dantas Antonino,
	Eduardo Jorge Valadares Oliveira, Carlos Augusto Grabois Gadelha, <i>Ministry of Health, Brazil</i>

Posters
G. Innovation
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
Open-source medical device compendium for global health
Amir Sabet Sarvestani, Kathleen H Sienko, <i>University of Michigan</i> ; Lonny Grafman, <i>Humboldt State</i>
University, United States of America
Innovative materials and technologies in orthopedics
Serian Doma, Bedriye Akdemir, Funda Özdilier, Osman Nacar, Ismet Köksal, Saim Kerman, <i>Turkish Medicine</i>
and Medical Devices Agency, Turkey
R&D and innovation in medical technologies in Lebanon
Sandy Rihana, Biomedical Engineering Department, Holy Spirit University, Lebanon
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
Improving access to medical devices in low-resource settings through local production and technology transfer: WHO 2013 survey results
Peng Si (<i>Nanyang Technological University, Singapore</i>); James Abbas (<i>Arizona State University, United</i>
States of America); Mladen Poluta (University of Cape Town, South Africa); Amir Sabet Sarvastani
(University of Michigan, United States of America); Adriana Velazquez-Berumen, World Health
Organization, Switzerland

	Posters
	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, <i>Chile</i> ; Manuel Duarte, Nicolas Beltran, Carlos Conca, <i>Facultad de Ingenieria, Universidad de Chile</i>
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, <i>Rice University, United States of America</i> ; Rohith R. Malya, AD Noland, <i>University of Texas Medical School at Houston, United States of America</i>
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, <i>University of Freiburg, Germany</i>
H.06	An electrical impedance based neonatal respiration monitor for pneumonia detection
	Khondkar Siddique-e Rabbani, Shahnaj Parvin, Imtiaz Ahamad Khan, Muhammad Abdul Kadir, <i>Department of Biomedical Physics & Technology, University of Dhaka, Bangladesh</i>
H.07	A smartphone-based mobile multi-modal optical imaging platform for cervical cancer screening
11.00	David Levitz, Ariel Beery, Amit Safir, <i>Israel</i>
Н.09	Digital tomosynthesis of the chest: serial radiographic response in patients with pulmonary tuberculosis John Sabol, <i>United States of America</i> ; Hyesun Hwang, Myung Jin Chung, Won-Jung Koh, Kyeongman Jeon, Kyung Soo Lee, <i>Department of Radiology and Center for Imaging Science, Samsung Medical Center,</i> Sungkyunkwan University School of Medicine, Korea
H.10	The design of a traditional adult male circumcision device
	Amir Sabet Sarvestani, Kathleen H Sienko, <i>University of Michigan, United States of America</i>
H.11	Non-invasive hemoglobin screening for diagnosis and monitoring of anemia
11.42	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, <i>Ateneo de Manila University, Philippines</i> ; Josephine R.
	Bundoc, <i>Physicians for Peace, Philippines</i> Affordable Multisensor Perinatal Monitoring Concept - The importance of signal quality indices for
H.13	successful mHealth implementation
	Lisa Stroux, Gari Clifford, University of Oxford, United Kingdom
	German healthcare stakeholders perspectives regarding the value of a diagnostic device for heart failure:
H.16	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, <i>University of São Paulo, Brazil;</i> Y M Mascarenhas, P R Mascarenhas, <i>Brazil;</i> D Cardim, <i>Federal University of São Carlos, Brazil;</i> M R SIgnori, P H D Antonino, E J V Oliveira, C A G Gadelha, <i>Ministry of Health Brazil</i>

Posters								
H.29	Mobile-connected Doppler analyzer for fetal health evaluation in low-resource settings							
11.23	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								
11.50	Ingrid Lærdal, Ida Neuman, <i>Norway</i>							
H.31A	Innovative health technologies: Infant radiant warmer for neonatal thermoregulation							
	Ashish Gupta, <i>India</i>							
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, <i>Brazil</i>							
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, <i>United Kingdom</i>							
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							

	Posters							
I. Medical imaging								
1.02	Knowledge extraction of thoracic radiology reports using statistical natural language processing							
	Leandro Zerbinatti, Lincoln de Assis Moura Jr, <i>Universidade de São Paulo, Brazil</i>							
1.03	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							
1.04	The IOMP used equipment donation program							
	Mohammed Kazmain Zaidi, Idaho State University, United States of America							
1.05	Acquisition of four digital imaging devices in Benin: Weaknesses of the project and a proposed solution							
	Maliki Seidou Adjaratou, Pascal Soroheye, <i>Ministry of Health, Benin</i> ; Marcelin Oyedokoun, <i>National</i>							
	University Hospital, Benin							
1.06	Medical devices for screening and diagnosis							
	Tekin Kaya, Isbara Alp Sezen, Hüseyin Altug, Osman Nacar, Ismet Köksal, Ali Sait Septioglu, <i>Turkish Medicine</i>							
	and Medical Devices Agency, Turkey							
J. Policies for medical devices								
J.01	Brazilian industrial and innovation complex in health: Product development partnerships (PDP) to							
3.01	guarantee access to health technologies in Brazil							
	Valeria Monteiro do Nascimento, Paulo Henrique Dantas Antonino, Eduardo Jorge Valadares Oliveira,							
	Carlos Augusto Grabois Gadelha, <i>Ministry of Health, Brazil</i>							
J.02	Brazilian industrial and innovation complex in health: Access to health technology, offsets, procurement							
3.02	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, <i>Pan American Health Organization, Brazil</i> ; Paulo Henrique Dantas							
	Antonino, Eduardo Jorge Valadares Oliveira, Carlos Augusto Grabois Gadelha, <i>Ministry of Health, Brazil</i>							

Posters							
	K. Regulation of medical devices						
K.03	On regulatory policies for medical devices in low-resource countries						
	Khondkar Siddique-e Rabbani, <i>University of Dhaka, Bangladesh</i>						
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, <i>Turkish</i>						
	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, <i>Turkish Medicine and</i>						
	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						
14.14	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						
1.13	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						

Posters								
L. World Health Organization Medical Device Projects								
Compendium of innovative health technologies for low-resource settings								
Jennifer Barragan, Heike Hufnagel, Adriana Velazquez Berumen, World Health Organization, Switzerland								
2 Global medical device pricing survey								
Olumurejiwa Fatunde, Adriana Velazquez Berumen, World Health Organization, Switzerland								
Global Atlas of Medical Devices 2013								
Ricardo X. Martinez, Adriana Velazquez Berumen, World Health Organization, Switzerland								
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								
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								
Priority medical devices for Noncommunicable Diseases (NCDs) and Ageing Population								
Yukiko Nakatani, Adriana Velazquez Berumen, World Health Organization, Switzerland								
National Regulatory Authority (NRA) assessment tool for medical devices								
Yukiko Nakatani, Adriana Velazquez Berumen, World Health Organization, Switzerland								
WHO Global Biomedical Engineering Education and Professional Database								
Jennifer Barragan, Adriana Velazquez Berumen, World Health Organization, Switzerland								
United Nations Commission on Life-Saving Commodities								
Yukiko Nakatani, Laura Alejandra Velez Ruiz-Gaitan, Jennifer Barragan, Adriana Velazquez Berumen, World								
Health Organization, Switzerland								
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, <i>Mexico</i> ; Niranjan Khambete, <i>India</i> ; James Abbas, <i>United States of America</i> ; Tom Nakazaki,								
Japan; Nicolas Pallikarakis, Greece; Didier Vallens, France; Kamel Abdul Rahim, Jordan; Firas Mustafa Abu-								
Dalou, Jordan								

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

2nd Global Forum on Medical Devices		
Exhibitor list		
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 Facilites and Others

International Organization for Medical Physics

Palm Beach Home Care Nursing Inc

Sohum Innovation Lab

* Brochure only

2nd WHO Global Forum on Medical Devices

Workshop Programme (as of 18 November 2013)

Time	Friday 22 November								
09:00-09:10	Plenary / Welcome / Logistics								
	Salle 1	Salle 23	Salle 21/22	Salle 2	Salle 5/6	Salle 18	Salle 15		
	WHO/UN Tools to Improve Healthcare Delivery	Health Technology Assessment	Nomenclature, Standards and Regulations	Health Tech Management / Clinical Engineering	Medical Imaging and Radiation Safety	Innovation	Reproductive, Maternal, Newborn and Child Health		
09:15-10:00	Supporting integrated national strategic health planning, costing and health impact analysis: the OneHealth Tool (UNAIDS, UNDP, WHO, WB, UNFPA, UNICEF, the Futures Institute)	Creating synergies between national HTA and regional HTA agencies and hospitals in the assessment of medical devices (HTAI)	GMDN - a requirement for Unique Device Identification	Healthcare Technology Management (HTM): ACCE advanced clinical	Role of medical physics in promoting radiation safety culture in health care (IOMP)		MANDATE: priority setting for medical devices to reduce maternal,		
10:00-10:45	Service Availability and Readiness Assessment (SARA) tool for health system planning and management (WHO)		(GMDN Agency)	engineering workshops (ACCE)		Innovation Sandbox Workshop: engaging medtech entrepreneurs to improve health in low- and middle- income countries through the power of co-creation (CAMTech,	fetal and neonatal mortality (RTI International)		
10:45-11:10	Health break		Health break	Health break	Health break	Mass. General Hospital)	Health break		
11:10-12:00	Crucial role of medical devices in emergency & essential surgical care (WHO)		Partnership on regulatory harmonization (AHWP, APEC)	Improving data quality and technology management with mobile devices (Health Partners International)	Medical imaging education in developing countries (ISR, WFUMB, ISRRT)		Medical device introduction: adding the Non-pneumatic Anti Shock Garment (NASG) for obstetric haemorrhage to programs and policies (UCSF)		
12:00-13:30				Lunch / WHO visit					
	WHO/UN Tools to Improve Healthcare Delivery	Health Technology Assessment	Nomenclature, Standards and Regulations	Health Tech Management / Clinical Engineering	Biomedical Engineering	Innovation	Approaches to Improving Healthcare Delivery		
13:30-14:20	Kits for humanitarian health response (WHO/UNFPA/UNICEF)		International standards – state of play and future trends in the medical domain (DITTA)	Computerized Maintenance Management Systems (CMMS): essential features and pitfalls to avoid (ACCE)	Human resources for medical devices: the role of the Biomedical Engineer (WHO)	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)	Améliorer les pratiques des projets d'appui à l'équipement médical intégrant des dons (Improving practices in medical equipment support projects which include donations) (HUMATEM) * in French and English, not translated *		
14:30-15:20			Medical software – regulatory and legal trends (DITTA)	WHO template for technical specifications of medical equipment (WHO)	How to define the basic academic curriculum to train clinical engineers (CED/IFMBE)				
15:20-16:00				Health break					
16:00-16:50	Interagency list of medical devices for reproductive, maternal, newborn and child health (WHO/UNFPA/UNICEF)	child health (WHO/UNFPA/UNICEF) Information retrieval for HTA (NOKC)	National Regulatory Assessment tool (WHO)	A new generation web-based medical technology management system (INBIT, U. Patras)	Harmonization of biomedical engineering education: status and challenges (IFMBE)	Local production of medical devices in Africa: characterizing the landscape and assessing feasibility (WHO)	A tool for prevention and early diagnosis of neuro-degenerative diseases (Intl. U. of Japan)		
17:00-17:50			Digital hospital 21st century: you certainly can't manage it if you don't understand it [YCCMIIYDUI] (CHIRP)	Medical equipment donations: a toolkit for UK – developing country partnerships (THET)	Enhancing biomedical engineering education through innovation experiences (Nat. Univ. of Singapore)	Optimizing the WHO Compendium of Innovative Health Technologies for Low-Resource Settings (WHO)	Disaster preparedness for health technology managers (IUPESM)		

2nd WHO Global Forum on Medical Devices Workshop Tracks and Topics

WHO/UN Tools to Improve Healthcare Delivery

<u>Supporting integrated national strategic health planning, costing and health impact analysis: the OneHealth Tool</u>

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

<u>Creating synergies between national HTA and regional HTA agencies and hospitals in the</u> 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

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

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

Ms Aya Caldwell, CAMTech, Massachusetts General Hospital (USA)

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

Dr Balram Bhargava, Stanford-India Biodesign, (India)

<u>Local production of medical devices in Africa: characterizing the landscape and assessing feasibility</u>

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)

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.

Back

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.

Back

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.

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: <u>Health Technology Assessment international (HTAi)</u>

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.

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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.

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)

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.

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.

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.

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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.

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 (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.

Improving data quality and technology management with mobile devices

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

Organizers: <u>Health Partners International</u>

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.

Back

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.

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

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 reengineering 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.

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.

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

<u>International Organization for Medical Physics (IOMP)</u>
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".

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)

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.

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)

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.

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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: <u>IFMBE</u>

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.

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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 crossdiscipline 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.

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.

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 (<u>balrambhargava@yahoo.com</u>)
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 constrains — 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 medtech 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.

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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.

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

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.

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: <u>HUMATEM</u>

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 underrepresented 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: <u>International University of Japan/ Istituto Superiore Mario Boella</u>

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)

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 datamonitoring 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: <u>International Union for Physical and Engineering Sciences in Medicine (IUPESM)</u>

/ Health Technology Task Group (HTTG)

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

Dr Cari Borras, IUPESM/HTTG
Dr Fred Hosea, Kaiser Permenente

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.