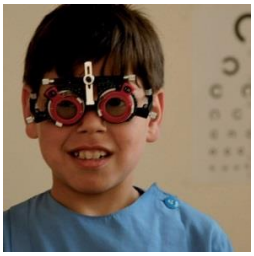
Third WHO Global Forum on Medical Devices

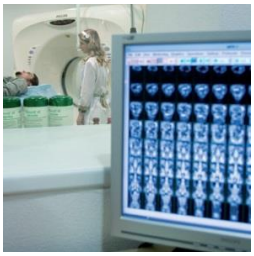
Report

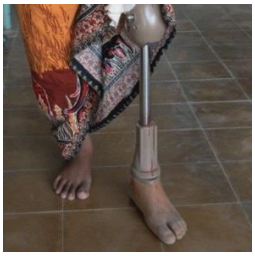
Centre International de Conférences Genève (CICG)
Geneva, Switzerland
10 – 12 May 2017

World Health Organization



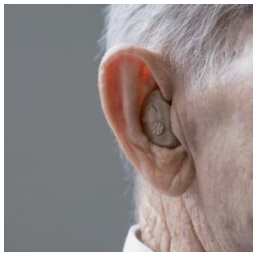
Innovation
Affordability
Safety
Equity
Effective

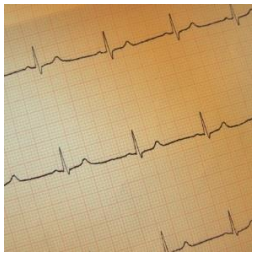


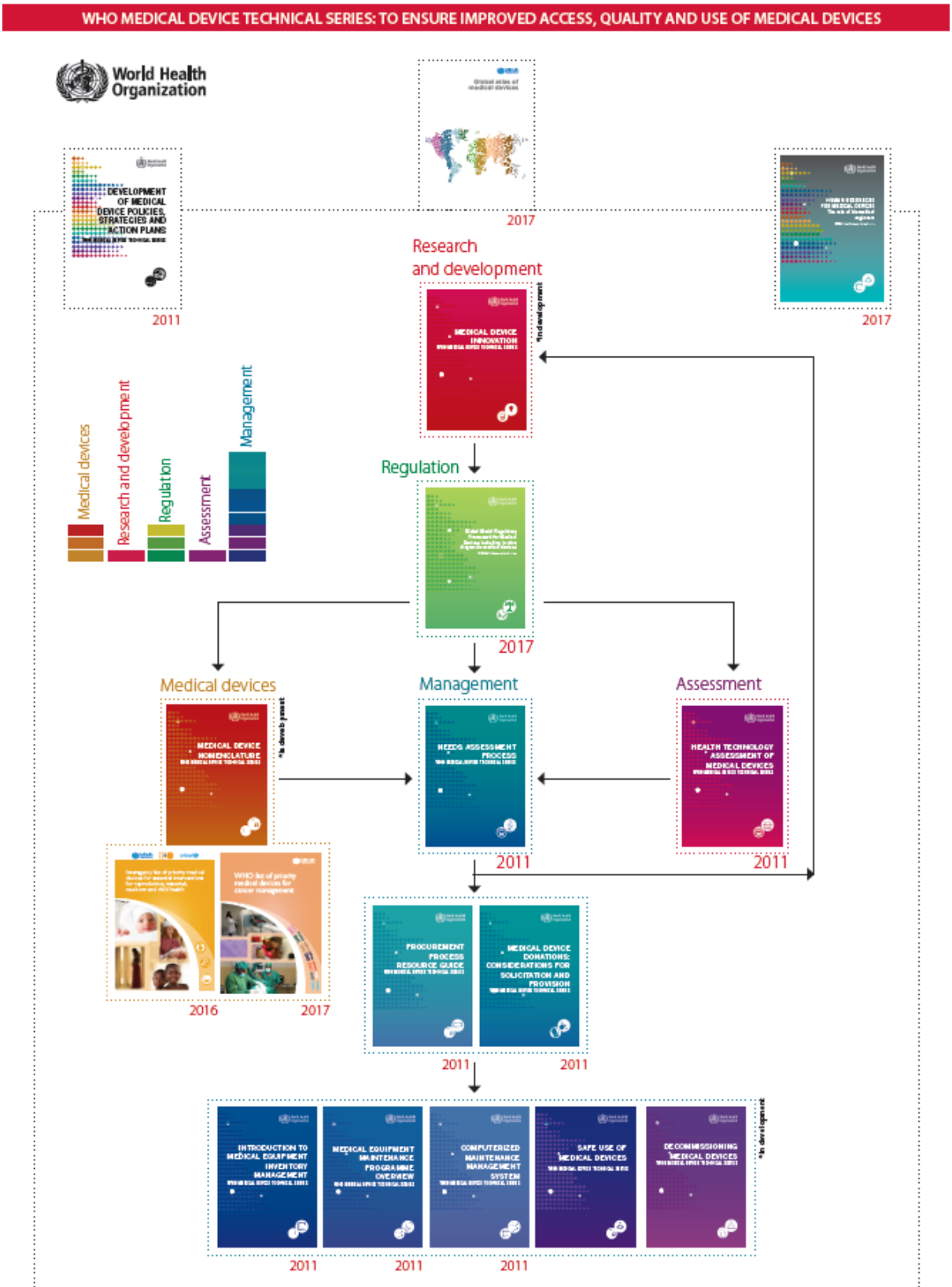


Improving access to safe, effective and innovative quality medical devices

Research
Assessment
Training
Maintenance







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

List of Acronyms

Organizations

ACCE	American College of Clinical Engineering
CED	Clinical Engineering Division of IFMBE
CERGAS	Centro di Ricerche sulla Gestione dell'Assistenza Sanitaria e Sociale
DITTA	Global Diagnostic Imaging, Healthcare ICT, and Radiation Therapy Trade Association
EPFL CODEV	Ecole polytechnique fédérale de Lausanne - Cooperation & Development Center
GE	General Electric
GMDN	Global Medical Device Nomenclature
GMTA	Global Medical Technology Alliance
IAEA	International Atomic Energy Agency
IFBLS	International Federation of Biomedical Laboratory Science
IFHE	International Federation for Hospital Engineering
IFMBE	International Federation for Medical and Biological Engineering
INBIT	Institute of Biomedical Technology
IOMP	International Organization for Medical Physics
ISPOR	International Society for Pharmacoeconomics and Outcomes Research
ISR	International Society of Radiology
ISRRT	International Society of Radiographers and Radiological Technologists
NAHU	Division of Human Health, IAEA
NHSRC	National Health System Resource Centre, India
PAHO	Pan American Health Organization
PUCP	Pontificia Universidad Católica del Perú
RAD-AID	Radiological Aid International
THET	Tropical Health and Education Trust
TPH	Tropical and Public Health Institute
UCLA	University of California in Los Angeles
UICC	Union for International Cancer Control
UNN	University Hospital of North Norway
UNSPSC	United Nations Standard Products and Services Code
WASPaLM	World Association of Societies of Pathology and Laboratory Medicine
WFSA	World Federation of Societies of Anaesthesiologists
WFUMB	World Federation for Ultrasound in Medicine and Biology
WFUNA	World Federation of United Nations Associations
WHF	World Heart Federation
WHO	World Health Organization
WHO AFRO	WHO Regional Office for Africa
WHO AMRO	WHO Regional Office for the Americas
WHO EMRO	WHO Regional Office for the Eastern Mediterranean
WHO EURO	WHO Regional Office for Europe
WHO SEARO	WHO Regional Office for South East Asia
WHO WPRO	WHO Regional Office for the Western Pacific

General

BME	Biomedical engineering
CE	Clinical engineering
CICG	Centre international de conférence de Genève
CMMS	Computerized maintenance management software
HTA	Health technology assessment
HTM	Health technology management
IT	Information technology
LMIC	Low and middle income countries
NGO	Non-governmental organization
POC	Point-of-care
UDI	Unique device identification

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Acknowledgements

The Third WHO Global Forum on Medical Devices is a demonstration of the WHO commitment towards improved access to safe, effective and innovative, quality medical devices as a contribution to universal health coverage and Sustainable Development Goals.

The World Health Organization would like to thank the following for their support and contribution to the Third WHO Global Forum on Medical Devices:

The Local Organizing Committee:

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Medical Devices Office, Innovation, Access & Use Unit, WHO, Geneva:

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Luca Pellandini

Collaborating organizations

WHO acknowledges the following collaborating organizations that co-organized workshops and parallel sessions

UN agencies		
IAEA	UNFPA	UNICEF
NGOs in Official Relations with WHO		
DITTA	GMTA	HTAi
HUMATEM	IFBLS	IFHE

IFMBE	IOMP	ISR
ISRRT	THET	UICC
WASPaLM	WFSA	
Other collaborating organizations		
ACCE	PATH	

Global Forum Report

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WHO Staff

Adriana Velazquez Berumen

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Blanca Leticia Fernandez Carballo

WHO Interns

Sophie Girardin, Switzerland; Yik Nga Lui, China

Background Introduction

Background information:

Considering that Member States recognized in resolution WHA60.29 and WHA67.20 that medical devices are indispensable for health care delivery but their selection, regulation and use present enormous challenges, it is proposed that the 3rd Global Forum is to be presented 10 years later to discuss the achievements that have been made in the field and the enormous challenges in low and middle income countries. This will also serve as an opportunity to share the WHO EMP strategy in the framework of Universal Health Coverage and the Sustainable Development Goals, which had been approved in 2015.

WHO organized the 1st Global Forum in Bangkok in 2010 and the 2nd in Geneva in 2013 , which had around 700 participants from 110 Member States. These fora have been the primary setting for dissemination and sharing of information on medical devices for Global Health. The programme includes presentation of best practices, challenges, and new tools for innovation, regulation, assessment, and management (procurement, technical specifications, donations, maintenance and appropriate safe use) of medical devices, as well as presentation the list of medical devices by health care facility, disease or clinical interventions.

Objectives of the Forum:

1. To define methods of increasing access to priority medical devices under Universal Health Coverage in compliance with the Sustainable Development Goals
2. To share evidence of best practices in regulating, assessment and management of medical devices
3. To demonstrate development and use of innovative appropriate affordable technologies to respond to global health priorities
4. To share WHO tools and guidelines on medical devices for better implementation
5. To present the outcomes of the implementation of the World Health Assembly resolutions on medical devices and the EMP strategy for 2030

A total of 571 people from 70 countries attended Forum presentation and participated in discussions on current practices.

Third WHO Global Forum on Medical Devices: context

The adoption of the first resolution on health technologies in May 2007 by the World Health Assembly WHA 60.29 , WHA 67.20 and WHA67.23 set the framework for an unprecedented focus on health technologies. Medical devices are indispensable for health care delivery but their selection, regulation and use present enormous challenges.

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.

The 2nd Global Forum on Medical Devices addressed the development of lists of medical devices by clinical intervention and disseminated information about innovative, appropriate, and affordable devices for low-resource settings in accordance with the WHA 60.29 resolution.

Now, the 3rd Global Forum on Medical Devices will consider the achievements that have been made in the field and the action plan to address challenges in low and middle income countries towards universal health coverage in the framework of the Sustainable Development Goals.

Resolutions of the World Health Assembly

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

The most important resolutions addressing medical devices are the following:

Box 1. Resolution WHA60.29 Health Technologies action points for Member States and the WHO Secretariat

Resolution WHA60.29, was the first resolution specific to medical devices and was approved in 2007.

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

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

(3) to develop methodological tools to support Member States in analysing their health technologies…

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

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

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

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

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

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

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

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

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

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

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

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

Medical devices in WHO, overview 2013 - 2017

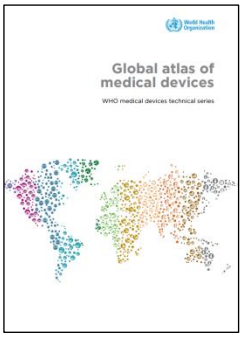
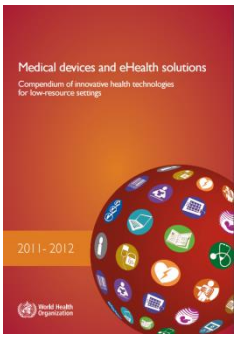
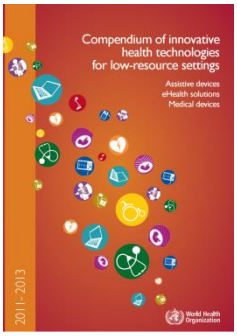
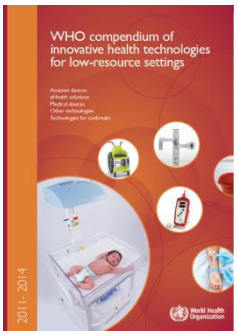
Following the discussion of the First Global Forum, WHO has continued to increase accessibility, affordability, and availability of medical devices through publications, workshops and consultation meetings.

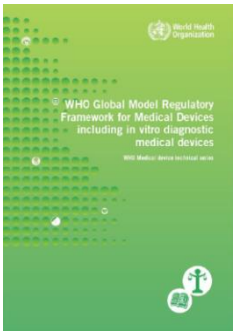
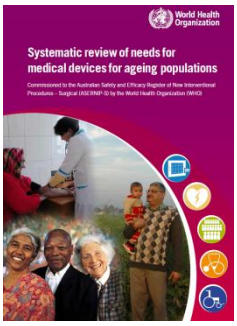
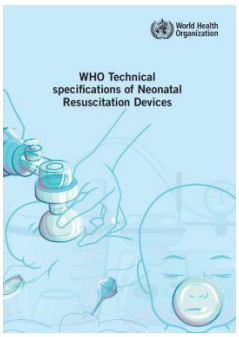
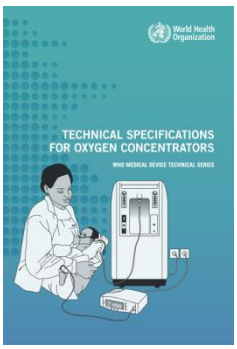
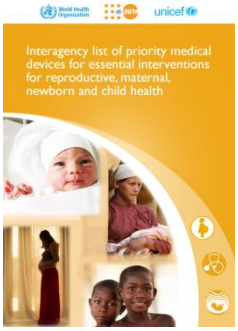
The work done in these last years have resulted in various publications and guidance, in the domains of :

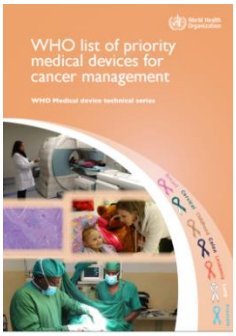
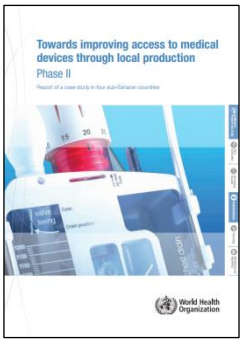
- innovation, with the call and the publication of the innovative technologies for low resources
- priority medical devices (for diagnosis and management of Ebola, for maternal, new born and child care as well as for cancer management);
- studies on local production and technology transfer
- development of technical specifications of
    - oxygen concentrator
    - neonatal resuscitation
    - personal protective equipment
- on regulations of medical devices

- the country , regional and global profiles
- on the role of biomedical engineers

All of the above were developed in the last 4 years were presented in the 3rd Global Forum and are listed below:

	Cover Image	Title	Year	Language	Website
COUNTRY INFORMAITON		Global Atlas of Medical Devices 2017	2017	English	Online Link
INNOVATION		Medical Devices and eHealth Solutions	2013	English	Online link
		Compendium of Innovative Health Technologies for Low-resource Settings	2014	English	Online link
		Compendium of innovative health technologies for low-resource settings, 2011-2014: Assistive devices, eHealth solutions, medical devices, other technologies, technologies for outbreaks	2015	English	Online link

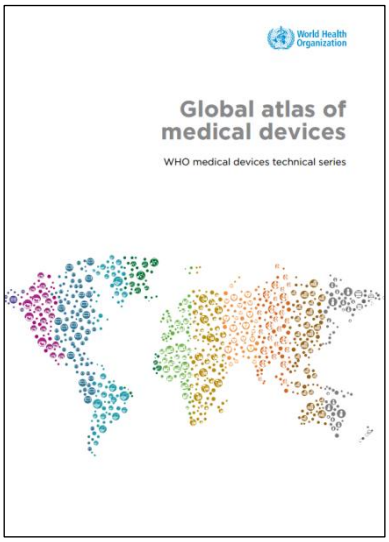
REGULATION		WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices	2017	English	Online Link
HEALTH TECHNOLOGY ASSESSMENT OF MEDICAL DEVICES		Systematic Review of Needs for Medical Devices for Ageing Population	2015	English	Online link
HEALTH TECHNOLOGY MANAGEMENT OF MEDICAL DEVICES		WHO technical specifications of neonatal resuscitation devices	2015	English	Online Link
		WHO technical specifications for oxygen concentrators	2015	English French Spanish	Online Link
PRIORITY MEDICAL DEVICES		Interagency list of priority medical devices for essential interventions on reproductive, maternal, new born and child health Liste interinstitutions de dispositifs médicaux prioritaires pour des interventions essentielles en santé reproductive, maternelle, néonatale et infantile	2015	English French	Online Link

PRIORITY MEDICAL DEVICES		WHO list of priority medical devices for cancer management	2017	English	Online Link
MEDICAL DEIVCE QUALITY AND SAFE USE		2013 Manual of Diagnostic Ultrasound	2013	English	Online link
HUMAN RESOURCES FOR MEDICAL DEVICES		Human resources for medical devices, the role of Biomedical Engineers	2017	English	Online Link
LOCAL PRODUCTION		Towards improving access to medical devices through local production: phase II: report of a case study in four sub-Saharan countries	2016	English	Online link

Medical Devices Publications launched in Global Forum

During the 3rd Global Forum on Medical Devices, 4 publications of WHO medical devices technical series were launched.

Global Atlas of Medical Devices 2017



The first Baseline Country Survey on Medical Devices was developed in 2009 and launched in February 2010 and was updated with a re-launch in November 2013. A total of 177 countries responded. In 2015, in response to resolution WHA67.23 on health interventions and technology assessment, WHO launched a global health technology assessment survey conducted by government or national institutes. Subsequently, in 2016, resolution WHA67.20 on the regulatory strengthening of medical products, including medical devices, led to a study analysing medical devices regulatory frameworks. The results of both the study and the global survey regarding medical devices have been included in this document.

The information collected by the surveys and studies has been processed into a comprehensive publication that includes statistical analyses of more than 100 aspects related to medical devicesns. The results are displayed in regional tables, country profiles, diagrams, charts and maps reflecting the global status quo. The country profiles incorporate facts indicating the national status of medical devices in areas such as: policies, regulations, selection, inventories and lists of medical devices by health care facilities or by diseases. The survey results reveal areas in which guidelines, documents and process policies are lacking and also serve as an important information archive to which Member States can refer and compare best practices. This information archive also provides a valuable basis for future studies. The aim of this publication is to raise awareness and bring evidence of the indispensable safe and good use of appropriate, affordable and quality medical devices in health care delivery to achieve better health outcomes.

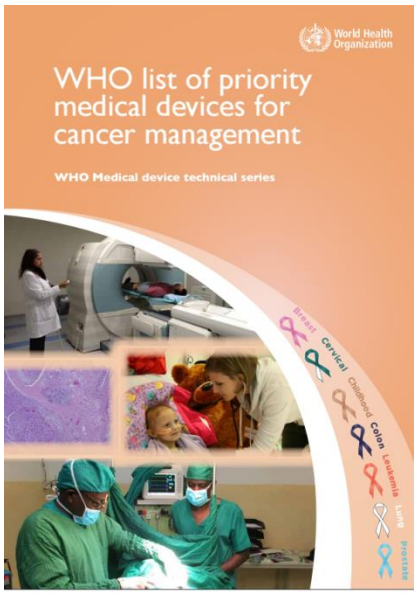
Human resources for medical devices, the role of biomedical engineers

In this book, part of the Medical device technical series, WHO presents the different roles the biomedical engineer can have in the life cycle of a medical device, from conception to use. It is recognized that medical devices are becoming ever more indispensable in health-care provision and among the key specialists responsible for their design, development, regulation, evaluation and training in their use – are biomedical engineers.

The publication includes country information on the number of biomedical engineers and similar professionals and technicians, as well as educational institutions and professional societies.

This publication had the support of the IFMBE, International Federation of Medical and Biological Engineering and was developed from 2013 to 2017.

WHO List of priority medical devices for cancer management

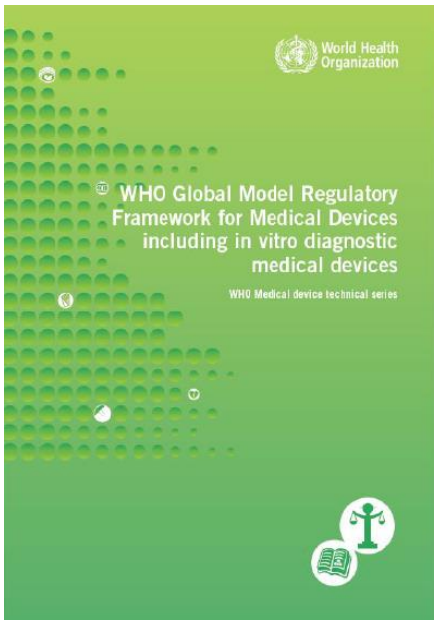


The WHO list of priority medical devices for cancer management describes the medical devices that are required to manage cancer, based on the list of clinical interventions selected from clinical guidelines on prevention, screening, diagnosis, treatment, palliative care, monitoring and end of life care.

This publication is a guidance tool that addresses medical devices that can be used for management of cancer and specifically describes medical devices for six types of cancer: breast, cervical, colorectal, leukemia, lung and prostate. It describes the interventions that happen in different clinical units: clinical assessment, endoscopies, clinical laboratory and pathology, medical imaging, nuclear medicine, surgery, radiotherapy, systemic therapy and palliative care.

The primary financial support for this study was provided by the OPEC Fund for International Development (OFID), (2013-2016).

WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices



The Model recommends guiding principles, harmonized definitions and specifies the attributes of effective and efficient regulation, to be embodied within binding and enforceable law. Its main elements refer to international harmonization guidance documents developed by the Global Harmonization Task Force (GHTF) and its successor, the International Medical Device Regulators Forum (IMDRF).

WHO Global Model Regulatory Framework for medical devices including in vitro diagnostic medical devices is intended to provide guidance to Member States that have yet to develop and implement regulatory controls relating to medical devices, as well as to jurisdictions that are continuing to improve their regulatory frameworks.

Third WHO Global Forum on Medical Devices: content

The Third WHO Global Forum on Medical Devices was convened on 10th to 12th May 2017 at the International Conference Center Geneva (CICG), in Switzerland.

Meeting Objectives

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

- To define methods of increasing access to priority medical devices under the Universal Health Coverage in compliance with the sustainable Development Goals
- To share evidence of best practices in regulation, assessment and management of medical devices
- To demonstrate the development and use of innovative, appropriate and affordable technologies that respond to global health priorities
- To share WHO tools and guidelines on medical devices for better implementation
- To present the outcomes of the implementation of the World Health Assembly resolution on medical devices and the EMP strategy for 2030

Programme overview

In February 2017, the Local Organizing Committee issued a call for abstracts with a tentative agenda and list of possible topics. An outstanding response from the community resulted in 323 abstracts submitted to the 80 members of the Programme Committee in less than five weeks.

From this pool of abstracts, the Committee developed a programme that included 64 plenary presentations, 130 oral presentations in parallel sessions, 104 posters, 7 films, and 46 workshops. Thus, the content of the programme was largely formed by submissions from the medical devices community and reflects its priorities, activities and needs.

The Forum began on May 9th with two pre-conference closed sessions: the WHO advisory committee meeting on innovation of personal protective equipment and the WHO model regulatory framework medical devices workshop and continued over the subsequent two days with plenary and parallel sessions. Each of the main days of the conference consisted of an opening and closing plenary and five sessions conducted in parallel both in the morning and in the afternoon. Over the course of these three days, the active involvement of the participants was essential to addressing the objectives of the Forum. An overview of the programme is provided below in Figure 3.

Numberalia of 3rd Global Forum on Medical Devices	
Participants	571
Oral paraellel session presentations	130
Posters	104
Plenary presentations	64
Workshops	46
Exhibitions	42
Videos	7

Tuesday 9th May 2017	
09:00 - 17:00	Pre-conference workshops (closed)
Wednesday 10th May 2017	
	Welcome Plenary Session
09:15 – 10:45	Workshop 1
11:00 – 12:30	Workshop 2
13:30 – 15:00	Workshop 3
15:30 - 17:45	Opening Plenary Session
	Plenary Panel Session 1
	Plenary Panel Session 2
17:45 - 18:45	Poster, video & exhibit session
Thursday 11th May 2017	
08:00 - 09:00	Regional Parallel session, Poster session
09:00 -10:45	Plenary Panel Session 3
	Plenary Panel Session 4
11:00 - 12:30	Oral Parallel Session 1
13:30 - 15:00	Oral Parallel Session 2
15:30 - 17:45	Plenary Panel Session 5
	Plenary Panel Session 6
	Plenary Panel Session 7
17:45 - 18:45	Poster, video & exhibit session
Friday 12th May 2017	
08:00 - 09:00	Regional Parallel session, Poster session
09-10:45	Plenary Keynote Address
	Plenary Panel Session 8
11:00 - 12:30	Oral Parallel Session 3
13:30 - 15:00	Oral Parallel Session 4
15:30 - 17:00	Plenary Panel Session 9
	Closing session
	Announcement of the 4th Global Forum on Medical devices

	Tuesday 9th, May 2017				Wednesday 10th, May 2017		
7:00 - 9:00					Info Desk Level 0		Registration (7:00 - 9:00) Poster & Exhibit Mounting
9:00 - 9:15					**Room**		**Plenary Welcome Session**
					1		Dr Suzanne Hill, Director Essential Medicine and Health Products Department, WHO
09:15-10:45	**Room**	**Pre conference sessions (closed)**			**Room**	**Track**	**Pre conference workshops (9:15 - 10:45)**
	5	WHO personal protective equipment advisory committee meeting (closed)			3	W1	Innovation of medical devices
					7	W2	Radiation/medical imaging
	6	WHO model regulatory framework workshop (closed)			17	W3	Hospitals
					13	W4	Surgery & emergency care
					15	W5	ICTs in health
					14	W6	Assessment of medical devices
					16	W7	Regulation and standards
					4	W8	Management/clinical engineering
					18	W9	Personal protective equipment (Closed)
					6	W10	Regulatory framework (Closed)
10:45-11:00	**Break**				**Break**		
11:00-12:30	5	WHO personal protective equipment advisory committee meeting (closed)			**Room**	**Track**	**Pre conference workshops**
					3	W10	Innovation of medical devices
	6	WHO model regulatory framework workshop (closed)			7	W2	Radiation/medical imaging
					17	W3	Public-private partnership
					13	W4	Laboratory & pathology
					15	W5	ICTs in health
					14	W6	Assessment of medical devices
					16	W7	Nomenclature systems
					4	W8	Management/clinical engineering
					18	W9	Personal protective equipment (Closed)
					6	W10	Regulatory framework (Closed)
12:30-13:30	**Lunch Break**				**Lunch Break**		
13:30-15:00	Info Desk Level 0	Registration Poster & Exhibit Mounting	5	Personal protective equipment (Closed)	**Room**	**Track**	**Pre conference workshops**
					3	W11	Innovation of medical devices
					7	W2	Radiation/medical imaging
			6	Regulatory framework (Closed)	17	W3	Quality & Market shaping
					13	W4	In vitro diagnostics
					15	W5	ICTs in health
					14	W12	Priority medical devices for diseases
					16	W13	Nomenclature systems
					4	W14	Tools for management
					18	W9	Personal protective equipment (Closed)
					6	W10	Regulatory framework (Open Session)
15:00-15:30	**Break**				**Break**		
15:30-17:00	Info Desk Level 0	Registration Poster & Exhibit Mounting	5	Personal protective equipment (Closed)	**Room**	Track	**Plenary sessions Salle 1**
					1	OS	**Opening Session**
			6	Regulatory framework (Closed)			Medical devices for health care delivery, global and regional perspectives
					1	PP1	**Plenary Panel Session 1**
							Medical devices for reproductive, maternal, neonatal and child care
					1	PP2	**Plenary Panel Session 2**
							Medical devices for communicable diseases
17:45 - 18:45	Info Desk Level 0	Registration Poster & Exhibit Mounting			**Adjourn (17:45)**		
					Level 0 EXP		Exhibit and poster sessions

Thursday 11th May 2017			Friday 12, May 2017			
Room	**Track**	**Regional Parallel Sessions**	**Room**	**Track**	**Regional Parallel Sessions**	**08:00 - 08:45**
6	PR1	Africa	6	PR1	Africa	
4	PR2	Americas	4	PR2	Americas	
7	PR3	Eastern Mediterranean	7	PR3	Eastern Mediterranean	
3	PR4	Europe	3	PR4	Europe	
5	PR5	South East Asia	5	PR5	South East Asia	
18	PR6	Western Pacific	13	PR6	Western Pacific	
20		Innovators Meeting	20		Innovators Meeting	
19		NGO Meeting	19		NGO Meeting	
Level 0	EXP	Exhibit and poster sessions	Level 0	EXP	Exhibit and poster sessions	
Break			**Break**			08:45-09:00
Room	**Track**	**Plenary sessions Salle 1**	**Room**	**Track**	**Plenary Session Salle 1**	**09:00-10:30**
1	PP3	**Plenary Panel Session 3**	1	PK1	**Dr Marie-Paule Kieny, ADG, WHO Key note**	
1		Innovation of medical devices			Medical devices in the context of the sustainable development goals	
1	PP4	**Plenary Panel Session 4**	1	PP8	**Plenary Panel Session 8**	
		Effective implementation of regulation of medical devices			Priority medical devices for cancer aare and other non communicable diseases	
Break			**Break**			10:30-11:00
Room	**Track**	**Parallel Sessions**	**Room**	**Track**	**Parallel Sessions**	**11:00-12:30**
1	PS1	Innovation of medical devices	1	PD1	Innovation of medical devices	
5	PS2	Regulation of medical devices	5	PD2	Priority Medical Devices by Healthcare Facility	
6	PS3	Assessment of medical devices	6	PD3	Assessment of medical devices	
4	PS4	Management of medical devices	4	PD4	Tools to support of medical device management	
3	PS5	Human resources and medical devices	7	PD5	Injection Safety Symposium	
13	PS6	Health service delivery: oxygen supply systems	13	PD6	Medical Devices for Emergencies and Disasters	
7	PS7	eHealth	3	PD7	eHealth	
14	PS8	Assistive devices				
18	PS9	Personal protective equipment (PPE)				
Lunch Break Poster change			**Lunch Break**			12:30-13:30
Room	**Track**	**Parallel Sessions**	**Room**	**Track**	**Parallel Sessions**	**13:30-15:00**
1	PS1	Innovation of medical devices	1	PD1	Innovation devices for newborn and child care	
5	PS2	Regulation of medical devices	3	PD2	Quality and safety of medical devices	
6	PS3	Assessment of medical devices	6	PD3	Radiation for diagnostic and treatment	
4	PS4	Management of medical devices	13	PD4	Innovation for in vitro diagnostics	
3	PS5	Human resources and medical devices	4	PD5	Affordability & appropriateness of medical devices	
13	PS6	Health service delivery: oxygen supply systems	5	PD6	Lists of medical devices, nomenclature & pricing	
7	PS7	Human Factor Engineering				
18	PS8	Reproductive Health and Research				
Break			**Break**			15:00-15:30
Room	Track	**Plenary sessions Salle 1**	**Room**	Track	**Plenary sessions Salle 1**	**15:30-16:15**
1	PP5	**Plenary Panel Session 5**	1	PP9	**Plenary Session 9**	
		Assessment of medical devices			Medical and Assistive Devices for Humanitarian Aid and Emergency/Disaster Relief	
1	PP6	**Plenary Panel Session 6**	1	CS	**Closing Session**	**16:15-17:00**
		Management of medical devices: from selection to safe use			Conclusions & Announcement of 4th Global Forum on Medical Devices	
1	PP7	**Plenary Panel Session 7**	**Adjourn (17:00)**			**17:00 - 17:45**
		Human Resources for medical devices.	Removal of posters & Exhibit unmounting (17:00 - 18:00)			
Adjourn (17:45)						**17:45**
Level 0	EXP	Exhibit and poster sessions				**17:45 - 18:45**

Figure 1. Overview of the programme of the 3rd WHO Global Forum on Medical Devices.

The full programme is provided in Appendix 1 and can be found on the WHO Medical Devices website, along with all the content of the Forum.

Box 3. Website of the Third WHO Global Forum on Medical Devices

http://www.who.int/medical_devices/global_forum/3rd_gfmd/en/

The website provides access to the programme, the list of participants and most of the presentations and poster PDF files.

The official language for submission of abstracts was English. The venue was the CICG, which offered a large plenary room, several smaller meeting rooms to accommodate parallel sessions and workshops, and open areas for poster presentations, video screening and exhibit spaces.

Workshops

Workshops took place on Wednesday, May 10th. There were 46 open workshops that were presented in the following 17 topics (Box 4)

Box 4. Workshop topics

1. Innovation of medical devices
2. Radiation/medical imaging
3. Hospitals
4. Surgery & emergency care
5. ICTs in health
6. Assessment of medical devices
7. Regulation and standards
8. Management/clinical engineering
9. Public-private partnership
10. Laboratory & pathology
11. Nomenclature systems
12. Quality & Market shaping
13. In vitro diagnostics
14. Priority medical devices for diseases
15. Tools for management
16. Regulatory framework (open & closed sessions)
17. Personal protective equipment (closed sessions)

Representatives from WHO, other UN agencies, NGOs in official relationships with WHO, academia, and/or professional organizations co-organized the various workshops with WHO. The final programme, summaries, abstracts and/or reports of the workshops are presented in Appendix 2.

Plenary sessions

Each of the 12 plenary sessions included brief presentations by invited leaders in their respective fields to address a specific topic. For each session, the presentations were followed by questions and comments from Forum participants and discussion. Plenary first was a welcome session given by Suzanne Hill, Director EMP, and plenary session 10 was given by ADG Marie Paule Kieny on Universal Health Coverage and the Sustainable Development Goals.

Box 5. Plenary session

1. Plenary Welcome Session by Suzanne Hill, Director EMP
2. Medical devices for health care delivery, global and regional perspectives
3. Medical devices for reproductive, maternal, neonatal and child care
4. Medical devices for communicable diseases
5. Innovation of medical devices
6. Effective implementation of regulation of medical devices
7. Assessment of medical devices
8. Management of medical devices: from selection to safe use
9. Human Resources for medical devices
10. Universal Health Coverage and the Sustainable Development Goals by Marie Paule Kieny, ADG
11. Priority medical devices for cancer care and other non-communicable diseases
12. Medical and Assistive Devices for Humanitarian Aid and Emergency/Disaster Relief

Oral parallel sessions

Taking into consideration the abstracts received, a programme was developed to facilitate the country presentations, academia and health care delivery perspectives to reflect their content in the conference topics. The programme included 130 oral presentations distributed across the following 22 tracks of the parallel sessions:

Box 6. Parallel session topics

1. Innovation of medical devices
2. Regulation of medical devices
3. Assessment of medical devices
4. Management of medical devices
5. Human resources and medical devices
6. Health service delivery: oxygen supply systems
7. eHealth
8. Assistive devices
9. Personal protective equipment (PPE)
10. Health service delivery: oxygen supply systems
11. Human Factor Engineering
12. Reproductive Health and Research
13. Priority Medical Devices by Healthcare Facility
14. Tools to support of medical device management
15. Injection Safety Symposium
16. Medical Devices for Emergencies and Disasters
17. Innovation devices for newborn and child care
18. Quality and safety of medical devices
19. Radiation for diagnostic and treatment
20. Innovation for in vitro diagnostics
21. Affordability & appropriateness of medical devices
22. Lists of medical devices, nomenclature & pricing

Posters

The abstracts that were not selected for presentations or that were submitted for poster presentation were featured on 104 posters organized by theme. Specific times were allotted for poster viewing. There were two distinct poster sessions, featuring each half of the poster. On Thursday afternoon, posters were switched.

Videos

There were 7 videos which were presented in the exhibition area.

Exhibit spaces

Governments, universities and NGOs were attributed exhibit spaces to display information related to their organisations. There were 42 stands, which list can be found in Appendix 1.

Attendees

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

Statistics of the participants

The total number of registered participants was 683, but all were not able to attend: 571 participants attended, coming from 70 Member States and from 12 intergovernmental organizations.

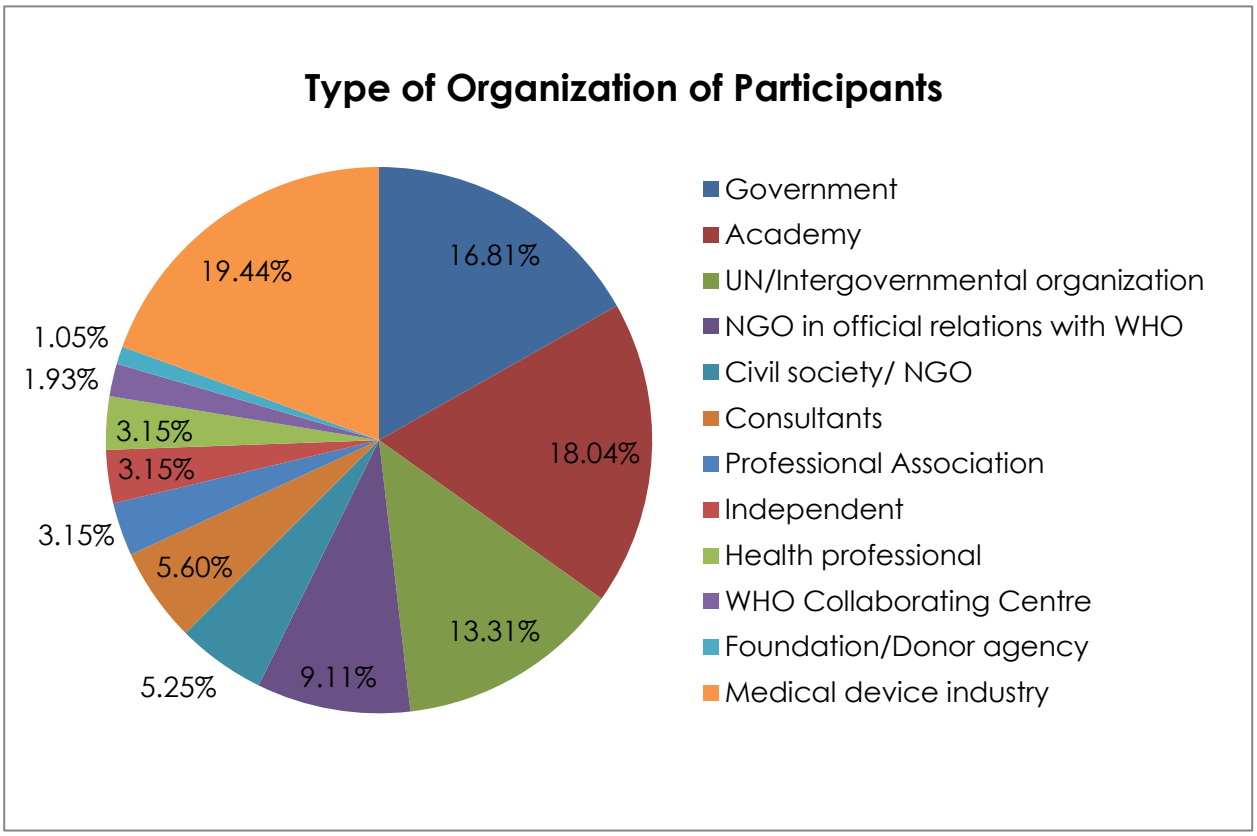
The Forum was attended by 571 people from 70 countries with 46% of the attendees being women.

The attendees came from all six WHO regions. At least 35 % of WHO Member States had a representative at the Forum. As can be seen by the density map in Figure 4, the attendees included participants from low - and middle- income countries, but there was a larger representation from high-income countries.

As can be seen by the density map in Figure 4, the attendees included participants from low - and middle-income countries, but there was a larger representation from high-income countries. The list of countries with the number of attendees from each country is shown in Figure 4.

Attendees represented a variety of organizations: with the largest numbers from the government or public agencies (37%) and academic sectors (22%). It is important to note the participation of professional associations and NGOs (18%), as well as academia (18%). The full breakdown by category is shown in Figure 2.

Appendix 6 contains the full list of participants of the Forum by category and country.



Participants per category	
Government	96
UN/Intergovernmental organization	76
WHO collaborating centers	11
Foundation/Donor agency	6
Academia	103
NGO in official relations with WHO	51
Civil society/ NGO	31
Professional Association	19
Consultants	32
Independent	18
Health professional	17
Medical device industry	111
Total	**571**

Figure 2. Type of organization of the participants.

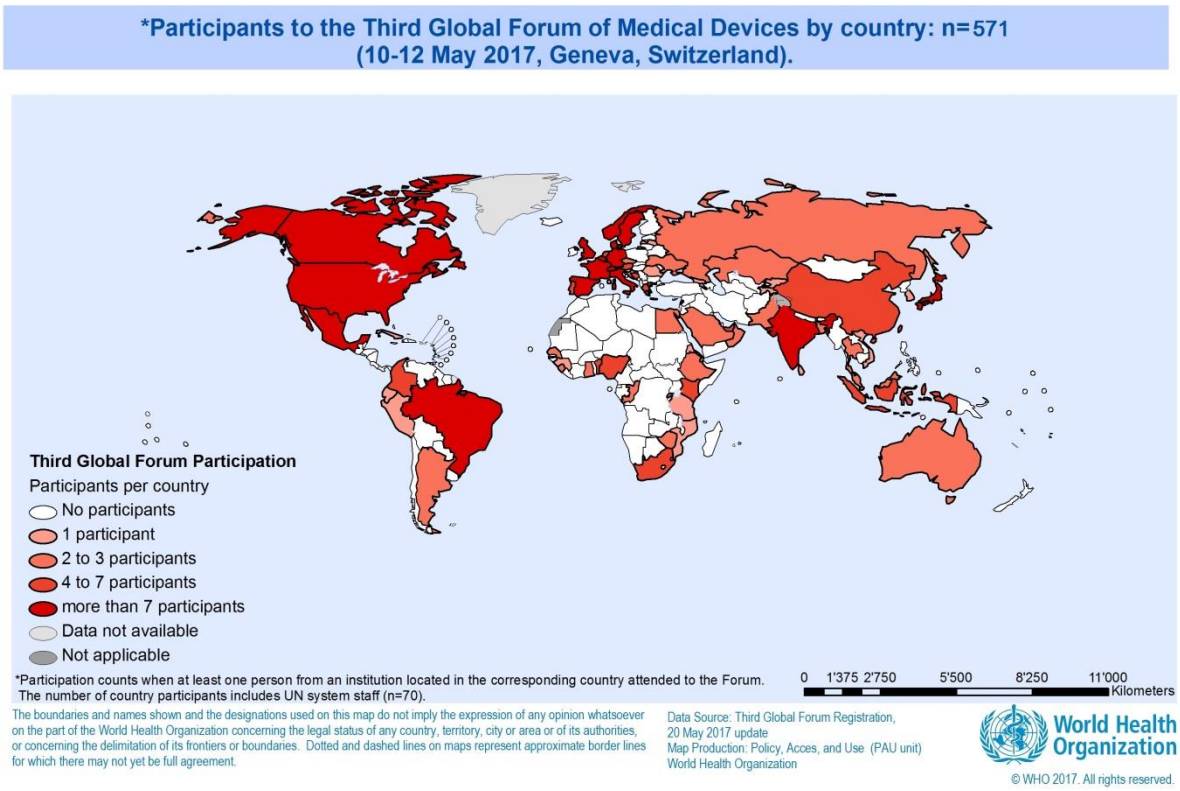


Figure 3. Number of participants by 70 countries.

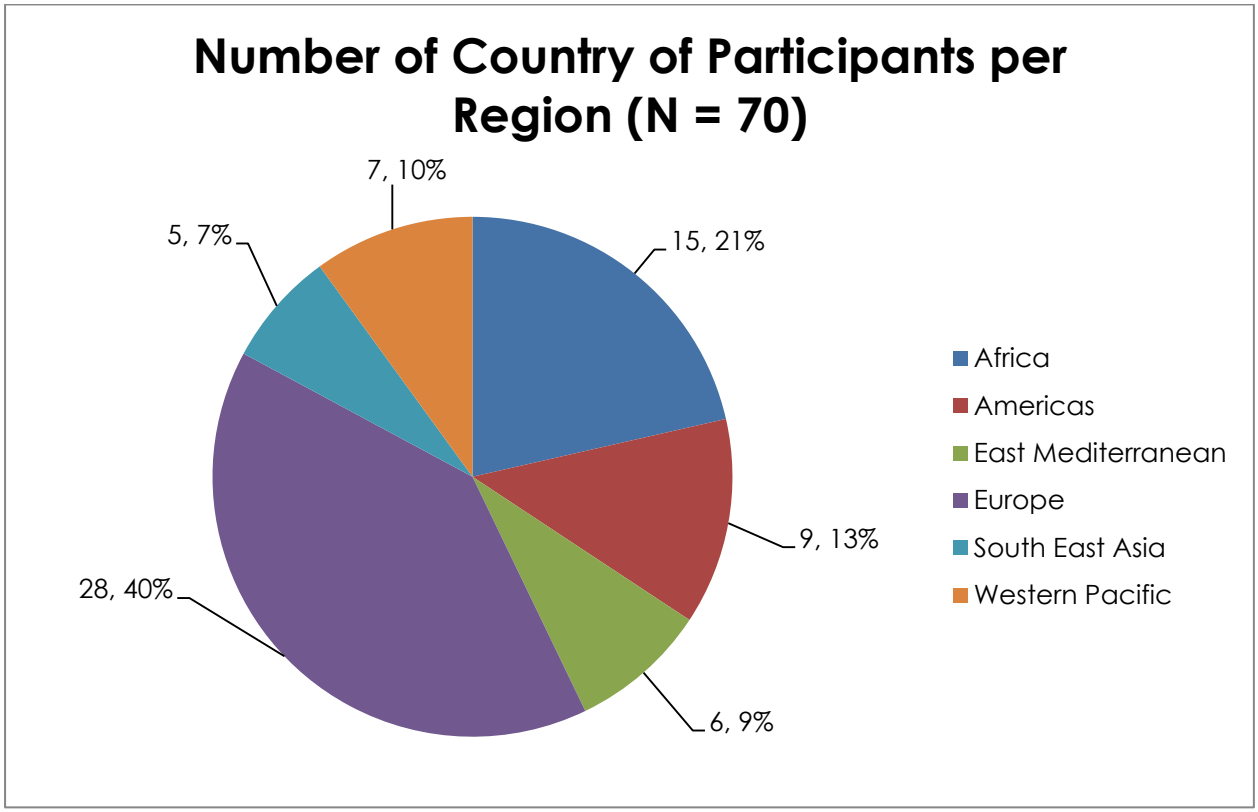


Figure 4. Number of country of participants per region

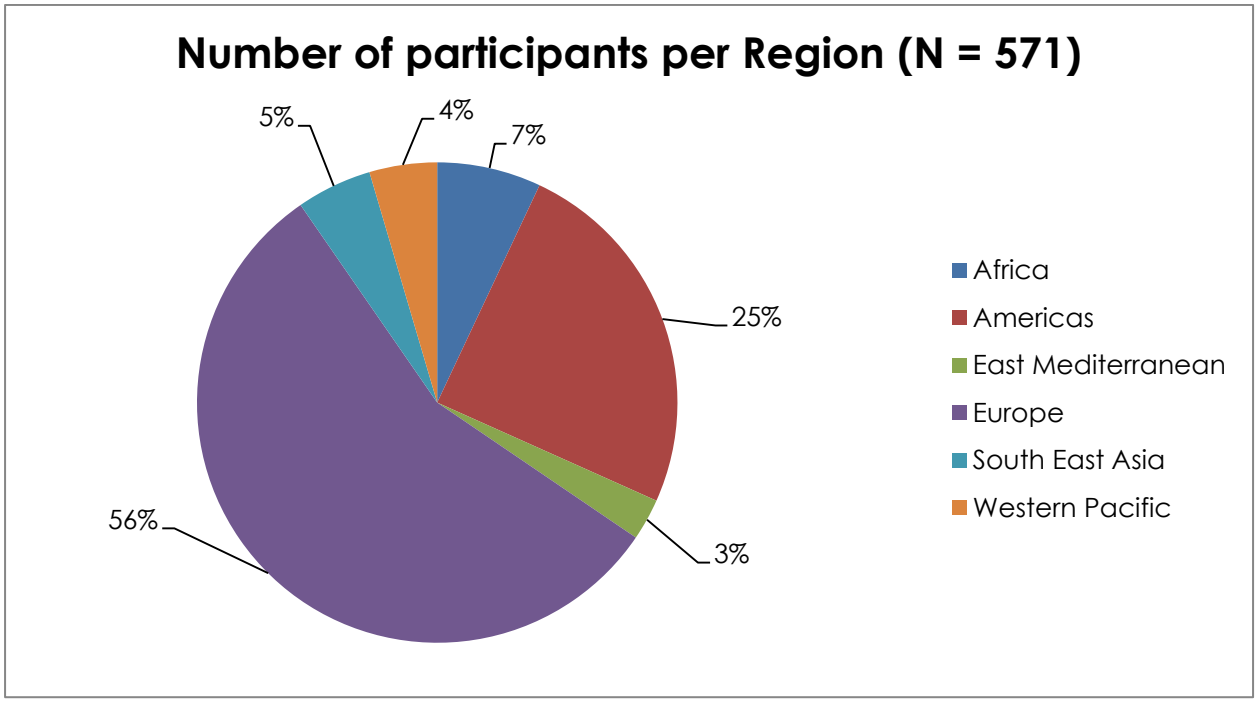


Figure 5. Number of participants per region

Third Global Forum on Medical Devices: Outcomes

During the 3rd Global Forum, the planned objectives were met, there was exchange of information on the areas of innovation, regulation, selection, assessment, management including procurement, donations , technical specifications, lists and safe use.

Evaluation

An electronic feedback survey was sent to all participants for the evaluation of the workshops, oral parallel sessions, plenary sessions and poster sessions.

Figures 6 and 7 provide a visual representation of two very important measures of participant satisfaction.

Figure 6 shows that over 98% of the participants felt that the conference fulfilled at least partially their reasons for attending, while Figure 7 shows that 94% would recommend the conference to others.

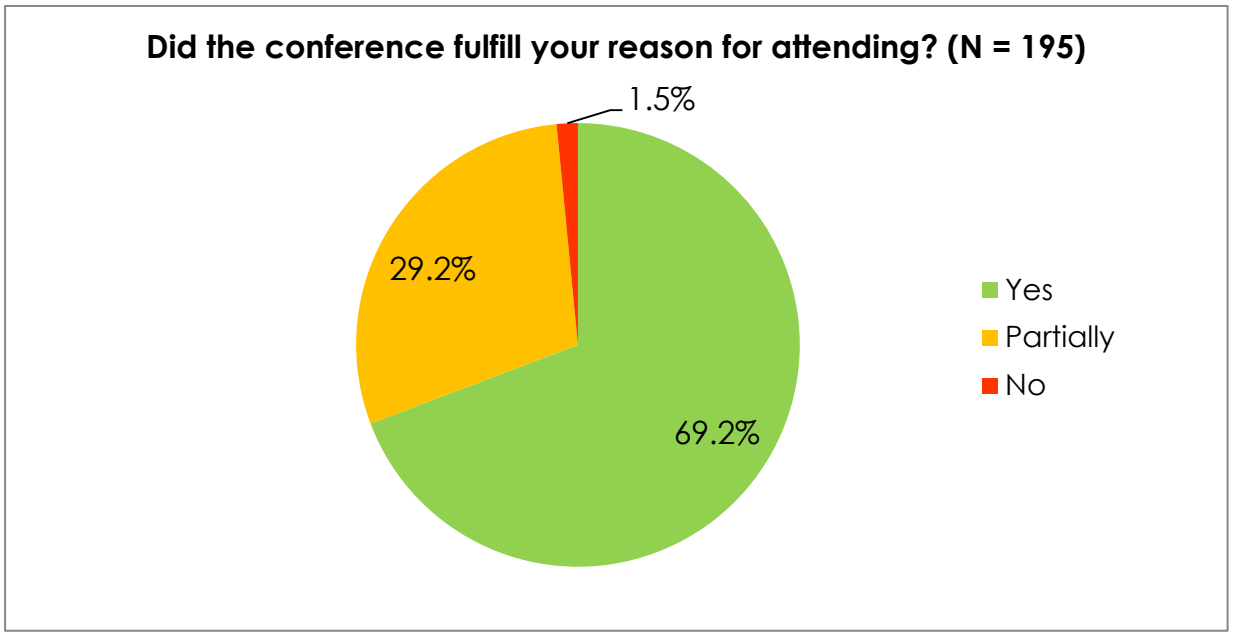


Figure 6. Did the conference fulfill you reason for attending? The data come from the online feedback survey that was sent to all participants one week after the event.

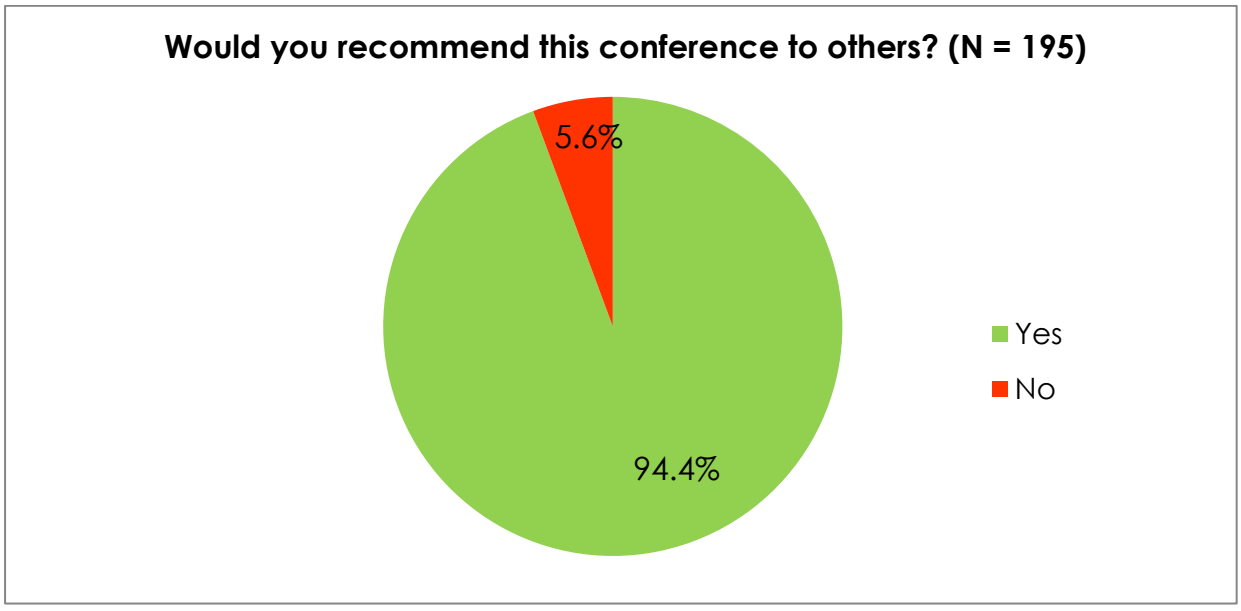


Figure 7. Would you recommend this conference to others? The data come from the online feedback survey that was sent to all participants one week after the event.

Fourth WHO Global Forum on Medical Devices

India presented a proposal to host the Fourth WHO Global Forum on Medical Devices in New Dehli, in August, 2018.

Statement of the Fourth WHO Global Forum on Medical Devices

The Ministry of Health & Family Welfare, Government of India has been a strong proponent of World Health Organization's initiative to convene the Global Forum on medical devices, as a part of its overall strategy to improve access to safe, effective, innovative, accessible, affordable and appropriate medical devices.

The Ministry of Health, Government of India through its agencies Central Drugs Standards Control Organization (CDSCO), the National Regulatory Authority of India and National Health Systems Resource Center (NHSRC), WHO Collaborating Centre for Priority Medical Devices & Health Technology Policy, would be pleased to host the 4th WHO Global Forum on Medical Devices in August 2018 at New Delhi, India, to make the most of the current environment of regulatory reform in the country.

This would be an opportune time for India to host this event with the Medical Device Rules 2017 being notified as part of the Drugs & Cosmetics Act & Rules, Materiovigilance Program of India being piloted, Medical Technology Assessment Board (MTAB), strengthened Health Technology Management, enabling landscape created to foster research and innovation under the Make in India vision of the Government of India to enable access to affordable, safe and effective diagnostics and medical devices globally. We would like to make the most of the present dynamic reform climate and high political will for the medical devices agenda in the country and the region, and share these updates at the next Global Forum. The 4th WHO Global Forum on Medical Devices would be demonstration of the member states and WHO commitment to towards improved access to safe, effective, innovative, quality medical devices and diagnostics, as a contribution to Universal Health Coverage and Sustainable Health Goals. This would further reinforce WHA 67.20 resolution for setting up the framework for unprecedented focus on Health technologies.

Thank you, the organizing committee of Global forum on medical devices for the confidence that you have placed in us. We would closely work with all levels of WHO – WHO Country office for India, WHO SEARO and WHO Headquarters for this upcoming forum. All the regions and member states are invited. We look forward to welcome you all at the 4th WHO Global Medical Device Forum at New Delhi, India next year in 2018.

Till then- Namaste and Jai Hind!

Third WHO Global Forum on Medical Devices: Conclusions

The time to prepare the 3rd Global Forum on Medical Devices was just 3 months, but due to the high interest in its contents, the response to submit papers and propose workshops was overwhelming, by the medical devices community , be its academia, governmental or professionals interested in the field.

This Forum remains to be the only Global Forum to discuss all aspects of medical technologies, from policies, to innovation, regulations, selection, use, management and it has drawn the attention of many stakeholders.

It is regrettable that there was no funding that could have been used to support experts from low and middle income countries that were not able to attend neither listen via internet as the technology was not available.

The organizing committee was very limited and thus it reflected in the lack of support in the meeting rooms but at the end, many committed participants helped inconditionally to manage the sessions.

It was very important to note the amount of participants from NGOs in official relations with WHO, as well as from WHO collaborating centers. It is the first time that many funding agencies and other UN organizations participated, (UNDP, UNFPA, UNICEF, IAEA), The Global Fund, FIND, PATH, etc. at workshops and plenary sessions.

The next issue is the active participation by many WHO colleagues from different units and regions: from: TB, Non communicable diseases, maternal newborn and child care, research and development (TDR), reproductive health (RHR), disabilities, trauma (NMH) and emergencies (WHE), health financing (HSF), prequalification, health workforce (HWF), Public health and environment (PHE), etc. This is a consequence of work that has been done with other units for the last 4 years, in which medical devices (medical technologies) are needed to achieve the interventions required for universal health coverage and the sustainable development goals.

Much work has to be done, to really increase access of appropriate affordable and good quality medical devices for health care workers and patients globally. All stakeholders, need to work in an organized coordintated way as the needs are immense in medical technologies, specially in LMIC, to target priority diseases, but the budget and staff dedicated to this in the UN organizations and donor organizations is very limited.

It should be noted that even if the Sustainable development goals quote that only medicines and vaccines are required to achieve universal health coverage, it should be acknowledged that medical devices are indispensable for health care provision for prevention, diagnostic, treatment, rehabilitiaon and palliative care, at all levels of care in all countries. The selection for the most appropriate, affordable and of good quality that can be used safely is complex process and requires expertise of health care workers and/ or patients.

Every workshop and panel presentation presented issues of great concern for users and thus this Global Forum is an invitation to keep on working together towards increasing access particularly for the ones that need it the most, the sick population in low resource settings.

WHO acknowledges all that collaborated for the Third Global Forum and encourages to keep on working towards the health of the population and looking forward to present new outcomes in the Fourth WHO Global Forum in India in 2018.

Appendix 1

Conference programme

Wed. 09:00 – 09:15: Plenary Welcome Session

Time	Plenary Welcome session - Wednesday 10th May 2017	Room
09:00 - 09:15	Dr. Suzanne Hill Director, Essential Medicines and Health Products , WHO	Salle 1

Wed. 09:15 – 10:45: Workshop 1

	Time	Ref ID	Workshop Session 1 - Wednesday 10th May 2017	Room
Wed. 09:15 - 10:45			**Innovation of Medical Devices**	
	09:15 - 10:00	A230-1	**Accelerating innovation: 10 lessons from 40 years** Dr. Patricia Coffey, PATH, United States of America	Salle 3
	10:00 - 10:45	R612	**End-to-end development of a regulated uterine balloon** Ms. Elizabeth Abu-Haydar, PATH, United States of America Chris De Villiers, Sinapi Biomedical, South Africa Patricia Coffey, PATH, United States of America	
			Radiation/Medical Imaging	
	09:15 - 10:00		**IAEA - Overview of human health guidance** Mr. Rajiv Prasad, International Atomic Energy Agency, Austria	Salle 7
	10:00 - 10:45	R635	**Implementation of international basic safety standards (BSS) for the use of radiological medical imaging devices** Dr. Maria Del Rosario Perez, WHO, Switzerland Jacques Abramowicz, WFUMB, United States of America Pablo Jimenez, PAHO, United States of America Miriam Mikhail, RAD-AID International, United States of America Ola Holmberg, IAEA, Austria María Pérez & Emilie Van Deventer, WHO, Switzerland Magdalena Stoeva, IOMP, Bulgaria Stewart Whitley, ISRRT, United Kingdom	
			Hospitals	
	09:15 - 10:00	A251	**Implications of medical equipment for building design** Mr. Walter Vernon, Mazzetti/Sextant/IFHE, United States of America	Salle 17
	10:00 - 10:45		**WHO - Safe hospitals** Dr. Jonathan Abrahams, WHO, Switzerland	
			Surgery & Emergency Care	
	09:15 - 10:00		**WHO - Surgical care and anaesthesia** Dr. Walter Johnson, WHO, Switzerland	Salle 13
	10:00 - 10:45		**WHO - Emergency and trauma care** Dr. Teri Reynolds, WHO, Switzerland	
			ICTs in Health	
	09:15 - 10:45	A110-3	**Digital transformation of healthcare in LMICs** Mr. Jan-Willem Scheijgrond, DITTA/Philips Healthcare, Netherlands Guy Frija, ISR, United States of America Emmanuel Akpakwu, WEF Philip James Leonard, Philips Electronics, United Kingdom Nicole Denjoy, COCIR Secretary General, Belgium	Salle 15
			Assessment of Medical Devices	
	09:15 - 10:45	R621	**The HTA of medical devices in LMICs** Prof. Aleksandra Torbica, Bocconi University, Italy Rosanna Tarricone & Carlo Federici, CERGAS-Bocconi University, Italy	Salle 14
			Regulation and Standards	
	09:15 - 10:45	A111	**Medical device regulations for regulators, manufacture, and users** Dr. Mary Overland, DITTA/GE Healthcare, United States of America Josephina Hansen, WHO, Switzerland Robert E. Geertsma, National Institute for Public Health and the Environment (RIVM), Netherlands	Salle 16

Wed. 09:15 – 10:45: Workshop 1 (cont.)

Wed. 09:15 - 10:45	**Health Technology Management/Clinical Engineering**			
	09:15 - 10:00	R646	**CE-HTM education, training, and professional credentialing** Mr. John Tobey Clark, University of Vermont, United States of America Anna Worm, THET, Benin Mario Forjaz Secca, IFMBE, Portugal-Mozambique Shauna Mullally, Northwest Territories Health System, Canada Rossana Rivas, CENGETS PUCP, Peru Yadin David, Biomedical Engineering Consultants, United States of America Mario Medvedev, University of Zagreb, Croatia James Wear, Consultant, United States of America	Salle 4
		R246	**Global HTM training and CED eCourse project** Mr. John Tobey Clark, University of Vermont, United States of America Ms. Anna Worm, THET, Benin Mario Forjaz Secca, IFMBE, Portugal-Mozambique Shauna Mullally, Northwest Territories Health System, Canada Rossana Rivas, CENGETS PUCP, Peru	
	10:00 - 10:45	A228-2	**CED role in linking global HT innovation/standards** Dr. Yadin David, Biomedical Engineering Consultants, United States of America Dr. Thomas Judd, IFMBE/CED, United States of America Shauna Mullally, Northwest Territories Health System, Canada Fred Hosea, Yachay Tech University, Ecuador	
		A241-3	**Global clinical engineering success stories** Mr. Thomas Judd, IFMBE/CED, United States of America Yadin David, IFMBE/CED Board, United States of America Fred Hosea, Yachay Tech University, Ecuador	
	Personal Protective Equipment for Ebola (Closed Session)			
	09:15 - 10:30		**WHO advisory committee meeting on innovation of personal protective equipment** Members of the committee	Salle 18
	Regulatory Framework (Closed Session)			
	09:15 - 10:30		**WHO model regulatory framework medical devices workshop** Participants of the workshop	Salle 6

Wed. 11:00 – 12:30: Workshop 2

Wed. 11:00 - 12:30	**Innovation of Medical Devices**			
	11:00 - 11:45	R81	**Technical characterization of appropriate medical equipment** Mr. Maurice Page, HUMATEM, France Matthieu Gani, CODEV/EssentialTech EPFL, Switzerland Mélanie Amrouche, Robin Walz, Blanc-Gonnet & Barbara Comte, HUMATEM, France	Salle 3
	11:45 - 12:30	A99-1	**Adoption of medical-technologies in infrastructure-poor environments** Ms. Gisela Abbam, GE Healthcare, United Kingdom Vikram Damodaran, Sally Lee, GE Healthcare, Singapore	
	Radiation/Medical Imaging			
	11:00 - 11:45	A229	**Defining medical imaging requirements for rural health center** Dr. Yadin David, Biomedical Engineering Consultants, LLC, United States of America Cari Borras & Mario Secca, IUPESM/HTTG, United States of America Taofeeq Ige, National Hospital Abuja, Nigeria	Salle 7
	11:45 - 12:30	A158	**Medical imaging equipment: global plan for improvement** Prof. Guy Frija, ISR, United States of America Magdalena Stoeva, IOMP, United Kingdom Stewart Whitley,ISRRT, United Kingdom	
	Public-Private Partnership			
	11:00 - 12:30		**Leveraging Public-Private Partnerships to Access Essential Technologies for Primary Care in Emerging Economies** Ms. Vanessa Candeias, Peter Varnum, Jennette Leung, Arnaud Bernaert, World Economic Forum, Switzerland	Salle 17

Wed. 11:00 – 12:30: Workshop 2 (cont.)

Wed. 11:00 - 12:30	**Innovation of Medical Devices**			
	11:00 - 11:45	R81	**Technical characterization of appropriate medical equipment** Mr. Maurice Page, HUMATEM, France Matthieu Gani, CODEV/EssentialTech EPFL, Switzerland Mélanie Amrouche, Robin Walz, Blanc-Gonnet & Barbara Comte, HUMATEM, France	Salle 3
	11:45 - 12:30	A99-1	**Adoption of medical-technologies in infrastructure-poor environments** Ms. Gisela Abbam, GE Healthcare, United Kingdom Vikram Damodaran, Sally Lee, GE Healthcare, Singapore	
	Radiation/Medical Imaging			
	11:00 - 11:45	A229	**Defining medical imaging requirements for rural health center** Dr. Yadin David, Biomedical Engineering Consultants, LLC, United States of America Cari Borras & Mario Secca, IUPESM/HTTG, United States of America Taofeeq Ige, National Hospital Abuja, Nigeria	Salle 7
	11:45 - 12:30	A158	**Medical imaging equipment: global plan for improvement** Prof. Guy Frija, ISR, United States of America Magdalena Stoeva, IOMP, United Kingdom Stewart Whitley,ISRRT, United Kingdom	
	Public-Private Partnership			
	11:00 - 12:30		**Leveraging Public-Private Partnerships to Access Essential Technologies for Primary Care in Emerging Economies** Ms. Vanessa Candeias, Peter Varnum, Jennette Leung, Arnaud Bernaert, World Economic Forum, Switzerland	Salle 17
Wed. 11:00 - 12:30	**Laboratory & Pathology**			
	11:00 - 11:45	R428	**The mobile laboratory: bringing high-quality testing to the patient** Ms. Susanne Andresen, International Federation of Biomedical Laboratory Science, Denmark Pierre Bouchelouche, Zealand University Hospital Koege, Denmark	Salle 13
	11:45 - 12:30	R244	**The evolving role of pathology** Prof. Lai Meng Looi, WASPaLM, Malaysia Dr Roberto Verna, WASPaLM, Italy Dr Jagdish Butany, WASPaLM, Canada	
	ICTs in Health			
	11:00 - 11:45	A242-1	**Clinical engineering, eHealth, and ICT global overview** Dr. Elliott Sloane, Center for Healthcare Information Research and Policy, United States of America	Salle 15
		A242-3	**Cybersecurity overview and case studies** Dr. Elliott Sloane, Center for Healthcare Information Research and Policy, United States of America	
	11:45 - 12:30	A242-2	**CE-IT innovation: how to make health care right** Mr. Mario Castaneda, Healthitek, United States of America Thomas Judd, IFMBE-CED, United States of America	
		R473	**Using clinical data in health technology management** Ms. Tracy Rausch, DocBox, United States of America Thomas Judd, IFMBE-CED, United States of America Yatin Mehta, Medanta the Medicity, India Kelly Flanagan, DocBox, United States of America Mario Castaneda, Healthitek, United States of America	
	Assessment of Medical Devices			
	11:00 - 11:45		**HTAi: First aid tools to the assessment of medical devices** Dr. Iñaki Gutierrez Ibarluzea, HTAi, Spain	Salle 14
	11:45 - 12:30	R554	**Health economic via web: the MAFEIP tool** Dr. Francisco Lupiáñez Villanueva, Universitat Oberta de Catalunya - Open Evidence, Spain Leandro Pecchia, University of Warwick, United Kingdom Ruth Vilar, Universitat Oberta de Catalunya - Open Evidence, Spain Arnold Senn, European Commission, Belgium	
	Nomenclature Systems			
	11:00 - 11:45	R24	**GMDN: an introduction** Mr. Mark Wasmuth, GMDN Agency, United Kingdom	Salle 16
	Health Technology Management/Clinical Engineering			
	11:00 - 11:45	R605	**Role of BMETs in health technology management** Mr. Ismael Cordero, Gradian Health Systems, United States of America Anna Worm, THET, Benin/United Kingdom Jocelyn Brown, 3rd Stone Design, United States of America	Salle 4
	11:45 - 12:30	R640	**IFMBE/CED role in global BME/CE recognition** Prof. James Goh, IFMBE, Singapore Prof. Ernesto Iadanza, IFMBE, Italy Yadin David, IFMBE/CED, United States of America	
		A228-2	**IFMBE/CED & global CE-HTM evidence based advances** Prof. Ernesto Iadanza, IFMBE, Italy Yadin David, IFMBE, United States of America	
	Personal Protective Equipment (Closed Session)			
	11:45 - 12:30		**WHO advisory committee meeting on innovation of personal protective equipment** Members of the committee	Salle 18
	Regulatory Framework (Closed Session)			
	11:45 - 12:30		**WHO model regulatory framework medical devices workshop** Participants of the workshop	Salle 6
12:15 - 12:45	12:15 - 12:45		**Lunch Break**	

Wed. 13:30 – 15:00: Workshop 3

Wed. 13:30 - 15:00	**Innovation of Medical Devices**			
	13:30 - 14:15	R279	**Innovation platform for LMIC medical technologies** Ms. Alexis Steel, CAMTech, Massachusetts General Hospital , United States of America Sandra Butler, Molly Ward & Krisitian Olson, Massachusetts General Hospital, United States of America	**Salle 3**
	14:15 - 15:00	A83	**Transforming from product innovation to comprehensive solutions** Dr. Trevor Gunn, Medtronic, United States of America	
	Radiation/Medical Imaging			
	13:30 - 14:15	R236	**How to combat the burden of disease in the developing world: the role of radiotherapy in the management of cervical, breast and prostate cancers** Prof. Patrick Kupelian, UCLA, United States of America	**Salle 7**
	14:15 - 15:00	A101	**Diagnostic imaging: health information systems and healthcare technology management** Dr. Miriam Mikhail, RAD-AID International, Switzerland Nikita Consul & Elise Desperito, Columbia University chapter of RAD-AID International, United States of America of America Melissa Culp, RAD-AID International, Switzerland	
	Quality			
	13:30 - 14:15	R446	**Good practice in ultrasound probe cleaning** Prof. Guy Frija, ISR, United States of America Nicole Denjoy, DITTA, Belgium	**Salle 17**
	14:15 - 15:00	A231	**Market Dynamics: Supporting Country Decision-Making On Medical Devices; Case Study on Optimizing the Deployment of Cervical Pre-cancer Treatment Devices** Mr. Ray Cummings, PATH, United States of America Tara Herrick & Bhavya Gowda, PATH, United States of America	
	In Vitro Diagnostics			
	13:30 - 14:15		**Revised WHO guidance on procurement of IVDs and other laboratory items: tips and tricks** Mr. Jason Williams, USAID, United States of America; Anita Sands, WHO, Switzerland	**Salle 13**
	14:15 - 15:00		**WHO - Prequalification of IVD** Ms. Helena Ardura, Deirdre Healy, WHO, Switzerland	
	ICTs in Health			
	13:30 - 14:15	R143	**Deep machine learning detection of preclinical diseases** Mr. Ludovico Valerio Ciferri Ceretti, International University of Japan, Japan Georg Aumayr, Johanniter, Austria Gianluca Colombo, OneoOffTech UG, Germany Mathew Summers, University of the Sunshine Coast, Australia Tamas Madl, HeartShield Ltd./Research Institute for Artificial Intelligence (OFAI), Austria Alessandro Vercelli, University of Turin, Italy	**Salle 15**
	Priority Medical Devices			
	13:30 - 14:15		**WHO - Priority medical devices** Ms. Adriana Velazquez Berumen; Gabriela Jimenez Moyao, Antonio Migliori & Natalia Rodriguez, WHO, Switzerland Adham Ismael Abdel, Alejandra Velez, WHO EMRO, Egypt	**Salle 14**
	Nomenclature Systems			
	13:30 - 15:00	R254	**Securing global supply chain utilizing UDI** Mr. Ralph Ives, GMTA, Switzerland Nicole Taylor-Smith & Lindsay Tao, GMTA, Switzerland	**Salle 16**
	Tools for Health Technology Management			
	13:00 - 14:15		**Computerized maintenance management systems (CMMS) requirements and results** Mr. Bill Gentles, ACCE, United States of America Martin Raab, Swiss TPH, Switzerland Claudio Meirovich, Meirovich Consulting, Spain Jitendra Sharma, AP MedTech Zone, India	**Salle 4**
	14:15 - 15:00	R552	**A reality check on biomedical engineering education** Prof. James Goh, IFMBE, Singapore Kingping Lin, IFMBE, Singapore Shankar Krishnan, Wentworth Institute of Technology, United States of America Ratko Magjarević, IFMBE/University of Zagreb, Croatia	
	Personal Protective Equipment (Closed Session)			
	13:30 - 15:00		**WHO advisory committee meeting on innovation of personal protective equipment** Members of the committee	**Salle 18**
	Regulatory Framework (Open Session)			
	13:30 - 15:00		**WHO model regulatory framework medical devices workshop** Ms. Josephina Hansen, WHO, Switzerland Adham Ismael Abdel, WHO EMRO, Egypt Johanna Koh, Singapore	**Salle 6**
	ADJOURN			

Wed. 15:30 – 17:45: Plenary Session I (Salle 1)

Time	Plenary Panel Session - Wednesday 10th May 2017	Room
Wed. 15:30 - 16:15	**Medical devices for health care delivery, global and regional perspectives** Chair: Dr. Pamphile Thierry Houngbo, Ministry of Health, Benin Co-chair: Ms. Josephina Hansen, WHO, Switzerland	Salle 1
	Presentation of WHO Global atlas of medical devices Ms. Adriana Velazquez Berumen, WHO Headquarters	
	Medical devices situation in the African region Dr. Stanislav Kniazkov, WHO Regional office for Africa	
	Developments and initiatives of medical devices in the Americas Mr. Alexandre Lemgruber, WHO Regional office of the Americas	
	Developments and initiatives of medical devices in the Eastern Mediterrenean Dr. Adham Abdel Moneim, WHO Regional office for Eastern Mediterrenean	
	Characteristics of countries in the European region Ms. Tifenn Humbert, WHO Regional Office for Europe	
	Perspectives of medical devices in India and other South Eastern Asia countries Dr. Gupta Madhur, WHO India Country Office	
	Plenary Panel Session 1 - Wednesday 10th May 2017	
Wed. 16:15 - 17:00	**Priority Medical Devices for Reproductive, Maternal, Neonatal, Child and Adolescent Care** Chair: Dr Sundaram Mangalabha, Madras Medical College, India Co-chair: Dr. Wilson Were, WHO, Switzerland	Salle 1
	Presentation of book " Interagency list of Priority medical devices for reproductive, maternal, new born and child health" Ms. Adriana Velazquez Berumen, WHO	
	Innovating and increasing access to medical devices for reproductive and maternal health Ms. Patricia Coffey, PATH, United States of America	
	Medical devices for reproductive health Ms. Seloi Mogatle, UNFPA, Copenhagen	
	Research and development in reproductive health Dr. Manjulaa Narasimhan, WHO	
	Integrating maternal new born and child health for universal health coverage Dr. Anshu Banerjee, WHO	
	Supply of medical devices for new born and children Mr. Paul Labarre, UNICEF	
	Plenary Panel Session 2 - Wednesday, 10th May 2017	
Wed. 17:00 - 17:45	**Medical Devices for Communicable Diseases** Chair: Dr. Dan Bausch, LSHTM, United Kingdom Co-chair: Dr. Nikki Shindo, WHO, Switzerland	Salle 1
	Challenges in TB diagnostics Dr. Christopher Gilpin, WHO, Switzerland	
	WHO Essential Diagnostics list proposal Dr. Francis Moussy, WHO, Switzerland	
	Innovation of diagnostics for infectious diseases Dr. Catharina Boehme, FIND	
	Role of Biomedical laboratory scientists in early diagnosis Ms. Anne Berndt, IFBLS	
	Clinician's view on need for innovate personal protective equipment for Ebola Dr. Mohammed Boie Jalloh, Sierra Leone	
	Definition of a Preferred product characteristics for innovative PPE Dr. May Chu, Colorado School of Public Health, United States of America	

Wed. 17:45 – 18:45 : Poster Presentation 1A at Level 0 (see Thursday Programme for the list of posters)

Thursday 11th May, 2017: Preliminary Programme

Thr. 08:00 – 08:45: Regional Parallel Sessions

Room	Track	Regional Parallel Sessions
6	PR1	Africa
4	PR2	Americas
7	PR3	Eastern Mediterranean
3	PR4	Europe
5	PR5	South East Asia
18	PR6	Western Pacific
20		Innovators Meeting
19		NGO Meeting
Level 0	EXP	Exhibit and poster sessions

Thr. 08:00 – 08:45: Poster Session 1B (Level 0)

Poster session - Wednesday, May 10th to Thursday, May 11th, 2017	
A. Assistive Products	
R333	Hands free body dryer (dry by yourself)
	Dr. Olga Patricia Barragan Vesga, Horacio Galeano Zabala, Inventionspro, Colombia
R177	Manual wheelchairs are great! But…
	Dr. Dafne Zuleima Morgado Ramirez, Catherine Holloway, University College London, United Kingdom
R281	Floss pick fastener
	Dr. Horacio Galeano Zabala, Olga Patricia Barragan Vesga, Inventionspro, Colombia
A88	Arm sled
	Dr. Horacio Galeano Zabala, Olga Patricia Barragan Vesga, Inventionspro, Colombia
R553	Towards better and more equal continence care
	Ms. Eszter Kacskovics, SCA Hygiene Products, Dr Gyula Markovics, SCA Hygiene Products
R296	Motion analysis for supervision of medication intake
	Prof. Maria Elena Algorri, Technische Hochschule Köln, Germany
C. Human Factors Engineering	
A230-2	Involving users as co-designers of medical devices
	Dr. Patricia Coffey, Maggie Kilbourne-Brook, PATH, United States of America
R559	Task-shifting contraceptive implant removal device
	Dr. Ibrahim Mohedas, Carrie Bell, Kevin Jiang, Kathleen Sienko, University of Michigan, United States of America; Zerihun Abebe, Delayehu Bekele, St. Paul's Hospital Millennium Medical College, Ethiopia
A185-2	Engaging stakeholders during Fuzzy front-end design
	Dr. Ibrahim Mohedas, Shanna Daly, Kathleen Sienko, University of Michigan, United States of America
D. Heathcare Technology Management/Clinical Engineering	
R542	Impact of clinical engineering in primary healthcare
	Ms. Priscila Avelar, Renato Garcia, IEB-UFSC/WHO Collaborating Centre Brazil; Carlos Alberto Silva, SMS/PMF, Brazil
R341	Maintenance of medical devices North-West India
	Dr. Vatsal Gupta, Semira Manaseki-Holland, Karin Diaconu, University of Birmingham, United Kingdom
R273	Working group - medical device donations developing countries
	Mr. Anders Lygdman, Sahlgrenska International Care AB, Sweden; Members of network
R660	Methodology for performance assessment of a biomedical engineering department (R255)
	Ms. Maria Eugenia Moreno Carbajal, Starmedica Hospital, Mexico
R420	Medical device service procedures mobile application
	Mr. Jean Ngoie, NHS Tayside, United Kingdom; Kelsea Tomaino, University of Waterloo, Canada
R372	Evaluation of medical devices in Benin
	Mr. Charles Pascal Soroheye, DIEM, Benin; Adjaratou Seidou Maliki, Marc Myszkowski
R188	Case study in spanish medical equipment companies
	Prof. Yariza Chaveco Salabarria, Dr. C Juan Carlos Rubio Romero, University of Málaga, Spain; Dr. C Rosa Mayelín Guerra Bretaña, University of Havana, Cuba
R348	Assessment of technologies for organs preservation
	Mr. Corrado Gemma, Carlo Martinoli, Ilaria Vallone, Paolo Lago, Fondazione IRCCS Policlinico San Matteo, Italy;

Thr. 08:00 – 08:45: Poster Session 1B (cont.)

A8-2	Codebook for planning, procurement, testing and commissioning
	Mr. Claudio Meirovich, Meirovich Consulting, Spain
A130	Managing Successful Medical device Warranty Period Maintenance
	Ms. Demeru Yeshitla Desta, ; Tegbar Yigzaw Sendeke, Sharon Kibwana, Mihereteab Teshome Tebeje, Jhpiego-Ethiopia, Ethiopia.
	E. Assessment (HTA) of medical devices
R349	The Internet as a tool for an Early awareness and alert (EAA) system in the field of diabetes
	Ms. Vânia Marlene Ferreira De Sousa, Miguel Antunes, INFARMED - National Authority of Medicines and Health Products, I.P., Portugal
A87	Defining criteria for local versus national HTA
	Dr. Katriene Bjørnebek Frønsdal, Arentz-Hansen H, Lauvrak V, Ormstad S, Fure B
R191	Ultrasound adjunct in breast cancer screening
	Mr. Flávio Mauricio Garcia Pezzolla, Priscila Avelar, Renato Garcia, IEB-UFSC, Brazil
R141	Technology decision-making process: MRI purchase in portugal
	Ms. Maria Maia, Faculty of Sciences and Technology, Portugal
R521	Priority-setting for medical devices and equipment
	Ms. Mutsumi Metzler, Mr. Todd Dickens, PATH, United States of America
R623	Prioritisation of medical devices and diagnostics in India
	Dr. Yogita Kumar, Gupta Madhur, World Health Organisation, Ameel Mohammed, National Health Systems Resource Centre, India
	F. Human Resources for Medical Devices
R136	Overcome the shortage of radiotherapy staff in LMICs
	Dr. Stefan Berz, Michael Sandhu, Access to Care Foundation; Patrick Kupelian, Varian Medical Systems, United States of America; José-Manuel Valentim, Varian Medical Systems; Switzerland; Jan, LäraNära Degerfält, AB, Sweden
R560	Design requirements for task-shifting medical devices
	Ms. Marianna Coulentianos, Amir Sabet Sarvestani, Kathleen Sienko, Richard Gonzalez, University of Michigan, United States of America
A175-2	Prototyping best practices by Ghanaian novice designers
	Mr. Michael Deininger; Kathleen Sienko, Shanna Daly, Jennifer Lee, University of Michigan, United States of America; Elsie Effah Kaufmann, University of Ghana, Ghana
A215	Intern programs of biomedical engineering education
	Prof. Kangping Lin; Tsai, Chenglun, Chung-Yuan Christian University, Chinese Taipei
A109	Educational partnership for human resources and medical devices: Danang, Vietnam
	Dr. Miriam Mikhail, Rad-Aid International, Diagnostic Radiologist Based In Geneva, Switzerland; Lindsey Minshew, Candice Bolan, Hector Robles, J Mark Mckinney, Mayo Clinic, Florida, United States of America; Phuong Thi Loan Nguyen, Danang General Hospital, Danang, Vietnam
A185-1	Usability assessment of a task-shifting medical device
	Dr. Ibrahim Mohedas; Gashaw Andargie, Mula Adefris, Biruk Mengstu,Takele Tadesse, University Of Gondar, Ethiopia; Jose Davila, Ajay Kolli, Kathleen Sienko, Kevin Jiang, Weiner, Annabel, University Of Michigan, United States Of America
R661	Rwanda biomedical technican training program
	Mr. Costica Uwitonze, Rwanda Association of Medical Engineering, Rwanda
R744	Integrated model of universities to promote the clinical engineering
	Prof. Beatriz Janeth Galeano Upegui , Universidad Pontificia Bolivariana, Colombia; Javier García, Juan Guillermo Barreneche, U de A; Nelson Escobar, UPB; Javier Camacho, EIA-CES; Sara Álvarez, ITM; Colombia
	K. Innovative In Vitro Diagnostics
R267	Rapid diagnostics of mosquito transmitted diseases
	Dr. Robert Burger, BluSense Diagnostics, Denmark
	L. Innovation for Mother & Child Care
R331	Unsupervised electronic stethoscope for childhood pneumonia diagnostic
	Dr. Mohamed-Rida Benissa, University of Geneva, Switzerland; J. Solà, F.Hugon,P.Starkov, F.Braun, S.Manzano, C.Verjus, A.Gervaix
A38	Field testing a neonatal phototherapy device: a novel approach
	Dr. Donna Brezinski, Gary E. Gilbert, Alyssa Pfister
R292	Objective feedback improves resuscitation training and practice
	Dr. Kevin Cedrone; Kristian Olson, Massachusetts General Hospital, United States of America; Santorino Data, Mbarara University of Science and Technology, Uganda
A230-3	A feeding cup for preterm infants
	Dr. Patricia Coffey; Christy Mckinney, Michael Cunningham, Robin Glass, Seattle Children's; Patricia Coffey, Steve Brooke, PATH, United States of America; Karoline Myklebust Linde, Cansu Akarsu, Laerdal Global Health; Norway

Thr. 08:00 – 08:45: Poster Session 1B (cont.)

R442	Test for management of preeclampsia
	Ms. Wendy Davis, GestVision, United States of America; Irina Buhimschi, Research Institute at Nationwide Children's Hospital; Catalin Buhimschi, The Ohio State College of Medicine; Kara Rood, The Ohio State College of Medicine, United States of America
R112	A multiband reflectance photometric device for reveal gestational age at birth
	Prof. Rodney Guimaraes, Zilma Reis, Universidade Federal de Minas Gerais (UFMG), Brazil
R228	Innovation in umbilical cord severance
	Dr. William Kethman, William Strobel, Novate Medical Technologies, LLC, United States of America
R505	New improved newborn resuscitator
	Mr. Frode Liland, Karoline M. Linde, Jennifer L. Gilbertson, Laerdal Global Health, Norway
A168	Acceptability of conventional and upright neonatal resuscitators
	Dr. Manjari Quintanar Solares; Gene Saxon, Patricia Coffey, PATH; Indira Narayanan, Georgetown University Medical Center; Stephen Wall, Save the Children, United States of America; Rinku Srivastava, State Innovations in Family Planning Services Project Agency; Syed Ali, Aligarh Muslim University, India
R102	Prematurity detection by light
	Prof. Zilma Reis, Rodney Nascimento Guimarães, Gabriela Luíza Nogueira Vitral, Maria Albertina Santiago Rego, Ingrid Michelle Fonseca, Universidade Federal de Minas Gerais, Brazil
R765	Hub-and-spoke models for point-of-care early infant diagnosis
	Mr. Jean-François Lemaire, Rebecca Bailey, Esther Turunga, Jennifer Cohn, Elizabeth Glaser Pediatric AIDS Foundation Switzerland; Flavia Bianchi, Emma Sacks, Elizabeth Glaser Pediatric AIDS Foundation, United States of America
R573	A bundle approch to care for small babies
	Ms. Karoline Linde, Sakina Girnary, Jennifer Gilbertson, Frode Liland, Laerdal Global Health, Norway
A107-1	Hypothermia alert device: saving newborn lives
	Mr. Ratul Narain; Gini Morgan, Bempu Heath, India
A107-2	Preventing apneas of prematurity
	Mr. Ratul Narain; Gini Morgan, Bempu Heath, India
A 107-3	Remote monitoring for critical infants
	Mr. Ratul Narain; Gini Morgan, Bempu Heath, India
A210	Warmer for resuscitation with intact placental circulation
	Dr. Thanigainathan Sivam; Mangalabharathi Sundaram, Institute of Child Health & Hospital for Children, Valiyaveetil Sashikumar, Phoenix Medical System, India
R293	Preventing a never event
	Dr. Peter Young; Maryanne Mariyaselam, Queen Elizabeth Hospital, United Kingdom; Sinéad Renouf, Venner Medical Internationl, United Kingdom
R613	Device to save postpartum-hemorrhaging women in advanced shock
	Ms. Moytrayee Guha, Massachusetts General Hospital, United States of America; Thomas Burke, Sandra Danso-Bamfo, Alyssa Cappetta, Charles Masaki, Moytrayee Guha, Melody Eckardt, Brett Nelson, Massachusetts General Hospital, United States of America; Monica Oguttu, , Kisumu Medical and Education Trust, Kisumu, Kenya; S.A.S. Kargbo, Ministry of Health & Sanitation, Sierra Leone; Niang Mansour, Centre de Formation et de Recherche, Santé de la Reproduction, Senegal; Vincent Tarimo, Muhimbili National Hospital, Tanzania
R557	Warming solution for neonatal surgeries in Nigeria
	Dr. Taiwo Akeem Lawal, Akinwale Coker, University of Ibadan, Nigeria; Robert Murphy, Matthew Glucksberg, David Gatchell, Northwestern University, United States of America
R262	Description of automated epartogram with decision support
	Dr. Marc Mitchell, D-tree International; Douglas Williams, United States of America; Gill, Roopan, University of British Columbia, Canada; Thomas Routen, Things Prime, Switzerland
R472	Validity of a device for jaundice screening
	Dr. Anne Cc Lee, Brigham and Women's Hospital, Harvard Medical School, United States of America; Lian Folger, Salahuddin Ahmed, Lauren Schaeffer, Nazmun Bably , Mahmood Rahman, Rachel Whelan, Pratik Panchal, Arun Roy, Sayed Rahman, Nazma Begum, Abdullah Baqui
R558	Microarray patch for treatment of neonatal sepsis
	Dr. Mary Carmel Kearney, Emma Mcalister, Patricia Gonzalez Vazquez, Maelíosa Mccrudden, Ryan Donnelly, Queen's University Belfast, United Kingdom
	O. Regulation of Medical Devices
A68	Recommendations for proper use of disinfectants
	Dr. Bochra Bejaoui, Zohra Jemmali, Olfa Drissi, National Agency for Sanitary and Environmental Control of Products, Tunisia
R649	Knowledge about materiovigilance in Cluj-Napoca, Romania
	Dr. Simona Maria Mirel, "Iuliu Haţieganu" University of Medicine and Pharmacy Cluj-Napoca, Romania

Thr. 08:00 – 08:45: Video Screening 1B

Wednesday 10th - Thursday 11th, May	
B. Health Information Systems: Medical Device Issues	
A211	A health and education m-App Dr. Livia Bellina, Ilenia Nucatola, MobileDiagnosis Onlus, Italy
R304	Towards global integration of digital diagnostics devices Dr. Lena Kruckenberg, Owen Johnson, Mike Messenger, University of Leeds, United Kingdom; Stephen Box, National Pathology Exchange, United Kingdom
I. Innovation of Technologies for Screening and Diagnosis	
A102	Diagnostic Imaging improvement in Malawi Dr. Miriam Mikhail, RAD-AID International, Switzerland; Melissa Culp, RAD-AID Internaitonal, United States of America

Thr. 09:00 – 10:30: Plenary Session II (Salle 1)

Plenary Panel Session 3 - Thursday 11th May 2017		
Thr. 09:00 - 09:45	**Innovation of Medical Devices** Chair: Dr. Kathleen Sienko, University of Michigan, United States of America Co-chair: Ukpor Friday Akogor, Lagos State Health Center, Nigeria	Salle 1
	WHO compendium of innovative technologies for low resource settings Ms. Adriana Velazquez, WHO, Switzerland	
	WHO Health product profile directory Dr. Ivan Ostojic, McKinsey	
	The Digital Health Atlas: a global registry for digital health tools and deployments Dr. Garret Mehl, WHO, Switzerland	
	Role of funding and develop agencies encourage innovation based on real needs? Ms. Jennifer Fluder, USAID	
	Innovation unit at UNICEF Mr. Kristoffer Gandrup Marino, UNICEF	
Plenary Panel Session 4 - Thursday 11th May 2017		
Thr. 09:45 - 10:30	**Effective Implementation of Regulation of Medical Devices** Chair: Ms. Agnes Kijo, Tanzania Food and Drugs Authority, United Republic of Tanzania Co-chair: Dr. Nazeeh Alothmany, Saudi Food and Drugs Authority, Saudi Arabia	Salle 1
	Presentation of book on WHO model regulatory framework for medical devices. Ms. Josephina Hansen, WHO Headquarters	
	The new EU directives of medical devices regulations Mr. Carlo Pettinelli, European Commission	
	Medical devices regulation reform in India Dr. Eswara Reddy, CDSCO, India	
	Asian Harmonization working party tools to regulate medical devices Ms. Johanna Koh, AHWP, Singapore	
	Medical devices regulations in AMRO, indicators for assessments Mr. Alexandre Lemgruber, PAHO, United States of America	
	Step by step regulations of medical devices guidance book Dr. Adham Ismail Abdel, EMRO, Cairo	

Thr. 11:00 – 12:30: Oral Parallel Session 1

Time		Parallel sessions - Thursday 11 May 2017	Room
Thu. 11:00-12:30		**Innovation of medical devices** Session Chair: Dr. Gaby Vercauteren, WHO, Switzerland Session Co-Chair: Fred Hosea, Yachay Tech University, Ecuador	Salle 1
	A180.2	Engineering innovations for clinical applications Prof. James Cho Hong Goh, Chwee-Teck Lim, International Federation of Medical and Biological Engineering, Singapore	
	R270	Medical device reforms & the landscape in India Dr. Madhur Gupta, World Health Organization Country Office, India	
	A63	Collaborative open design for safer medical devices Ms. Alice Ravizza, Arti Ahluwalia, Carmelo De Maria, Licia Di Pietro, Jacopo Ferretti, Andrés Díaz Lantada , Mannan Mridha, Philippa Ngaju Makobore, June Madete, Albo Aabloo, Arni Leibovits	
	R490	Designing high quality global health technologies Dr. John Langell, Bernhard Fassl, Tyson Schwab, Dean Wallace, Roger Altizer, Tomasz Petelenz, Walter Prendiville, University of Utah, United States of America	
	A151	Designing global health technology for commercial scale Ms. Jocelyn Brown, Robert Miros, 3rd Stone Design/Hadleigh Health Technologies, United States; Adam Lewis, Gradian Health Systems, United States of America	
	R259	Temperature protocol that minimises early neonatal deaths Prof. Hippolite Amadi, Imo State University Nigeria & Imperial College London, United Kingdom; Olateju Eyinade K., Adesina Temilade C., University of Abuja Teaching Hospital, Nigeria	
Thu. 11:00-12:30		**Regulation of medical devices** Session Chair: Ms. Thangavelu Sasikala Devi, Medical Device Authority, Malaysia Session Co-Chair: Ms. Josephina Hansen, WHO, Switzerland	Salle 5
	R609	Actions of medical device post-market surveillance Prof. Kangping Lin, International Federation of Medical and Biological Engineering, Singapore; Yueh-Tzu Hung, Shiu-Huei Yeh, Yu-Wen Huang, Pei-Weng Tu, Food and Drug Administration, Ministry of Health and Welfare, Chinese Taipei	
	R611	A new academic program for MD regulatory affairs professionals Prof. Folker Spitzenberger, Heike Wachenhausen, University of Applied Sciences Luebeck, Germany	
	R619	Medical device competency regulatory program in Malaysia Ms. Sasikala Devi Thangavelu, Medical Device Authority, Malaysia	
	R539	Validation and verification of IVDs in Kenya Ms. Bintiomar Tsala, Kenya Medical Laboratory Technicians and Technologists Board, Kenya	
		Collaborating Centre PAHO/WHO for the Regulation on Health Technology (Medical Devices). Impact in regional regulatory work Ms. Dulce María Martínez Pereira, State Center of Medicine and medical Devices, Cuba	
Thu. 11:00-12:30		**Assessment of medical devices** Session Chair: Dr Iñaki Gutierrez, HTAi, Spain Session Co-Chair: Ms. Mirella Marlow, NICE, United Kingdom	Salle 6
	R468	INAHTA perspective of assessment of medical devices Dr. Sophie Werkö, INAHTA; Gino De Angelis, CADTH, Canada	
	R561	Assessment of medical devices in low-income settings Dr. Leandro Pecchia, IFMBE, United Kingdom; Nicolas Pallikarakis, University of Patras, Greece	
	R315	Horizon scanning to ensure timely HTA Dr. Vigdis Lauvrak, The Norwegian Institute of Public Health; Ellen Nilsen, Norwegian Directorate of Health, Norway	
	A87	Using other's HTAs: adopt or adapt? Dr. Katrine Bjørnebek Frønsdal, Lauvrak V, Skår Å, Giske L, Sæterdal I, Fure B, Norwegian Institute of Public Health, Norway	
	R468	Implementation considerations in a HTA of dialysis Mr. Gino De Angelis, Eftyhia Helis, Janet Crain, Kristen Moulton, Laura Weeks, CADTH, Canada	

Thr. 11:00 – 12:30: Oral Parallel Session 1 (cont.)

Thu. 11:00-12:30		**Management of medical devices** Session Chair: Ms. Vanessa Candeias, World Economic Forum , Switzerland Session Co-Chair: Mr. Tom Judd, IFMBE CED, United States of America	**Salle 4**
	R96	Medical equipment management Prof. Nikolaos Pallikarakis, Institute of Biomedical Technology (NIBIT), Greece	
	A73	HTM implementation in Saint George hospital Lebanon Mr. Riad Farah, Lebanon	
	R173	Good governance of equipment in public sector Dr. Pamphile Thierry Houngbo, Ministry of Health, Benin; Prof. Joske. F. G. Bunders-Aelen, Vrije Universiteit Amsterdam, The Netherlands	
	R46	Strengthening utility and maintenance of medical devices Mr. Demeru Yeshitla Desta; Ismael Cordero, Gradian Health System, United States of America; Ayalew Firew, Kibwana Sharon, JHpiego-Ethiopia.	
Thu. 11:00-12:30		**Human resources and medical devices** Session Chair: Prof James Goh, IFMBE, Singapore	**Salle 3**
	A243	The involvement of IFMBE in developing countries Prof. Mario Forjaz Secca, IFMBE	
	R622	IOMP initiatives on equipment related professional capacities Prof. Magdalena Stoeva, International Organization for Medical Physics (IOMP), United Kingdom	
	A179-1	Clinical engineering in China Prof. Bao Jiali, Zhu Chaoyang, Zhejiang University, China	
	R653	Apprenticeship model for clinical engineering workforce development Mr. Abdul Basit, Malcolm Birch, Barts Health NHS Trust, United Kingdom	
	A198-1	Biomedical engineering education: studies harmonisation Prof. Nikolaos Pallikarakis, Institute of Biomedical Technology (NIBIT), Greece	
Thu. 11:00-12:30		**Assistive devices** Session Chair: Prof. Shankar Mutukrishnan, Wentworth Institute of Technology, United States of America Session Co-Chair: Dr. Emma Tebbutt, WHO, Switzerland	**Salle 14**
	R197	A novel device to screen newborns for hearing loss in resource constrained settings to prevent speech loss Mr. Nitin Sisodia, Gopinathan, Karthikeyan, Sohum Innovation Lab, India	
	R529	Evaluation of performance leads to better products? Mr. Jesper Nordlinder, SCA Hygiene Products, Sweden	
	A249	Dynamical orthostatic chair Mr. Walef Robert Ivo Carvalho, Instituto Nacional de Telecomunicações, ; Ana Letícia Goncalves, National Institute of Telecomunications (Inatel), Brazil	
	R651	Hand orthosis for radial or cubital injury Ms. Rosa Itzel Flores Luna, Ruben Valenzuela-Montes, Hanna L. Garcia-Guerra, David de Jesus-Cruz, Mariano Garcia del Gállego, Alvaro Ayala-Ruiz, National Autonomous University of Mexico (UNAM), Mexico	
	R217	Disrupting the barriers to uncorrected refractive errors Dr. Shivang R. Dave, Nicholas J. Durr, Daryl Lim, Eduardo Lage, PlenOptika, Inc.; Department of Biomedical Engineering, Johns Hopkins University, United States of America; Ramakrishnan Mahadevan, Sriram Ravilla, Aurolab, India; Department of Biochemistry, Universidad Autonoma de Madrid, Medical School, Spain; Sanil Joseph, Thulasiraj D. Ravilla, Aravind Eye Care System, India	
Thu. 11:00-12:30		**eHealth** Session Chair: Dr. Abdelbaset Khalaf, Tshwane University of Technology, South Africa	**Salle 7**
	A10	Medical internet of things and embedded intelligence in healthcare Dr. Abdelbaset Khalaf, Tshwane University of Technology, South Africa	
	R68	Development of innovative tools for improving rural health care and safety Dr. Mannan Mridha, The Royal Institute of Technology, Sweden; Hashem. Md. Abul, Department of Soil Science, Bangladesh Agricultural University, Mymensingh, Bangladesh	
	A248	Conquering the leprosy last mile: the role of mobile-phones! Prof. Phillip Olla, Audacia Bioscience, Canada	
	R655	Non-invasive and minimally invasive medical devices Prof. Ratko Magjarević, IFMBE / University of Zagreb, Croatia	

Thr. 11:00 – 12:30: Oral Parallel Session 1 (cont.)

Thu. 11:00-12:30		**Health service delivery: Oxygen supply systems (round-table)** Session Chair: Dr Dino Rech, Bill and Melinda Gates Foundation, United States of America	Salle 13
		Availability and oxygen use in small hospitals Dr. Wilson Were, WHO, Switzerland	
	A194	Methods for strengthening the market for safe oxygen delivery Ms. Lisa Smith, PATH, United States of America	
	R140	Medical device ownership models and maintenance contracting approaches Ms. Lisa Smith, Michael Ruffo, PATH, United States of America	
	R574	Quantifying gaps in access using medical device census information Mr. Michael Ruffo, Lisa Smith, PATH, United States of America; Prabhat, Anjaney, National Health System Resource Center, India	
	A195	Multi-country suitability assessment for available pulse oximeters Mr. Michael Ruffo, Ben Creelman, Gene Saxon, Lisa Smith, PATH, United States of America	
	R307	Strengthening policy advocacy for medical devices Ms. Jaclyn Delarosa, PATH, United States of America	
	R595	Oxygen system technologies Mr. Kristoffer Gandrup-Marino, UNICEF, Denmark	
Thu. 11:00 - 12:30		**Personal Protective Equipment (PPE) for Ebola [Special Session]** Session Chair: Dr Nahoko Shindo, WHO, Switzerland Session Co-Chair: Dr May Chu, Colorado School of Public Health, United States of America	Salle 18
		Laboratory Evidence and Research Prof. Daniel Bausch, UK Public Health Rapid Support Team, United Kingdom	
		End Users Perspectives Dr. Andrew Hall, Mosoka Fallah, United Kingdom	
		Occupational Health and Infection Protection Control Dr. Trish Perl, University of Texas Southwestern Medical Center, United States of America	
		Technical Specifications and Logistics and Procurement Dr. Fatma Selcen Kilinc-Balci, John McGhie, International Procurement Agency, Netherlands	
		Preparing the preferred product characteristics (PPC) for innovative PPE Dr. May Chu, Colorado School of Public Health, United States of America; Adriana Velazquez, WHO, Switzerland	

Thr. 12:30 – 13:30: Lunch Break

Thr. 13:30 – 15:00: Oral Parallel Session 2

Thu. 13:30-15:00		**Innovation of medical devices** Session Chair: Dr. Prashant Jha, All India Institute of Medical Sciences, India Session Co-Chair: Prof. Kathleen Sienko, University of Michigan, United States of America	Salle 1
	R591	How UNICEF supply has driven innovation within medical devices Mr. Kristoffer Gandrup-Marino, UNICEF, Denmark	
	R562	Small team medical device innovation for low-resource settings Dr. Ryan Lewis, Megadyne a Johnson & Johnson Family of Companies, United States of America	
	R430	Designing solutions to global health challenges: the Johns Hopkins CBID model Prof. Youseph Yazdi, Acharya Soumya, Johns Hopkins University, United States of America	
	R625	Design for real-world device evaluation Prof. David Matchar, Bibhas Chakraborty, Duke-NUS Medical School, Singapore	
	R106	Transfer of medical devices manufacturing technology Dr. Luca Passaggio, LP Medical Consulting Sagl, Switzerland	

Thr. 13:30 – 15:00: Oral Parallel Session 2 (cont.)

Thu. 13:30-15:00		**Regulation of medical devices** Session Chair: Dr. Maura Linda Sitanggang, Ministry of Health, Indonesia Session Co-Chair: Ms. Josephina Hansen, WHO, Switzerland	**Salle 5**
	R577	Global medical device regulatory harmonization Mr. Eugene Saxon, PATH, United States of America	
	A78	Voluntary certification for medical devices Mr. Mohammad Ameel, National Health Systems Resource Centre, India	
	R231	Unifying efforts against counterfeiting and forging documents Dr. Nazeeh Alothmany, Saudi Food and Drugs Authority, Saudi Arabia	
Thu. 13:30-15:00		**Human factors engineering** Session Chair: Dr. John Langell, University of Utah, United States of America	**Salle 7**
	A234	Teaching appropriate medical device design to engineers Prof. Walter Karlen, ETH Zürich, Switzerland	
	R343	Applying human centered design for medical devices Ms. Jennifer Fluder, Marissa Leffler, Avery Waite, USAID, United States of America	
	R496	Human-centered design of medical devices for global users Prof. Beth Kolko, University of Washington/Shift Labs, United States of America	
	R647	Student-based maternal needs assessment for Sub-Saharan Africa Prof. Kathleen Sienko, Timothy Johnson, Ibrahim Mohedas, Maria Young, University of Michigan, United States of America; Elsie Effah Kaufmann, University of Ghana, Ghana; Samuel Obed, Korle Bu Teaching Hospital, Ghana; Kwabena Danso, Thomas Konney, Tawiah Odoi, Henry Opare-Addo, Cornelius Turpin, Komfo Anokye Teaching Hospital, Ghana; Zerihun Abebe, St. Paul's Hospital Millennium Medical College, Ethiopia	
Thu. 13:30-15:00		**Human resources and medical devices** Session Chair: Dr. James Goh, IFMBE, Singapore Session Co-Chair: Mr. Andrew Jones, THET, United Kingdom	**Salle 3**
	R49	Networking from Colombian clinical engineers Ms. Andrea Rocio Garcia Ibarra, Biomedical engineer-MoH consultant, Colombia	
	A155	Biomedical and clinical engineering development in Bangladesh Dr. Md Ashrafuzzaman, Military Institute of Science and technology, Bangladesh	
	R172	Roles of CE in medical device development Mr. Hiroki Igeta, Japan Association for Clinical Engineers / Aso Iizuka Hospital, Japan	
	R724	Addressing challenges in educating biomedical engineers to meet the global needs Prof. Shankar Muthukrishnan, Wentworth Institute of Technology, United States of America	
Thu. 13:30-15:00		**Health service delivery: Oxygen supply systems** Session Chair: Mr. Ismael Cordero, PATH, United States of America Session Co-Chair: Dr. Lisa Stroux, Independent, United Kingdom	**Salle 13**
	R319	Automating the diagnosis of childhood pneumonia Ms. Elina Naydenova, University of Oxford, United Kingdom	
	A42	Triaging infection and pneumonia among <5 years old children Dr. Mohammad Shah, Save the Children US, United States of America; Walter Karlen, ETH Zürich, Switzerland	
	R523	Validation study of an electricity-free oxygen concentrator Prof. Roger Rassool, David Peake, Jim Black, FREO2 Foundation, Australia; Bryn Sobott, The University of Melbourne, Australia	
	R481	An oxygen storage system Dr. James Black, Roger Rassool, Bryn Sobott, David Peake, FREO2 Foundation, Australia; Sheila Bagayana Mutetire, Mbarara Regional Referral Hospital, Uganda; Peter Moschovis, Massachusetts General Hospital/Harvard Medical School, USA	
	R510	Transitioning from improvised to safer BCPAP therapy Mr. Michael Eisenstein, Mr. Eugene Saxon, PATH, United States of America	

Thr. 13:30 – 15:00: Oral Parallel Session 2 (cont.)

Thu. 13:30-15:00		**Management of medical devices** Session Chair: Mr. Paolo Lago, IRCCS San Matteo Hospital Foundation, Italy	**Salle 4**
	R295	Value based procurement (panel) Mr. Joseph Gatewood, Global Medical Technology Alliance, Switzerland	
	R589	Procurement of complex medical equipment and the considerations for product selection, installation, training, after sales service and maintenance Mr. Paul Labarre, UNICEF Supply Division, Denmark	
	R385	Developing compendium of generic specification for public health procurement Dr. Shashi Sinha, National Health System Resource Centre, India; Ameel Mohammad , Ajai Basil, Anjney Shahi, P.V Vigneshwaran, Consultants, NHSRC, Ministry of Health & Family Welfare, India	
	R39	The status of medical equipment in Sub-Sahara Africa Ms. Anna Worm, THET, Benin; Theogene Namahungu, Minister of Health, Rwanda; Harold Chimphepo, Minister of Health, Malawi; Charles P. Soroheye, DIEM, Benin	
Thu. 13:30-15:00		**Assessment of medical devices** Session Chair: Prof. Panagiotis Kanavos, London School of Economics, United Kingdom Session Co-Chair: Dr. Adham Ismail Abdel Moneim, EMRO, WHO	**Salle 6**
	R194	ISPOR international initiatives on the assessment of the value of medical technologies (Round table) Oyvind Melien, Norwegian Directorate of Health, Norway; Mirella Marlow, The National Institute for Health and Care Excellence (NICE), United Kingdom; Katharina Hawlik, Ludwig Boltzmann Institute for Health Technology Assessment (LBI-HTA), Austria; Yves Verboven, MedTech Europe, Belgium	
	R255	Justification of new types of practices involving medical exposure (Round table) Ms. Eva Godske Friberg, Norwegian Radiation Protection Authority, Norway; Ritva Bly, Radiation and Nuclear Safety Authority, Finland; Torsten Cederlund, Swedish Radiation Safety Authority, Sweden; Nellý Pétursdóttir, Icelandic Radiation Safety Authority, Iceland; Hanne Waltenburg, Danish Health Authority, Radiation Protection, Denmark	
	R556	How to involve citizens and patients in HTA Dr. Francesca Moccia, Cittadinanzattiva, Italy	
Thu. 13:30-15:00		**WHO - Medical Devices and Digital Tools for Reproductive Health and Research (Round-table)** Session Chair: Dr. Garrett Mehl, WHO, Switzerland Session Co-Chair: Mr. Mario Festin, WHO, Switzerland	**Salle 18**
		Electronic MEC and Postpartum FP compendium Dr. Mary Lynn Gaffield, WHO, Switzerland	
		RHR Task sharing guidelines interactive tool Dr. Joshua Vogel, WHO, Switzerland	
		DMPA self injection and subcutaneous syringe Dr. Caron Kim, WHO, Switzerland	
		Management of Victims of Sexual Assault Dr. Claudia Garcia Moreno and Avni Amin, WHO, Switzerland	
		Dual HIV and syphilis testing Dr. Melanie Taylor, WHO, Switzerland	
		Odon Device Dr. Mercedes Bonet Semenas, WHO, Switzerland	

Thr. 15:30 – 17:45: Plenary Session III (Salle 1)

Plenary Panel Session 5 - Thursday 11th May 2017		
Thr. 15:30 - 16:15	**Assessment of Medical Devices** Chair: Dr. Nikolaos Pallikarakis, NIBIT, Greece Co-chair: Ms. Adriana Velazquez, WHO, Switzerland	**Salle 1**
	Role of biomedical engineer in assessing medical devices Dr. Leandro Pecchia, Italy, representing HTAD-IFMBE	
	The INAHTA perspective in assessment of devices in high and middle income countries Dr. Sophie Werkö, Sweden , representing INAHTA	
	HTAi, professionals moving to assess innovative medical devices Dr. Iñaki Gutierrez, Spain, representing HTAi	
	Assessment is needed for regulations of medical devices, how to develop a methodology? Dr. Oyvind Melien, Norway , representing ISPOR	
	REDETSA, network in the Americas Mr. Alexandre Lemgruber; PAHO, Washington DC	
	The advancement of assessments of medical devices in EMRO region Dr. Adham Ismail Abdel, EMRO, Cairo	
	HTA mechanisms Dr. Tessa Edejer, WHO, Switzerland	
Plenary Panel Session 6 - Thursday 11th May 2017		
Thr. 16:15 - 17:00	**Management of medical devices: from selection to safe use** Chair: Mr. Thomas Judd, IFMBE CED, United States of America Co- chair: Mr. Mulugeta Mideksa Amene, Independent, Ethiopia	**Salle 1**
	Donations of medical equipment , challenges in low income countries Ms. Cathy Blanc-Gonnet, HUMATEM, France	
	Developing country road map for Health technology management Dr. Jitendar Kumar, India	
	Health technology management initiatives Ernesto Iadanza, CED IFMBE, Italy	
	Supporting the need for integrated delivery Dr. Jessica Jones, Bill and Melinda Gates Foundation, United States of America	
	National medical equipment policies and planning for universal health coverage Mr. Roberto Ayala, CENETEC, Mexico	
	Technical specifications for procurement of medical devices Ms. Adriana Velazquez, WHO, Switzerland	
Plenary Panel Session 7 - Thursday 11th May 2017		
Thr. 17:00 - 17:45	**Human Resources for Medical Devices** Chair: Mr. Costica Uwitonze, Rwanda Association of Medical Engineering, Rwanda Co-chair: Mr. Andrew Jones, THET, United Kingdom	**Salle 1**
	Presentation of the book Human resources for medical devices, the role of Biomedical Engineer Ms. Adriana Velazquez, WHO, Switzerland	
	Global Strategy on Human Resources for Health: workforce 2030 Dr. Giorgio Cometto, WHO, Switzerland	
	Role of Biomedical engineers in the development, innovation and use of medical devIces Prof. James Goh, IFMBE, Singapore	
	Role of medical physicists for management of non communicable diseases Prof. Magdalena Stoeva, IOMP	
	The role of radiographers and radiologists to support radiation safety and quality Dr. Stewart Whitley, ISRRT	
	Initiative to survey health workforce required to provide cancer care management Ms. Rosa Giuliani, Italy, representing ESMO	
Plenary Panel Keynote Session - Friday 12th May 2017		

Thr. 17:45 – 18:45: Poster Presentation 2A & Video Screening 2A at Level 0 (see Thursday Programme for the list of posters)

Friday 12th May, 2017: Preliminary Programme

Fri. 08:00 – 08:45: Regional Parallel Sessions

Room	Track	Regional Parallel Sessions
6	PR1	Africa
4	PR2	Americas
7	PR3	Eastern Mediterranean
3	PR4	Europe
5	PR5	South East Asia
13	PR6	Western Pacific
20		Innovators Meeting
19		NGO Meeting
Level 0	EXP	Exhibit and poster sessions

Fri. 08:00 – 08:45: Poster Session 2B (Level 0)

Poster session - Thursday, May 11th, to Friday, May 12th, 2017	
B. Health Information Systems: Medical Device Issues	
R43	Mobile phone microscope imaging for eHealth applications at low resource setting; image processing for automatic CBC
	Mr. Mulugeta Mideksa Amene, Independent, Ethiopia
R288	Open-source low-cost wearable physical activity tracker
	Dr. Jelena Dragas, ETH Zurich, Switzerland; Walter Karlen, ETH Zürich, Switzerland
R100	Field based validation of integrated clinical severity assessments of children 2-59 months of age by community health workers using the mHealth Medsinc platform
	Prof. Barry Finette, University of Vermont College of Medicine; THINKMD, Inc. Megan Mclaughlin, Susan Zimmerman, Thinkmd; Shah, Rashed, Save The Children-Us; Mark Yound, Unicef; John Canning, Physicians Computing Company; Barry Heath, University of Vermont College of Medicine, United States of America; Rahman, Kazi Asadur, Ituki Chakma, Hosneara Khondker, Save The Children-International, Bangladesh; Salvator Nibitanga, Denis Muhoza, Awa Seck, Valarie Zombre, Ilboudo, Adama, Issiaka Garango, Unicef Burkina Faso; Michelle Grunauer, Enrique Teran, Marisol Bahamonde Universidad San Francisco de Quito, Ecuador; Edy Quizhpe, Ministry Of Health, Ecuador
R167	Patients families co-producing and checking medical records
	Dr. Richard Fitton, Tameside and Glossop Clinical Commissioning Group Manchester, United Kingdom; Sarwar Shah
A150	Following the evolution of chronic diseases
	Mr. Rene Ivan Gonzalez Fernandez; Margarita Mulet, Juan Dayron Lopez, Alejandro Lopez, Olivia Canto, Icid Digital Medical Technology, Cuba
R479	Mobile control of risk factors of NCDS
	Prof. Bao Jiali, Zhejiang University, China; Zhu Chaoyang, Bao Jiaming, Zheng Xiuxiu
A11-1	Telerradiology network in Amazonas rainforest
	Mr. Leonardo Melo, Diagnext.com, Brazil; Alessandro Melo, Universidade Federal Fluminense, Brazil
G. Innovation Process/R&D of Medical Devices	
A175-1	Influence of prototype type on stakeholder engagement
	Mr. Michael Deininger; Shanna Daly, Jennifer Lee, Kathleen Sienko, University of Michigan, United States of America; Elsie Effah Kaufmann, Samuel Obed, University of Ghana, Ghana
R522	Healthcare management in Brazil: investments in R&D of medical devices
	Mr. Carlos Eduardo De Andrade Lima Da Rocha, Oswaldo Cruz Foundation, Brazil; Fabio Kurt Schneider, Federal University of Technology, Brazil
H. Medical Devices for Emergencies and Disasters	
R263	Developing 21st century PPE against infectious diseases
	Mr. Matthieu Gani, EPFL - Cooperation and Development Center; Manuel Schibler, Geneva University Hospital; Mathieu Soupart, Médecins Sans Frontières; Beat Stoll, University of Geneva; Switzerland
R478	An improved PPE suit for disease outbreaks
	Ms. Margaret Glancey, Patience Osei, Soumyadipta Acharya, Youseph Yazdi, Johns Hopkins University, United States of America
A167	Novel transport isolator for highly contagious diseases
	Dr. Knut Erik Hovda; Broch Brandsaeter, Espen Rostrup Nakstad, Fridtjof Hayerdahl, The Norwegian CBRNE Centre of Medicine, Department of Acute Medicine, Oslo University Hospital

Fri. 08:00 – 08:45: Poster Session 2B (cont.)

R191	A Breath of Hope
	Dr. Oladayo Olakulehin, LigandCorp, Canada
R600	Multiple victims triage using Fuzzy
	Dr. Leandro Zerbinatti, Silveira S.Vieira, Wesley O. Trindade, Ivan G. Duarte, Marcio O. Peres, Rodrigo O. Pastorelli, Uninove-Universidade Nove de Julho, Brazil
R807	Survey on medical devices appropriate for low and middle income countries
	Ms. Barbara Comte, Mélanie Amrouche, Robin Walz and Maurice Page, Humatem, France
R808	Cooperation between biomedical training programs, a challenge for biomedical area
	Ms. Mélanie Amrouche, Barbara Comte, Robin Walz, Humatem, France
I. Innovative Technologies for Screening and Diagnosis	
R456	Laboratory evaluation of EID point-of-care in Kenya
	Ms. Nancy Bowen, Leonard Kingwara, NPHLS, MOH; Dorcus Abuya, NHRL; Rose Wafula, NASCOP; Kenya
A139	Assessment & selection: lead garments in diagnostic imaging
	Dr. Miriam Mikhail, Rad-Aid International; Adam Lustig, Bryan Ashley, Kyle Jones, Ari Isaacson, Robert Dixon, The University of North Carolina at Chapel Hill, United States of America
R311	Design of collimator systems for interventional procedure
	Prof. Seungwoo Park, Korea Institute of Radiological & Medical Sciences, Korea
J. Innovative Technologies for Treatment	
R564	User-friendly delivery platforms for MgSO4 therapy - Evaluation
	Dr. Patricia Coffey, Mutsumi Metzler, Elizabeth Abu-Haydar, Nancy Muller, Dr. David McAdams, Mike Eisenstein, PATH, United States
R497	Affordable alternative orthopedic drills in emerging markets
	Dr. Elise Huisman, Lawrence Buchan, Michael Cancilla, Florin Gheorghe, Arbutus Medical, Canada
A165	Safe medication management in LMICs
	Prof. Beth Kolko; Bradley Younggren, University of Washington/Shift Labs, United States of America
R251	A new handheld cordless thermal coagulator
	Prof. Walter Prendiville, Sankaranarayanan Rengaswamy, Basu Partha, IARC, France; Parham Groesbeck African Centre of Excellence for Women's Cancer Control Zambia; Wallace Dean, Pickett Tim, Riddle Mike, Liger Medical; Juan Felix, University S California, United States of America
R159	A pneumonia prevention system
	Mr. Dr. Peter Young; Maryanne Mariyaselam, Queen Elizabeth Hospital, United Kingdom
R289	Medical device for feldenkrais therapy
	Mr. Ruben Valenzuela, UNAM, Mexico; Rosa Itzel Flores Luna, Angelo Sandoval Villegas, Diana Hernández Matehuala, José Alberto Lira Montanez
A97	Growing rods system for early onset scoliosis
	Prof. Jaw-Lin Wang; Po-Liang Lai, Chang Gung University; Jaw-Lin Wang, National Taiwan University, Taiwan
R226	Design and fabrication of needle crusher
	Prof. Akinwale Coker, Chibueze Achi, Charles Akintunde, Taiwo Hammed, Mynepalli Sridhar, University of Ibadan, Nigeria
A249	Testing normal pressure hydrocephalus disease
	Mr. Walef Robert Ivo Carvalho; Amanda Kelly da Silva, Ana Flávia de Almeida, Fernando Campos Gomes Pinto, Thiago Moreira de Carvalho Vieira
A185-3	Contraceptive implant removal device target product profile
	Dr. Ibrahim Mohedas; Zerihun Abebe, Delayehu Bekele, St. Paul's Hospital Millennium Medical College, Ethiopia; Tina Al-Khersan, Amy Kamdem, Caitlin Choi, Kathleen Sienko, University of Michigan, United States of America
R608	Affordable clubfoot brace for LMIC clubfoot treatment
	Mr. Saketh Kalathur, MiracleFeet, India; Shriya Soora, MiracleFeet, United States of America
R153	PVC free blood bag
	Ms. Alice Ravizza, Italy; Hans Gullikssson, Lena Stigh
A172	Safer medication administration for labor/delivery
	Prof. Beth Kolko; Bradley Younggren, University of Washington/Shift Labs, United States of America

Fri. 08:00 – 08:45: Poster Session 2B (cont.)

K. Innovative In Vitro Diagnostics	
R455	Evaluation of a FVE DBS protocol, Kenya
	Ms. Dorcus Abuya, Edward Onkendi, National HIV Reference Lab, Kenya
R330	Low-cost inkjet-printed paper diagnostics
	Dr. Blanca Leticia Fernandez Carballo; Albert Comellas-Del-Castillo, Borros Salvador, Institut Químic de Sarrià Grup d'Enginyeria de Materials (GEMAT), Universitat Ramón Llull, Spain
A164	Low-cost point-of-care rt-qPCR system for RNAvirus detection
	Dr. Blanca Leticia Fernandez Carballo; Christine Mcbeth, Ian Mcguiness, Maxim Kalashnikov, Christoph Baum, Fraunhofer Institute for Production Technology IPT, Germany; Salvador Borros, Grup d'Enginyeria de Materials (GEMAT), Institut Químic de Sarrià, Universitat Ramón Llull, Spain; Andre Sharon, Alexis F Sauer-Budge, Fraunhofer USA Center for Manufacturing Innovation, USA, & Biomedical Engineering Department, Boston University, United States of America
R515	Novel bedside diagnostics for methanol poisoning
	Dr. Knut Erik Hovda, Gaut Gadeholt, Dag Jacobsen, Oslo University Hospital, Oslo, Norway
A153	New urine dipstick for improved preeclampsia screening
	Dr. Brandon Leader, Emily Gerth-Guyette, Nicole Advani, Kelly Randels, PATH, United States of America
R652	Implementing leprosy diagnostic and monitoring solution in Pakistan
	Prof. Phillip Olla, Audacia Bioscience, Canada
A75	A system for heart disease screening and prognosis
	Mr. Rene Ivan Gonzalez Fernandez, Jorge Aguilera-Perez, Gisela Montes De Oca, Marisabel Lopez-Fernandez, Pedro Luis Gonzalez, ICID Digital Medical Technology, Cuba
R508	An innovative fetal heart rate monitor
	Ms. Sakina Girnary, Ida Neuman, Kate Halvorsen, Karoline Linde, Jennifer Gilbertson, Laerdal Global Health, Norway
R657	Enabling and scaling early detection of breast cancer in lmics
	Mr. Mihir Shah, UE LifeSciences; Ophira Ginsburg, Laura and Isaac Perlmutter Cancer Centre at Nyu Langone Medical Center; Ari Brooks, Pennsylvania Hospital, United States of America
R218	Ultra-low-cost endoscopy for gastroesophageal cancer screening in low-income countries
	Prof. Pietro Valdastri, Joseph Norton, Simone Calo', University of Leeds, United Kingdom; Beatriz Plaza, Andrew Durkin, MiracleFeet; Federico Campisano, Douglas R. Morgan, Keith L. Obstein, Vanderbilt University, United States of America
R572	An innovative education model for cervical cancer screening training
	Ms. Maria Young, Julia Kramer, Visualize, United States of America;
R305	Differential diagnosis of fever in West/East Africa
	Dr. Konstantinos Mitsakakis, Oliver Strohmeier, Nils Paust, Roland Zengerle, Sebastian Hin, University of Freiburg, Germany; Benjamin Lopez-Jimena, Manfred Weidmann, University of Stirling, United Kingdom; Seamus Stack, Mast Group Limited, United Kingdom; Mohammed Bakheit, MAST Diagnostica GmbH, Reinfeld; Vanessa Klein, Hahn-Schickard; Sieghard Frischmann, MAST Diagnostica GmbH, Germany; Cheikh Fall, Amadou Sall, Institut Pasteur de Dakar, Senegal; Khalid Enan, Central Laboratory, Khartoum, Sudan; Liz Gillies, Mast Group Limited, Liverpool, United Kingdom; Sven Goethel, Viorel Rusu, MagnaMedics Diagnostics BV, Geleen, The Netherlands
M. Quality and Safety of Medical Devices	
R234	Medical devices in legal metrology framework
	Ms. Lejla Gurbeta, Medical Device Inspection Laboratory Verlab; Almir Badnjević, Verlab Ltd., International Burch university, University of Sarajevo, University of Bihac; Lejla Gurbeta, Verlab Ltd, International Burch University, Bosnia and Herzegovina
R504	Global quality and safety alliance in imaging
	Ms. Monika Hierath, Guy Frija, Don Frush, International Society of Radiology (ISR), United States

Fri. 08:00 – 08:45: Video Screening 2B (Level 0)

Thursday 11th - Friday 12th, May	
D. Healthcare Technology Management/Clinical Engineering	
R272	Transforming asaesthesia services in Somaliland
	Mr. Robert Neighbour, Diamedica, United Kingdom
K. Innovation for In Vitro Diagnostics	
	Disc-shaped point-of-care platform for infectious disease diagnosis
	Dr. Konstantino Mitsakakis, Univeristy of Freiburg & Hahn-Schickard, Germany
L. Innovation for Mother & Child Care	
R326	Journey of premature baby Yohannes in Ethiopia
	Ms. Seung Eun Lee, Kelemua Abera, GE Healthcare, Ethiopia
A79	Affordable bubble CPAP for low-resource settings
	Mr. Robert Neighbour, Diamedica, United Kingdom

Fri. 09:00 – 10:30: Plenary Session 4 (Salle 1)

Plenary Panel Keynote Session - Friday 12th May 2017		
Fri. 9:00 - 9:30	Universal Health Coverage and the Sustainable Development Goals Ms. Marie Paule Kieny, WHO, Switzerland	**Salle 1**
Plenary Panel Session 8 - Friday 12th May 2017		
Fri. 09:30-10:30	**Priority Medical Devices for Cancer Care and Other Non Communicable Diseases** Chair: Dr. Andre Ilbawi, WHO, Switzerland Co-chair: Dr. Joseph Akpaloo, Komfo Anokye Teaching Hospital, Ghana	**Salle 1**
	Presentation of the priority medical devices for cancer management book Ms. Adriana Velazquez, WHO, Switzerland	
	The importance of laboratory and pathology for a good diagnosis and treatment , need for recognition and availability Dr. Jagdish Butany, WASPaLM, Canada	
	Surgery, indispensable intervention everywhere is not available Dr. Walter Johnson, WHO, Switzerland	
	The role of IAEA to support guidance on radiation technologies Dr.Rajiv Ranjan Prasad, IAEA, Austria	
	Nuclear medicine, important to support diagnosis Dr. Angelika Bischof Delaloye, WFNMB, Switzerland	
	The role of the medical industry to develop appropriate technologies Dr. Nicole Denjoy, DITTA, Brussels	
	Public private partnerships Dr. Vanessa Candeias, World Economic Forum, Switzerland	

Fri. 11:00 – 12:30: Oral Parallel Session 3

Fri. 11:00-12:30		**Innovation of medical devices** Session Chair: Dr. Yadin David, IFMBE, United States of America Session Co-Chair: Dr. Caridad Borras, IUPESM, China	**Salle 1**
	R487	Effectiveness of aerospace technology and methodology of transfer of class 2 medical devices: safety and safeguard achievements Dr. Renato Giordano, EasyDial Inc., United States of America	
	A180-1	Silk-based scaffolds for tissue engineering applications Prof. James Cho Hong Goh, IFMBE, Singapore	
	R644	Enabling local production of medical devices Dr. Jitendar Sharma, Nitin Bharadwaj, Rohit Chhabra, Andhra Pradesh MedTech Zone, India	
	R50	A shared determination to drive sustainable healthcare solutions ... a technology perspective Mr. Vikram Damodaran, GE Healthcare India; Lee Sally, GE Healthcare, Singapore	
	R583	GANDHI: global affordable need driven health innovations Dr. Prashant Jha, All India Institute of Medical Sciences, India	
Fri. 11:00-12:30		**Assessment of medical devices** Session Chair: Dr. Sophie Werkö, INAHTA, Sweden Session Co-Chair: Mr. Alexandre Lemgruber, PAHO-WHO, United States of America	**Salle 6**
	A197	Incorporating patient perspectives in Canadian HTAs Mr. Gino De Angelis, Laura Weeks, CADTH Canada	
		Health technology assessment of innovative medical devices Dr. Iñaki Gutierrez Ibarluzea, HTAi, Spain	
	R149	Role of HTA in open innovation (round table) Debjani Mueller, CMeRC, South Africa; Marco Marchetti, Andrea Urbani, Policlinico A. Gemelli, Catholic University of the "Sacred Heart", Italy; Valentino Megale, Open Biomedical Initiative; PG Kanavos, LSE, UK; Paolo Morgese, European Research for Deerfeld Institute	

Fri. 11:00 – 12:30: Oral Parallel Session 3 (cont.)

Fri. 11:00-12:30		**Priority medical devices by healthcare facility** Session Chair: Prof. Mario Forja Secca, IFMBE, Mozambique Session Co-Chair: Ms. Susan Wilburn, Health Care Without Harm, Argentina	**Salle 5**
	R593-2	Oxygen generators type PSA: solution for the supply of oxygen in Senegal Ms. Awa Ndiaye Ep Diouf, Ministère de la Santé et de l'Action sociale, Senegal	
	A8-1	Equipment planning synchronised with hospital design and construction Mr. Claudio Meirovich, Spain	
	A171	Developing and advancing freeze-preventive vaccine carriers Mr. Steven Diesburg, PATH, United States of America	
	R659	Strategic operation processes to scale a high specialty hospital from a general hospital Ms. Claudia Cardenas Alanis, Escala Biomédica; Leila Dib Fajer, University Iberoamericana; Sandra Rocha Nava, National Institute of Cancerology, Mexico	
Fri. 11:00-12:30		**Medical Devices for Emergencies and Disasters** Session Chair: Ms. Alejandra Velez, Independent, Mexico Session Co-Chair: Dr. Teri Reynolds, WHO, Switzerland	**Salle 13**
	A228-3	Improving emergency preparedness through hybrid interactive training Dr. David Yadin, IFMBE, United States; Rossana Rivas, UPCH/PUCP/CENGETS PUCP, Peru; Tobey Clark, University of Vermont, United States	
	A112	Accelerating innovation during a global health crisis Mr. Vikas Meka, Marissa Leffler, Jennifer Fluder, Avery Waite, USAID, United States of America	
	R645	Medecins Sans Frontieres medical equipement framework Ms. Gabriela Jimenez Moyao, Oscar Rodriguez, Tom Lauwaert, Jean Claude Tewa, Medecins sans frontieres (MSF), Belgium; Benoit Pierre Ligot, Paul Damien Chateau, MSF, France; Hugues Gaertner, MSF, Spain; Malcom Townsend, MSF, Switzerland; Lizette Van De Kamp, Sean King, MSF, Netherlands	
	R465	Choosing a product that works: household water treatment in emergencies Dr. Batsirai Majuru, WHO, Switzerland	
	R593	Proposed acquisition of 162 ambulances and 4 mobile units Ms. Awa Ndiaye Ep Diouf, Ministère de la Santé et de l'Action sociale Senegal; Amad Diouf, Division Etudes et Programmation, Direction des Infrastructures des Equipements et de la Maintenance, Senegal	
Fri. 11:00-12:30		**eHealth** Session Chair: Prof. Marc Nyssen, IFMBE, Belgium	**Salle 3**
	A11-2	Telecom innovation in mobile health units Prof. Leonardo Melo, Diagnext, Brazil; Alessandro Melo, Universidade Federal Fluminense, Brazil	
	R168	Disabled patient correcting medical records online Dr. Richard Fitton, Tameside and Glossop Clinical Commissioning Group; Edna Davies UK Patient's mother, United Kingdom	
	A176	The use of expert systems and artificial intelligence to prevent disease around the world: an experience in Mexico Prof. Alvaro Rios, Rafael Bueno, Medical High Technologies, Mexico	
	R749	Medical informatics in low resource settings Prof. Marc Nyssen, IFMBE, Belgium	
Fri. 11:00 - 12:30		**Tools to support medical device management** Session Chair: Mr. Paolo Lago, IRCCS San Matteo Hospital Foundation, Italy Session Co-Chair: Ms. Maria Eugenia Moreno, Starmedica Hospital, Mexico	**Salle 4**
	R152	Appropriate CMMS systems – potential for health systems development Mr. Martin Raab, David Huser, Alexandre Vanobbhergen, Swiss Topical and Public Health Instititute, Switzerland	
	A198-2	Web-based medical equipment management system Prof. Nikolaos Pallikarakis, Panayiotis Malataras, Institute of Biomedical Technology (INBIT), Aris Dermitzakis, University of Patras/Biomedical Technology Unit, Patras, Greece	
	R511	Proposal: WHO nomenclatures for medical devices Mr. Murilo Contó, PAHO / WHO; Leandro Safatle, ANVISA, Brazil; Vania Canuto, Ministry of Health, Brazil	

Fri. 11:00 – 12:30: Oral Parallel Session 3 (cont.)

Fri. 11:00-12:30		**Injection Safety Symposium** Session Chair: Dr. Edward Kelley, WHO, Switzerland Session Co-Chair: Prof. Benedetta Allegranzi, WHO, Switzerland	**Salle 7**
		Overview of the WHO Injection Safety Policy and Implementation Strategy Dr. Edward Kelley, Benedetta Allegranzi, WHO, Switzerland	
		Working together with industry under POPS Injection Safety Ms. Lisa Hedman, WHO, Switzerland	
		Achievements and challenges in Egypt Dr. Alaa Hashish, WHO, Egypt	
		Sustaining progress achieved in injection safety Dr. Evelyn McKnight, HonoReform Foundation, United States of America	
		Launch of POPS IS and closing remarks by Assistant Director General Dr. Marie Paule Kieny, WHO, Switzerland	

Fri 12:30 – 13:30: Lunch Break

Fri. 13:30 – 15:00: Oral Parallel Session 4

Fri. 13:30-15:00		**Innovation of medical devices for newborn and children care** Session Chair: Dr. Mohammad Shah, Save the Children US, United States of America Session Co-Chair: Dr. Wilson Were, WHO, Switzerland	**Salle 1**
	R238	Groundbreaking devices to save lives at birth Mr. Vinesh Kapil, Karen Clune, U.S. Agency for International Development, United States of America	
	R648	Newborn essential solutions and technologies Dr. Megan Heenan, Queen Dube, Josephine Langton, Robert Miros, Jocelyn Brown, Megan Heenan, Elizabeth Molyneux, Maria Oden, Rebecca Richards-Kortum, Rice 360 Institute for Global Health, United States of America	
	R634	Phototherapy to reduce exchange transfusions Mr. Luciano Moccia, Firetree Asia Foundation, China; Arnolda Gaston,University of Sydney, Australia; Trevisanuto Daniele,Padua University Hospital, Italy	
	R310	Premature breathing system Prof. Anjelica Gonzalez, Yale University, United States of America	
Fri. 13:30-15:00		**Quality and safety of Medical Devices** Session Chair: Prof. Shankar Mutukrishnan, Wentworth Institute of Technology, United States of America Session Co-Chair: Dr. Caridad Borras, IUPESM, United Kingdom	**Salle 3**
	R641	Non-ionizing radiation for diagnostic and cosmetic purposes Prof. Adele C. Green, ICNIRP, International Commission on Non-Ionizing Radiation Protection, Germany; Jacques S. Abramowicz, World Federation for Ultrasound in Medicine and Biology (WFUMB), United States of America; Emilie Van Deventer, World Health Organization (WHO), Switzerland	
	A190-2	The single-use reuse problem in low-income settings Dr. Ryan Lewis, Megadyne a Johnson & Johnson Family of Companies, United States of America	
	R215	Equipments for safer anaesthesia for everybody today Dr. Philippe Mavoungou, WFSA, United Kingdom	
	R513	Neonatal resuscitation equipment maintenance to prevent infection Dr. Manjari Quintanar Solares, Siobhan Brown, PATH, United States of America	
	A116	Is ultrasound safe for my baby? Prof. Jacques Abramowicz, WFUMB and University of Chicago, United States of America	

Fri. 13:30 – 15:00: Oral Parallel Session 4 (cont.)

Fri. 13:30-15:00		**Radiation for diagnostic and treatment** Session Chair: Prof. Magdalena Stoeva, IOMP, United Kingdom Session Co-Chair: Ms. Maria del Rosario Perez, WHO, Switzerland	**Salle 6**
	R695	Innovations in multimodality imaging devices Prof. Habib Zaidi, Geneva University Hospital, Switzerland	
	R317	Diagnostic imaging: vital role in management of non- communicable diseases Dr. Miriam Mikhail, RAD-AID International, diagnostic radiologist, consultant, Switzerland; Nikita Consul, Columbia University chapter of RAD-AID International, United States of America; Elise Desperito, Melissa Culp, RAD-AID International, United States of America	
	A91	Improving universal health coverage : Kenya PPP example Ms. Gisela Abbam, Farid Fezoua, GE Healthcare Africa, Ministry of Health, Kenya	
	R453	Status of radiological equipment used in Nepal Dr. Kanchan P. Adhikari, National Academy of Medical Sciences, Bir Hospital, Nepal	
	A110	Ensuring Radiological Security in the Context of Cancer Treatment Ms. Kristina Hatcher, U.S. Department of Energy, United States of America	
		IAEA perspective on radiotherapy Mr. Rajiv Prasad, IAEA, Austria	
Fri. 13:30-15:00		**Innovation for in vitro diagnostics** Session Chair: Prof. Francis Moussy, WHO, Switzerland Session Co-Chair: Dr. Gaby Vercauteren, WHO, Switzerland	**Salle 13**
	A173	A new point-of-care diagnostic test for sickle cell disease Ms. Mutsumi Metzler, Patricia Coffey, Mercy Mvundura, Jeanette Lim, PATH, United States of America	
	R701	Key considerations in implementing point-of-care in Kenya Ms. Nancy Bowen, Ministry of Health, Kenya; Wafula, Rose, Nascop, Kenya	
	R305	Integrated human diagnostics and vector control towards OneHealth Dr. Konstantinos Mitsakakis, University of Freiburg & Hahn-Schickard, Germany	
		Prequalification for in vitro diagnostics Ms. Deirdre Healy, WHO, Switzerland	
Fri. 13:30-15:00		**Affordability, Appropriateness, Acceptability, Availability and Accessibility of Medical Devices** Session Chair: Ms. Jacqueline Cahill, the Canadian Continence Foundation, Canada Session Co-Chair: Dr. Mario Medvedec, University Hospital Centre Zagreb, Croatia	**Salle 4**
	R463	Appropriate digital X-ray system with eHealth services Mr. Romain Sahli, Ecole Polytechnique Fédérale de Lausanne, Switzerland	
	A99-2	Skill development for growth in emerging markets Ms. Gisela Abbam, GE Healthcare; Marut Setia, Head of Education and Professional Services	
Fri. 13:30 - 15:00		**List of medical devices, nomenclature & pricing (round-table)** Session Chair: Prof. Renato Garcia Ojeda, IEB-UFSC, Brazil Session Co-Chair: Prof. Nikolaos Pallikarakis, IFMBE, Greece	**Salle 5**
		National Lists of medical devices by country, global nomenclature for medical devices and medical devices pricing Mr. Alexandre Lemgruber, WHO AMRO, United States of America; Adham Ismail Abdel Moneim, WHO EMRO, Egypt; Adriana Velazquez, WHO, Switzerland; Murillo Conto, PAHO, United States of America	

Fri. 15:30 – 17:15: Plenary Session V (Salle 1)

Plenary Panel Session 9 - Friday 12th May 2017		
Fri. 15:30 - 16:15	**Medical and Assistive Devices for Humanitarian Aid and Emergency/Disaster Relief** Chair:Abiolu Rilwan, Ikorodu Metropolitan Hospital, Nigeria Co-chair: Dr. Teri Reynolds, WHO, Switzerland	**Salle 1**
	Essential resources for emergency care Dr. Ian Norton, Teri Reynolds, WHO, Switzerland	
	The role of biomedical engineer in conflict zones Mr. Rodrigo Acosta Zermeno, ICRC Syria	
	Main challenges of medical devices in conflict zones Ms. Gabriela Jimenez , MSF	
	Medical devices in NCD kit for refugees Ms. Alejandra Velez , WHO EMRO	
	What to medical devices to procure for red cross Mr. Georg Schmidt, ICRC, Austria	
	Presentation of the WHO List of 50 Priority Assistive Products Dr. Emma Tebbutt, WHO, Switzerland	
Closing Session - Friday 12th May 2017		
Fri. 16:15 - 16:45	**Conclusions and way forward** Chair: Ms. Adriana Velazquez, WHO, Switzerland	**Salle 1**
	Presentation of all the chairs conclusions Final statements	
	Announcement of the 4th Global Forum on Medical Devices	
	Closure of the 3rd Global Forum on Medical Devices	
17:00	**ADJOURN**	

Fri. 17:00 – 18:00: Removal of Posters and Exhibit Unmounting

List of Exhibitors

MAP	3rd WHO Global Forum Exhibitor list
	UN Agencies
U1	WHO - World Health Organization
U2	IAEA - International Atomic Energy Agency
	NGOs in Official Relations with WHO
NW1	DITTA - Global Diagnostic Imaging, Healthcare ICT, and Radiation Therapy Trade Association
NW2	GMTA - Global Medical Technology Alliance
NW3	HUMATEM
NW4	IFBLS - International Federation of Biomedical Laboratory Science
NW5	IFHE - International Federation for Hospital Engineering
NW6	IFMBE - International Federation for Medical and Biological Engineering
NW7	IOMP - International Organization for Medical Physics
NW8	IRS - International Society of Radiology
NW9	PATH - Program for Appropriate Technology in Health
NW10	THET - Tropical Health and Education Trust
NW11	UICC - Union for International Cancer Control
NW12	WASPaLM - World Association of Societies of Pathology and Laboratory Medicine
NW13	WFSA - World Federation of Societies of Anaesthesiologists
NW15	Stop TB
	Academia
A1	All India Institute of Medical Sciences, India
A2	Duke-NUS (National University of Singapore) Medical School, United States
A3	Ecole polytechnique fédérale de Lausanne - Cooperation & Development Center (EPFL CoDEV), Switzerland
A4	Institute of Biomedical Technology (INBIT), Greece Biomedical Technology Unit of the University of Patras (BITU/UPAT), Greece
A6	Johns Hopkins University, United States
A9	The University of Melbourne, Australia
A10	Universidade Federal de Minas Gerais, Brazil
A11	University College London, United Kingdom
A12	University of Birmingham, United Kingdom
A13	University of Freiburg, Germany
A14	University of Geneva, Switzerland
A15	University of Leeds, United Kingdom
A16	University of Vermont, United States
A17	University of Warwick, United Kingdom
A18	University of Washington, United States
A19	Wentworth Institute of Technology, United States
	WHO Collaborating Centers
CC1	NHSRC - National Health System Resource Centre
	Civil society/NGO
N2	CAMTech, Massachusetts General Hospital
N3	Firetree Asia Foundation
N4	Health Care Without Harm
	Government
G1	USAID, United States
G2	Andhra Pradesh MedTech Zone, India
G5	Medical Device Authority Malaysia, Malaysia
G6	Military Institute of Science and technology, Bangladesh
G7	Ministère de la Santé et de l'Action sociale, Sénégal
	Health Facilities
H1	Sahlgrenska International Care AB

Appendix 2

Workshop

3rd WHO Global Forum on Medical Devices
Workshops

Ref ID	Workshop Session 1 - Wednesday 10th May 2017
	Innovation of Medical Devices
A230-1	**Accelerating innovation: 10 lessons from 40 years**
	Dr. Patricia Coffey, PATH, United States of America
R612	**End-to-end development of a regulated uterine balloon**
	Ms. Elizabeth Abu-Haydar, PATH, United States of America Chris De Villiers, Sinapi Biomedical, South Africa Patricia Coffey, PATH, United States of America
	Radiation/Medical Imaging
	IAEA - Overview of human health guidance
	Mr. Rajiv Prasad, International Atomic Energy Agency, Austria
R635	**Implementation of international basic safety standards (egulators) for the use of radiological medical imaging devices**
	Dr. Maria Del Rosario Perez, WHO, Switzerland Jacques Abramowicz, WFUMB, United States of America Pablo Jimenez, PAHO, United States of America Miriam Mikhail, RAD-AID International, United States of America Ola Holmberg, IAEA, Austria María Pérez & Emilie Van Deventer, WHO, Switzerland Magdalena Stoeva, IOMP, Bulgaria Stewart Whitley, ISRRT, United Kingdom
	Hospitals
A251	**Implications of medical equipment for building design**
	Mr. Walter Vernon, Mazzetti/Sextant/IFHE, United States of America
	WHO - Safe hospitals
	Dr. Jonathan Abrahams, WHO, Switzerland
	Surgery & Emergency Care
	WHO - Surgical care and anaesthesia
	Dr. Walter Johnson, WHO, Switzerland
	WHO - Emergency and trauma care
	Dr. Teri Reynolds, WHO, Switzerland
	ICTs in Health
A110-3	**Digital transformation of healthcare in LMICs**

Mr. Jan-Willem Scheijgrond, DITTA/Philips Healthcare, Netherlands
Guy Frija, ISR, United States of America
Emmanuel Akpakwu, WEF
Philip James Leonard, Philips Electronics, United Kingdom
Nicole Denjoy, COCIR Secretary General, Belgium

	Assessment of Medical Devices
R621	**The HTA of medical devices in LMICs**
	Prof. Aleksandra Torbica, Bocconi University, Italy Rosanna Tarricone & Carlo Federici, CERGAS-Bocconi University, Italy
	Regulation and Standards
A111	**Medical device regulations for regulators, manufacture, and users**
	Dr. Mary Overland, DITTA/GE Healthcare, United States of America Josephina Hansen, WHO, Switzerland Robert E. Geertsma, National Institute for Public Health and the Environment (RIVM), Netherlands
	Health Technology Management/Clinical Engineering
R646	**CE-HTM education, training, and professional credentialing**
	Mr. John Tobey Clark, University of Vermont, United States of America Anna Worm, THET, Benin Mario Forjaz Secca, IFMBE, Portugal-Mozambique Shauna Mullally, Northwest Territories Health System, Canada Rossana Rivas, CENGETS PUCP, Peru Yadin David, Biomedical Engineering Consultants, United States of America Mario Medvedev, University of Zagreb, Croatia James Wear, Consultant, United States of America
R246	**Global HTM training and CED eCourse project**
	Mr. John Tobey Clark, University of Vermont, United States of America Ms. Anna Worm, THET, Benin Mario Forjaz Secca, IFMBE, Portugal-Mozambique Shauna Mullally, Northwest Territories Health System, Canada Rossana Rivas, CENGETS PUCP, Peru
A228-2	**CED role in linking global HT innovation/standards**
	Dr. Yadin David, Biomedical Engineering Consultants, United States of America Dr. Thomas Judd, IFMBE/CED, United States of America Shauna Mullally, Northwest Territories Health System, Canada Fred Hosea, Yachay Tech University, Ecuador
A241-3	**Global clinical engineering success stories**
	Mr. Thomas Judd, IFMBE/CED, United States of America Yadin David, IFMBE/CED Board, United States of America Fred Hosea, Yachay Tech University, Ecuador
Ref ID	**Workshop Session 2 - Wednesday 10th May 2017**
	Innovation of Medical Devices
R81	**Technical characterization of appropriate medical equipment**

	Mr. Maurice Page, HUMATEM, France Matthieu Gani, CODEV/EssentialTech EPFL, Switzerland Mélanie Amrouche, Robin Walz, Blanc-Gonnet & Barbara Comte, HUMATEM, France
A99-1	**Adoption of medical-technologies in infrastructure-poor environments**
	Ms. Gisela Abbam, GE Healthcare, United Kingdom Vikram Damodaran, Sally Lee, GE Healthcare, Singapore
	Radiation/Medical Imaging
A229	**Defining medical imaging requirements for rural health center**
	Dr. Yadin David, Biomedical Engineering Consultants, LLC, United States of America Cari Borras & Mario Secca, IUPESM/HTTG, United States of America Taofeeq Ige, National Hospital Abuja, Nigeria
A158	**Medical imaging equipment: global plan for improvement**
	Prof. Guy Frija, ISR, United States of America Magdalena Stoeva, IOMP, United Kingdom Stewart Whitley,ISRRT, United Kingdom
	Public-Private Partnership
	Leveraging Public-Private Partnerships to Access Essential Technologies for Primary Care in Emerging Economies
	Ms. Vanessa Candeias, Peter Varnum, Jennette Leung, Arnaud Bernaert, World Economic Forum, Switzerland
	Laboratory & Pathology
R428	**The mobile laboratory: bringing high-quality testing to the patient**
	Ms. Susanne Andresen, International Federation of Biomedical Laboratory Science, Denmark Pierre Bouchelouche, Zealand University Hospital Koege, Denmark
R244	**The evolving role of pathology**
	Prof. Lai Meng Looi, WASPaLM, Malaysia Dr Roberto Verna, WASPaLM, Italy Dr Jagdish Butany, WASPaLM, Canada
	ICTs in Health
A242-1	**Clinical engineering, eHealth, and ICT global overview**
	Dr. Thomas Judd, IFMBE-CED, United States of America
A242-3	**Cybersecurity overview and case studies**
	Dr. Thomas Judd, IFMBE-CED, United States of America
A242-2	**CE-IT innovation: how to make health care right**
	Mr. Mario Castaneda, Healthitek, United States of America Thomas Judd, IFMBE-CED, United States of America
R473	**Using clinical data in health technology management**
	Ms. Tracy Rausch, DocBox, United States of America Thomas Judd, IFMBE-CED, United States of America Yatin Mehta, Medanta the Medicity, India Kelly Flanagan, DocBox, United States of America Mario Castaneda, Healthitek, United States of America

Assessment of Medical Devices	
	HTAi: First aid tools to the assessment of medical devices
	Dr. Iñaki Gutierrez Ibarluzea, HTAi, Spain
R554	**Health economic via web: the MAFEIP tool**
	Dr. Francisco Lupiáñez Villanueva, Universitat Oberta de Catalunya - Open Evidence, Spain Leandro Pecchia, University of Warwick, United Kingdom Ruth Vilar, Universitat Oberta de Catalunya - Open Evidence, Spain Arnold Senn, European Commission, Belgium
Nomenclature Systems	
R24	**GMDN: an introduction**
	Mr. Mark Wasmuth, GMDN Agency, United Kingdom
Health Technology Management/Clinical Engineering	
R605	**Role of BMETs in health technology management**
	Mr. Ismael Cordero, Gradian Health Systems, United States of America Anna Worm, THET, Benin/United Kingdom Jocelyn Brown, 3rd Stone Design, United States of America
R640	**IFMBE/CED role in global BME/CE recognition**
	Prof. James Goh, IFMBE, Singapore Prof. Ernesto Iadanza, IFMBE, Italy Yadin David, IFMBE/CED, United States of America
A228-2	**IFMBE/CED & global CE-HTM evidence based advances**
	Prof. Ernesto Iadanza, IFMBE, Italy Yadin David, IFMBE, United States of America

Ref ID	Workshop Session 3 - Wednesday 10th May 2017
	Innovation of Medical Devices
R279	**Innovation platform for LMIC medical technologies**
	Ms. Alexis Steel, CAMTech, Massachusetts General Hospital , United States of America Sandra Butler, Molly Ward & Krisitian Olson, Massachusetts General Hospital, United States of America
A83	**Transforming from product innovation to comprehensive solutions**
	Dr. Trevor Gunn, Medtronic, United States of America
	Radiation/Medical Imaging
R236	**How to combat the burden of disease in the developing world: the role of radiotherapy in the management of cervical, breast and prostate cancers**
	Prof. Patrick Kupelian, UCLA, United States of America
A101	**Diagnostic imaging: health information systems and healthcare technology management**
	Dr. Miriam Mikhail, RAD-AID International, Switzerland Nikita Consul & Elise Desperito, Columbia University chapter of RAD-AID International, United States of America of America Melissa Culp, RAD-AID International, Switzerland
	Quality
R446	**Good practice in ultrasound probe cleaning**
	Prof. Guy Frija, ISR, United States of America Nicole Denjoy, DITTA, Belgium
A231	**Market Dynamics: Supporting Country Decision-Making On Medical Devices; Case Study on Optimizing the Deployment of Cervical Pre-cancer Treatment Devices**
	Mr. Ray Cummings, PATH, United States of America Tara Herrick & Bhavya Gowda, PATH, United States of America
	In Vitro Diagnostics
	Revised WHO guidance on procurement of IVDs and other laboratory items: tips and tricks
	Mr. Jason Williams, USAID, United States of America; Anita Sands, WHO, Switzerland
	WHO - Prequalification of IVD
	Ms. Helena Ardura, Deirdre Healy, WHO, Switzerland
	ICTs in Health
R143	**Deep machine learning detection of preclinical diseases**
	Mr. Ludovico Valerio Ciferri Ceretti, International University of Japan, Japan Georg Aumayr, Johanniter, Austria Gianluca Colombo, OneoOffTech UG, Germany Mathew Summers, University of the Sunshine Coast, Australia Tamas Madl, HeartShield Ltd./Research Institute for Artificial Intelligence (OFAI), Austria Alessandro Vercelli, University of Turin, Italy

	Priority Medical Devices
	WHO - Priority medical devices
	Ms. Adriana Velazquez Berumen; Gabriela Jimenez Moyao, Antonio Migliori & Natalia Rodriguez, WHO, Switzerland; Adham Ismael Abdel, Alejandra Velez, WHO EMRO, Egypt
	Nomenclature Systems
R254	**Securing global supply chain utilizing UDI**
	Mr. Ralph Ives, GMTA, Switzerland Nicole Taylor-Smith & Lindsay Tao, GMTA, Switzerland
	Tools for Health Technology Management
	Computerized maintenance management systems (CMMS) requirements and results
	Mr. Bill Gentles, ACCE, United States of America Martin Raab, Swiss TPH, Switzerland Claudio Meirovich, Meirovich Consulting, Spain Jitendra Sharma, AP MedTech Zone, India
R552	**A reality check on biomedical engineering education**
	Prof. James Goh, IFMBE, Singapore Kingping Lin, IFMBE, Singapore Shankar Krishnan, Wentworth Institute of Technology, United States of America Ratko Magjarević, IFMBE/University of Zagreb, Croatia
	Personal Protective Equipment (Closed Session)
	WHO advisory committee meeting on innovation of personal protective equipment
	Members of the committee
	Regulatory Framework (Open Session)
	WHO model regulatory framework medical devices workshop
	Ms. Josephina Hansen, WHO, Switzerland Adham Ismael Abdel, WHO EMRO, Egypt Johanna Koh, Singapore

Workshop Session – Wednesday 10th May 2017	
Innovation of Medical Devices	
A230-1	Accelerating Innovation: 10 Lessons From 40 Years
Abstract	Dr. Patricia Coffey, PATH, United States of America For over 40 years, PATH has been advancing affordable, lifesaving medical devices that are sustainable and culturally appropriate, and meet the needs of consumers at the bottom of the pyramid and health systems where the technologies will be used. Our stepwise and systematic approach to end-to-end medical device and health technology development begins with research/design and moves through each successive phase: develop/validate, approve/recommend, introduce/optimize, and scale, in an iterative pattern. Our early upstream research and development efforts resulted in not only the development but also subsequent introduction and scale of global health cornerstones such as Soloshot auto-disable syringes and vaccine vial monitors. The middle or far right of the value chain is where we work on technology validation, health system fit, market dynamics, policy alignment, regulatory approvals, introduction, and scale. Successful implementation of this approach has resulted in the launch of many health products including Caya Contoured Diaphragm, SE200 chlorine generator, Sayana Press, an intradermal adapter for a conventional needle and syringe, and the Nifty feeding cup, among others. Based on our vast and diverse innovation experience in incubating and accelerating medical device innovation, we will share ten key lessons learned related to both product and market development.
R612	End-to-end development of a Regulated Uterine Balloon
Abstract	Ms. Elizabeth Abu-Haydar, PATH, United States of America; Chris De Villiers, Sinapi Biomedical, South Africa; Patricia Coffey, PATH, United States of America Fourteen million cases of postpartum hemorrhage (PPH) occur each year, leading to approximately 12,000 maternal deaths globally. The most common cause of PPH is uterine atony; treatment of uterine atony follows a well-defined stepwise approach, including drugs and mechanical interventions followed by surgery as a last resort. When first-line drug treatments fail to stop severe bleeding, WHO recommends uterine balloon tamponade (UBT) as a second-line intervention. PATH, working closely with Sinapi biomedical (a South African manufacturer of high-quality, low-cost medical devices) supported the design, development, and testing of a highly innovative and affordable UBT to fill a much-needed gap. For the workshop, we would present our experience taking the Sinapi UBT from idea to a regulated medical product, focusing on the following: 1) setting a target product profile; 2) designing for manufacture; 3) obtaining regulatory approvals; 4) developing a manufacturing strategy [high quality, high volumes at an acceptable cost]; 4) building partnerships to support introduction; 5) using cost-effectiveness analysis and impact modeling to inform roll-out decisions; and 6) developing marketing and communication assets to support demand generation. A systematic approach to these issues supports a more sustainable and impactful introduction of this lifesaving technology.
Report from the Organizers	• We had prepared for demonstration and more direct participation by participants and the set up (more like lecture/presentation) was not conducive for that • Attendance seemed low and I wonder if it were later in the day on the first day whether there might have been more people
R81	Technical Characterization of Appropriate Medical Equipment
Abstract	Mr. Maurice Page, HUMATEM, France; Matthieu Gani, CODEV/EssentialTech, EPFL, Switzerland; Mélanie Amrouche, Robin Walz, Blanc-Gonnet & Barbara Comte, HUMATEM, France In its document "Medical Devices: Managing the Mismatch", WHO is developing the concept of appropriate medical equipment, a concept that is valid in all countries, whether high-, medium- or low-income countries. Equipment is fairly well suited to high-income countries in which they are developed. This is not the case in low- and middle-income countries.

In order to facilitate and encourage the procurement of appropriate medical equipment in low- and medium-resource countries, it is important to specify the technical, non-commercial, characteristics of this appropriate equipment.

The authors have developed a set of 8 main characteristics which could be used to quantify the technical level of conformity of equipment to the appropriate medical equipment concept. A radar graph could be used to easily visualize the level of conformity attained.

This workshop aims to present for discussion to the participants of the workshop these characteristics in order to achieve, if possible, a consensus on the way to quantify the level of technical conformity of medical equipment to the appropriate medical equipment concept.

A99-1	Adoption Of Medical-Technologies In Infrastructure-Poor Environments
Abstract	Ms. Gisela Abbam, DITTA, Belgium; Vikram Damodaran, Sally Lee, GE Healthcare, Singapore

Context-specific approach to build solutions creates value in the form of clinical and economic outcomes in underserved populations. Scientifically identifying barriers to adoption therefore increases the probability of success if the solution were designed appropriately.

A large part of medical technology has been derivative in nature. Something designed in a mature environment for an informed user being "de-featured" and "costed-out" to suit the needs of the developing world. However, adoption of such technology has remained sub-optimal. Involving the end users upfront, on the other hand, leads to a sustainable offering that translates to outcomes. Using fundamentals of design thinking and an immersive, co-creative approach with the consumer, patient or provider, helps identify core underlying problems to solve for, barriers to adoption and therefore the value propositions that will enhance efficacy and efficiency of care delivery.

Taking one example of an infant warmer from the maternal and child health portfolio of products, the presentation will walk through the details of the discovery process, the innovative design and the resultant adoption in the market.

This approach has led to the creation of more than 20 innovative products, 9 of which are part of the WHO Compendium of innovative technology solutions.

R279	Innovation Platform to LMIC Medical Technologies
Abstract	Ms. Alexis Steel, CAMTech, Massachusetts General Hospital, United States of America; Sandra Butler, Molly Ward & Krisitian Olsa, Massachusetts General Hospital, United States of America

CAMTech, headquartered at MGH Global Health, will work closely with workshop participants to identify clinical challenges and begin to brainstorm solutions through an accelerated workshop. CAMTech will also provide potential roadmaps for participants to move these technologies forward towards patient impact and commercialization. CAMTech's core methodology is utilize a model of co-creation to identify clinical challenges, source promising innovations and develops value-based medical technologies that improve health in LMICs. With a growing emphasis on value in the US healthcare sector, investing in affordable health technologies will be of increasing mutual benefit to both high and low income countries. Traditional medical technology innovation arises in academic medical centers, pharmaceutical companies, or biotechnology companies in HICs. Products are then frequently either stripped down or donated as-is to LMICs. This model of innovation is often too far removed from patients and front-line providers with insights into their own pain points. Furthermore, these traditional or institutionalized processes fail to consider the qualities of LMICs that serve as advantages to driving out-of-the-box solutions. These include: unique preferences that inspire creativity, overwhelming need, room in the physical and social infrastructure for rapid implementation of technologies or processes, and social and economic incentives for Value-Based Design.

Report from Organizers

Utilizing its core methodology of "co-creation", CAMTech's (based at MGH Global Health) Senior Manager of Global Operations, Alexis Steel, and Project Manager, Molly Ward, worked with 40+ participants to identify clinical challenges, source promising innovations and develop

game-changing medical technologies that will ultimately improve health in LMICs. CAMTech focused on the growing emphasis on value in the US healthcare sector's increasing need to invest in affordable health technologies in both high and low income countries. Over the course of the workshop, CAMTech utilized its model of innovation to drive emphasis on patient and front-line provider's needs through identifying their own "pain points". Through using this model, CAMTech divided the participants into eight teams to work together to identify clinical challenges and brainstorm solutions through an accelerated workshop. The participants worked collaboratively in cross disciplinary teams to create out-of-the-box solutions including unique preferences that inspire creativity, overwhelming need, room in the physical and social infrastructure for rapid implementation of novel technologies, and social and economic incentives for *Value-Based Design*. In addition, CAMTech began to provide roadmaps for participants to move these technologies forward towards patient impact.

A83	Transforming From Product Innovation To Comprehensive Solutions
Abstract	Dr. Trevor Gunn, Medtronic, United States of America

Since the beginning of the financial crisis, healthcare systems, insurers, and patients are increasingly under financial pressures. In response, the Medical Technology industry has developed a series of increasingly sophisticated solutions, services and partnerships to improve outcomes, lower costs, and bring efficiency to healthcare delivery and patient experiences. Solutions vary not just by country but by provider and may include: standardization programs, inventory management, and enhanced recovery and surgical follow up. In order to achieve these gains, new mechanisms have been dusted off and others entirely built from scratch: Public Private Partnerships, Innovative Procurement mechanisms, Risk-sharing and outcomes-based pricing are a tip of the iceberg that is transforming healthcare. The moderator and panel will outline a few of the opportunities and challenges inherent in this rapidly moving paradigm for the medical device sector.

Radiation/Medical Imaging

	IAEA – Overview of human health guidance
Abstract	Mr. Rajia Prasad, International Atomic Energy Agency, Austria

The IAEA is one of the leading publishers in the field of nuclear science and technology, with titles on nuclear and radiological safety, emergency response, nuclear power, nuclear medicine, nuclear waste management, nuclear law and safeguards as well as relevant topics in food and agriculture, earth science, industry and the environment.

The Cyber Learning Platform for Network Education and Training (CLP4NET) is an online e-Learning platform developed to facilitate sustainable education in the nuclear sector by empowering web-based development and dissemination of high quality e-learning resources and learning environments, in a way that is cost-effective, scalable and easy to use.

The Human Heath Campus is designed to serve as an informative resource for health professionals, working in Medical Physics, Nuclear Medicine, Radiology, Radiation Oncology, and Nutrition, providing insight into different aspects of modern clinical practice.

The IAEA assists Member States with the coordination of research projects, expert guidance, equipment, the development of internationally harmonized guidelines, training and knowledge exchange.

R635	Implementation of International Basic Safety Standards (BSS) for the use of radiological medical imaging devices
Abstract	Dr. Maria Del Rosario Perez, WHO, Switzerland; Jacques Abramowicz, WFUMB, United States of America; Pablo Jimemez, PAHO, United States of America; Miriam Mikhail, RAD-AID International, United States of America; Ola Holmberg, IAEA, Austria; María Pérez & Emilie Van Deventer, WHO, Switzerland; Magdalena Stoeva, IOMP, Bulgaria; Stewart Whitley, ISRRT, United Kingdom

Advanced technologies have opened new horizons for the use of radiation medical devices in diagnostic imaging and image-guided interventions, including the use of ionizing radiation (e.g. computed tomography, fluoroscopy) as well as non-ionizing radiation (e.g. ultrasound, magnetic resonance imaging). Although safety and efficacy of procedures have improved,

incorrect or inappropriate handling of these technologies can introduce potential hazards for patients and staff (e.g. unnecessary exposure can arise from procedures that are not indicated and/or not properly performed, accidental exposures can result from unsafe or inappropriate use of radiation technology). The International Basic Safety Standards (BSS) for Protection against Ionizing Radiation and for the Safety of Radiation Sources represent a global benchmark for setting national regulations in the field of radiation protection. Co-sponsored by eight international organizations, the BSS include a robust set of safety requirements for medical use of ionizing radiation. In contrast, similar BSS for non-ionizing radiation are lacking, and international organizations are considering joining efforts to bridge this gap. This paper summarizes the experience and lessons learned during the process of implementing the BSS for medical exposures, focusing on identified challenges and opportunities to enhance radiation safety and quality in medical imaging.

Report from Organizers

The International Basic Safety Standards (BSS) on ionizing radiation are co-sponsored by the IAEA, WHO, PAHO, FAO, ILO, EC, FAO and UNEP. WHO is cooperating with BSS cosponsors to support its BSS implementation, prioritizing radiation protection (RP) in medical exposures. Presenters from Norway and India shared their experiences indicating that implementation of the BSS requires an administrative framework involving dialogue and cooperation between relevant authorities and professional societies, beyond revising national laws and regulations. Among the major challenges the justification of medical radiation exposure for new technologies, procedures or devices and of screening programs was mentioned. There are not enough radiation safety officers in medical facilities to ensure procurement of appropriate and safe devices. There is a need for increased number of medical physicists, for integration of radiation protection into HTA and for promotion of clinical audit programmes to ensure that clinical benefit outweighs radiation detriment. Presenters from the IOMP, ISRRT, RAD-AID International and WFUMB discussed their respective roles as medical physicists, radiologists and radiographers, and the actions conducted to promote the BSS as part of their missions and global outreach programs. It was noted that similar BSS for non-ionizing radiation are lacking and some international organizations are joining efforts to bridge this gap.

A229 Defining Medical Imaging Requirements For Rural Health Center

Abstract

Dr. Yadin David, Biomedical Engineering Consultants, LLC, United States of America; Cari Borras & Mario Secca, IUPESM/HTTG, United States of America; Taofeeq Ige, National Hospital Abuja, Nigeria

Rural health centers are established to prevent patients from being forced to travel to distant urban medical facilities. To manage patients properly, rural health centers should be part of regional and more complete systems of medical health care installations in the country on basis of referral programs. Patient management challenges faced by rural health centers impact the criteria for the type of medical imaging services that should be available in such facilities.

To make the work of the center's practitioners more effective and efficient, this workshop assesses what health conditions may require medical attention in those centers. Information is provided on how to use basic imaging modalities, such as radiography and ultrasound, emphasizing the need for thoughtful service planning, careful equipment and imaging protocol selection, continuous staff training, and the implementation of quality control programs. This workshop is also valuable resource for physicians, medical physicists and biomedical engineers who provide virtual and physical consultations to meet these needs. Thus, these centers should have the infrastructure needed to transport patients to urban hospitals when they need more complex health care. The coordination of all the activities is possible only if rural health centers are led by strong and dedicated managers.

Report of Organizers

Diagnosing and treating medical conditions as early as possible improves patient outcomes. In rural health centers it is important to provide medical imaging technology and supporting infrastructure locally. Such capability will reduce the volume of patients being forced to travel to distant urban medical facilities. To manage patients properly, rural health centers should be part of and be integrated into the systems of medical health care installations in the country on the basis of referral programs. The criteria for the type of medical imaging services that should be available in such facilities is dependent on local patients' needs and the referral system capabilities.

	Efficient and effective work of such a center is critically dependent upon provisioning of training on how to use basic imaging modalities, such as radiography and ultrasound, on planning for thoughtful maintenance support, careful selection of equipment and imaging protocols, continuous staff training, and the implementation of quality control programs. We recommend to continue offering this plan for action based on the collaboration of biomedical engineers and medical physicists in the workshop's faculty and on the publication (http://www.springer.com/us/book/9789811016110) that were found by the audience to be valuable.
A158	Medical Imaging Equipment: Global Plan For Improvement
Abstract	Prof. Guy Frija, ISR, United States of America; Magdalena Stoeva, IOMP, United Kingdom; Stewart Whitley, ISRRT, United Kingdom Increasing availability of medical imaging equipment has led to an increase in the number of imaging procedures and thus an increase in medical radiation exposure globally. As the purchase and maintenance of imaging equipment is very cost-intensive, renewal practices vary greatly and are often neglected at the cost of patient and staff safety. In addition, shortage of skilled personnel is still a major factor in poor medical equipment management practice globally. The ISR, IOMP and ISRRT will in this joint workshop outline the need for access to up-to-date imaging equipment, including dose reduction software and dose reconstruction systems to ensure improved patient and staff safety globally. We will highlight the importance of global workforce development plans for radiologists, medical physicists and radiographers in order to ensure safe use and proper use and maintenance of imaging equipment. Developing and underdeveloped countries need support not only in improving the medical imaging equipment base, but also for developing sustainable training programs for health professionals to establish a safety culture based on teamwork, including quality control and risk management procedures.
Report from Organizers	Joint workshop of the International Society of Radiology with the International Organization for Medical Physics (IOMP) and the International Society of Radiographers and Radiological Technologists (ISRRT). ISR gave recommendations for a global plan for the development of Medical Imaging in developing countries, including the adoption and adaptation of a regulatory framework inspired by the IAEA BSS or the European BSS Directive, focus on strategic issues like justification, optimization, equipment quality, occupational exposures; the use of new concepts such as Clinical Decision Support and clinically-based Diagnostic Reference Levels; the development of a regional campaign inspired by Eurosafe Imaging, AfroSafe, ArabSafe, Image Gently etc. In addition the importance of working in close contact but in full independence form local competent authorities was emphasised and the need to bridge the gap between competent authorities in radiation protection and health policy authorities was highlighted. The need to develop a regional plan for new and up-dated equipment acquisition, in particular focused on digital radiology, PACS, CT of new generation and to start considering the potential of the use of deep learning in the context of rural centers and develop an ambitious research project based on their needs was emphasised. In addition the importance of workforce development in the field of radiology, medical physics and radiography and the necessity to work together as a team were highlighted. The WHO was called upon to help developing such approach.
R236	How to Combat The Burden Of Disease In The Developing World: The Role Of Radiotherapy In The Management Of Cervical, Breast And Prostate Cancers
Abstract	Prof. Patrick Kupelian, UCLA, United States of America It is well-recognized that the burden of cancer is growing dramatically in the developing world. However, the nature of this burden is not as well understood: the developing world has a unique burden of disease in terms of stage at diagnosis and common types of cancer, among other factors. As such, the clinical approach in developing countries may differ from that in the developed world.

Radiotherapy has a central role in managing the cancers the disproportionally affect the developing world, in terms of both incidence rate and severity: breast, cervical, uterine, vaginal, vulvar, and prostate cancers. Different radiotherapy techniques are used for breast conservation for women with early stage breast cancer who elect to keep their breast. Radiation is also used to decrease recurrences and improve survival in patients with advanced breast cancers after surgery. In cervical cancer, external and internal radiotherapy approaches are often the primary treatment in advanced stages. Radiation also plays a primary role in managing a variety of other cancers that affect women, such as brain, head and neck, lung and gastrointestinal cancers.

A101	Diagnostic Imaging: Health Information Systems And Healthcare Technology Management
Abstract	Dr. Miriam Mikhail, RAD-AID International, Switzerland; Nikita Consul & Elise Desperito, Columbia University chapter of RAD-AID International, United States of America; Melissa Culp, RAD-AID International, Switzerland

Established in 2008, RAD-AID International is a "non-state actor in official relations with the WHO". RAD-AID's mission is to improve and optimize access to medical imaging in low and middle income settings, increasing radiology's contribution to global public health initiatives – as warranted by epidemiology. To achieve this, multidisciplinary teams collaborate with partner-site institution colleagues to rationally and comprehensively address needs. Such partnerships begin with formal Radiology Readiness and PACS Readiness assessments to obtain baseline data on local institutional needs. From those data, stakeholders map goals and the way forward. Imaging is a critical healthcare service and relies heavily upon information systems for patient tracking; computer systems for image viewing; and equipment for imaging—such as radiography, ultrasound, and CT units. For example, formal assessment data may direct partners to set goals for medical technology procurement, then stepwise implementation plans are created including maintenance, service, warranties, educational support, and stakeholder agreement. Therein human capacity building constitutes a sustainable, vital component to address diagnostic imaging gaps and to strategically promote appropriate use of medical devices. This methodology supports the Sustainable Development Goals of Good Health & Well-Being, Quality Education; Decent Work & Economic Growth; Reduced Inequalities; and Partnerships for the Goals.

Hospitals

A251	Implications Of Medical Equipment For Building Design
Abstract	Mr. Walter Vernon, Mazzetti/Sextant/IFHE, United States of America

Medical equipment and devices are large consumers of energy, space, and supplies over the course of the life of a healthcare building. Over time, sustainability efforts have focused on other aspects of a building - lighting, ventilation, cooling. But the increasing use of powered equipment is more than offsetting savings realized in these domains, so that the equipment is rapidly becoming the largest energy consumer in the building. This session will focus on the impacts of medical equipment on the healthcare built environment, and emerging strategies for better managing that risk. This issue was first raised by the WHO in its forthcoming book Health in the Green Economy, of which I was one of two primary authors.

At the same time, technology is making care available outside of the hospital and health complex, creating new opportunities for eliminating buildings and resultant travel.

This session will examine all of these trends, offering opportunities for improving care while reducing environmental impact.

	Safe Hospitals
Abstract	Dr. Jonathan Abrahams, WHO, Switzerland

The Safe Hospitals Initiative aims to ensure that health facilities continue to provide health-care services in times of emergencies and disasters. This workshop will address the protection and functionality of medical devices and infrastructure as critical elements of this Initiative. Safe hospitals can resist exposure to all types of hazards where medical equipment stay in good

working condition and are protected from damage and whereby health personnel are able to provide medical assistance in safe and secure settings. A brief introduction on the Safe Hospitals Initiative will be followed by a discussion on the Hospital Safety Index (HSI), a tool that is used to assess hospital's safety and vulnerabilities, make recommendations on necessary actions and promote low-cost/high-impact measures for improving safety and strengthening emergency preparedness. The Safe Hospitals Initiative provides a critical approach to emergency and disaster risk management for the health sector to enable countries and communities to prevent, prepare for, respond to and recover from all types of emergencies and disasters, aligned with the Sendai Framework for Disaster Risk Reduction 2015-2030.

Report from Organizers

The Safe Hospitals Initiative workshop, participated by around 20 delegates, aimed to raise awareness on how to ensure that health facilities continue to provide health-care services in times of emergencies; and explored what participants have already contributed or will contribute further towards safe hospitals. It addressed the protection and functionality of medical devices and infrastructure as critical elements. First, it showed a film clip on "hospitals safe from disasters": https://www.youtube.com/watch?v=_Je3E50AK2I. It demonstrated that hospitals can resist exposure to all types of hazards where medical equipment stay in good working condition and are protected from damage; and whereby health personnel are able to provide medical assistance in secure settings. A brief introduction on the Safe Hospitals Initiative followed, then, finally by a discussion on the Hospital Safety Index, a tool that is used to assess hospital's safety and vulnerabilities, make recommendations on necessary actions and promote low-cost/high-impact measures for improving safety and strengthening emergency preparedness. The workshop provided delegates a critical approach to emergency and disaster risk management to enable countries, communities and participants, through their stories, to prevent, prepare for, respond to and recover from all types of emergencies and disasters.

Surgery & Emergency Care	
	WHO – Surgical care and anaesthesia
	Mr. Walter Johnson, WHO, Switzerland
	WHO – Emergency and Trauma Care

Report from Organizers

Dr. Teri Reynolds, WHO, Switzerland

This workshop will focus on WHO resources for strengthening emergency and trauma care.

We will discuss the role of technologies within the emergency care system, and present a range of WHO initiatives for emergency and trauma care strengthening, inviting input from participants on priority resources.

ICTs in Health	
A110-3	Digital Transformation of Healthcare in LMICs

Abstract

Mr. Jan-Willem Scheijgrond, DITTA/Philips Healthcare, Netherlands; Guy Frija, ISR, United States of America; Emmanuel Akpakwu, WEF; Philip James Leonard, Philips Electronics, United Kingdom; Nicole Denjoy, COCIR Secretary General

Digitalization has reached a turning point in healthcare, shifting value from devices to software and services. Medical devices are increasingly digitally connected, enabling better care to more people at lower cost.

There is a huge opportunity for LMICs to leapfrog compared to mature markets. But while there are many digital health projects in LMICs, the majority are still in pilot stages (ITU facts and figures 2016, p.2. www.itu.int/en/mediacentre/Pages/2016-PR30.aspx). Policy makers and the health professionals in LMICs are keen to embrace the potential benefits of digital technologies, but are also cognizant of the challenges.

The session will focus on topics such as decision support tools for better diagnostics, standards and interoperability, and sharing of data for better population health management.

Speakers will discuss the specific challenges and opportunities facing LMICs that have started this transformative journey, provide recommendations on how to progress and share insights on emerging trends in the digital transformation of healthcare. The objective is to stimulate a discussion not only about the importance of digital innovation, but also to identify trends, barriers, and opportunities to scale digital health in LMICs in a sustainable manner.

A242-1 Clinical Engineering, eHealth, and ICT Global Overview

Abstract Dr. Thomas Judd, IFMBE-CED, United States of America

Many ICT innovations are rapidly being adapted and adopted to health and healthcare applications. Apps, smartphones with health monitoring adapters, text messaging, wireless and wearable sensors, cloud-based systems and tools, and personal, medical, and population medical records are being deployed around the globe. Safe and efficient use requires innovations in regulatory and management strategies that properly measure and balance cost, risk, and health benefits for each application.

For medical devices, threats must be managed, including assurance of reliable ICT infrastructure, protection of privacy and general cybersecurity control, human factors and usability, and a significant number of interoperability decisions and trade-offs must be considered.

Fortunately, many low-cost and open source solutions have emerged, which can be considered for adoption by each country. The life-cycle maintenance and ownership cost of ICT-based solutions is an important consideration, too, and require good health technology management strategies for sustainable success. This session will discuss key trends and opportunities, and will encourage sharing success stories and strategies between participants.

A242-3 Cybersecurity overview and case studies

Abstract Dr. Thomas Judd, IFMBE-CED, United States of America

For medical devices, threats must be managed, including assurance of reliable ICT infrastructure, protection of privacy and general cybersecurity control, human factors and usability, and a significant number of interoperability decisions and trade-offs must be considered.

Drivers: (1) researchers publicizing hacks of medical equipment are increasing the noise and increasing urgency in an already challenging domain; (2) hospital medical devices are critical to care delivery, but have challenges in security, these devices may be used as vectors to further compromise; (3) Internet of Things (IOT) proliferation in hospitals; (4) broad and general usage EHRs with weak security controls to prevent compromise; and (5) Latin America and Africa are especially challenged in the security of these systems.

Response: educate and change the culture, e.g., to address the above drivers by developing IT controls, identify the tools that clinical IT staff need to build, and address other cultural aspects of healthcare IT that will stifle progress. An educational framework needs to be established that leads to appropriate healthcare cybersecurity policy, e.g., we need to provide knowledge of attackers, measure risk, and set up a security function within health care. Perhaps an international forum via WHO with IFMBE CED could lead this effort.

A242-2 CE-IT Innovation: How to Make Health Care Right

Abstract Mr. Mario Castaneda, Healthitek, United States of America; Thomas Judd, IFMBE-CED, United States of America

The current atmosphere for global healthcare technology (HT) innovation is changing as healthcare is delivered through EHR-enabled care or eHealth. Examples can be seen in medical device integration from US's Kaiser Permanente over the past 10 years, as well as various applications in Europe, Asia (particularly from India), and Latin America & the

Caribbean.

Great innovation lessons come from service sectors like transportation (Uber) and housing (Airbnb). They have achieved better services and lower costs for users. HT can use proven industry innovation models and processes to solve pressing health care problems, particularly in developing countries.

Innovative HT solutions for developing countries primary care are needed to go beyond creating and building affordable technologies to meet budgets. Innovation should produce technologies that meet the specific need and are easy to use, compact, sturdy, and require minimum maintenance. Considering cost first perpetuates the poverty model and misses the health objective.

How CEs are engaged in these processes can help change the culture of HT innovation.

R473	Using clinical data in health technology management
Abstract	Ms. Tracy Rausch, DocBox, United States of America; Tom Judd, IFMBE-CED, United States of America; Yatin Mehta, Medanta the Medicity, India; Kelly Flanagan, DocBox, United States of America; Mario Castaneda, Healthitek, United States of America

As healthcare becomes more globally accessible, the diversity, volume, and complexity of integrated medical devices continue to increase. With such technology development and expansion, the requirements for medical device evaluation, purchasing, implementation and maintenance are becoming more complex, and the demands on Health Technology Management (HTM) staff are increasing globally. This presentation will discuss how analysis of near-patient data collected within an Integrated Clinical Environment platform can provide HTM staff the ability to more efficiently manage the life cycle of medical technologies. Medical device data was collected during normal operations of a post-operative cardiac ICU and retrospectively analyzed to provide metrics for HTM decision making and daily operations. These analytics of can provide metrics for HTM staff that assists in capital equipment planning, preventative and unplanned maintenance, risk mitigation, adverse event investigation, and real-time status of medical devices.

Report from Organizers	The world-wide Clinical Engineering (CE) community has found many significant and innovative ways to contribute to global ICT - eHealth initiatives, such as through IHE Patient Care Devices (IHE.org) for integrating medical device information into EHRs, device cybersecurity, and tools that link clinical and health IT data with needed Health Technology Management information.
R143	Deep machine learning detection of preclinical diseases
Abstract	Mr. Ludovico Valerio Ciferri Ceretti, International University of Japan, Japan; Georg Aumayr, Johanniter, Austria; Gianluca Colombo, OneoOffTech UG, Germany; Mathew Summers, University of the Sunshine Coast, Australia; Tamas Madl, HeartShield Ltd./Research Institue for Artifical Intelligence (OFAI), Austria; Alessandro Vercelli, University of Turin, Italy

Clinical diagnoses of age-related conditions (e.g. frailty) are based on specific signs and symptoms of the disease state. The assumption that preclinical states of these conditions display milder versions of the same clinical signs and symptoms is fundamentally flawed and lacks empirical evidence. More importantly, such assumptions preclude the detection of previously unknown signs and symptoms specific to preclinical stage.

The aim of the workshop is to discuss from an interdisciplinary perspective the development of an AI based semi-autopoietic platform that employs deep learning paradigms to detect and recognize unique preclinical signs and symptoms of age-related diseases. The platform builds on two EU Horizon 2020 funded projects in the domain of predictive platforming for neuro-degenerative syndromes like dementia, and is designed to detect data patterns predicting outcome without bias from existing clinical diagnostic heuristics.

The rationale of the platform is to address the needs of a rapidly ageing population and its increasing economic impacts on national health care. An AI interface capable of early detection of preclinical symptoms of functional decline and individually tailored responses has

the potential to significantly reduce the burden on the healthcare system by implementing intervention before disease becomes evident.

Report from Organizers

Summary — Clinical diagnoses of age-related conditions (e.g. frailty) are based on specific signs and symptoms of the disease state. The assumption that preclinical states of these conditions display milder versions of the same clinical signs and symptoms is fundamentally flawed and lacks empirical evidence. More importantly, such assumptions preclude the detection of previously unknown signs and symptoms specific to preclinical stage.

The session has discussed, from an interdisciplinary perspective, the state of development of an AI based semi-autopoietic platform that employs deep learning paradigms to detect and recognize unique preclinical signs and symptoms of age-related diseases. The platform builds on two EU Horizon 2020 funded projects in the domain of predictive platforming for neuro-degenerative syndromes like dementia, and is designed to detect data patterns predicting outcome without bias from existing clinical diagnostic heuristics.

The rationale of the platform is to address the needs of a rapidly ageing population and its increasing economic impacts on national health care. An AI interface capable of early detection of preclinical symptoms of functional decline and individually tailored responses has the potential to significantly reduce the burden on the healthcare system by implementing intervention and prevention plans before disease becomes evident.

Keywords — Medical Informatics and Ubiquitous Healthcare, Alzheimer's disease, Frailty, Analysis of sleep and speech disorder, Multimedia services, E-health

Links: http://www.nico.ottolenghi.unito.it/eng/Research/Research-Groups/Brain-development-and-disease

http://www.usc.edu.au/sunshine-coast-mind-neuroscience-thompson-institute

http://www.activeageing.unito.it/

Assessment of Medical Devices

R621 The HTA of Medical Devices in LMICs

Abstract

Prof. Aleksandra Torbica, Bocconi University, Italy; Rosanna Tarricone & Carlo Federici, CERGAS-Bocconi University, Italy

In the last two decades, both the production and use of health technology assessments (HTA) for priority setting in low-income and middle-income countries (LMICs) have steadily increased. However, conducting and using HTA in those settings frameworks poses numerous challenges and many of them have been investigated in the literature (e.g. scarcity, quality and accessibility of data, gaps in competences).

The evaluation of medical devices poses additional challenges since it requires adequate structural, methodological and procedural approaches for their assessment and, in addition, it will be more dependent on country-specific technological, socio-cultural and institutional characteristics. These issues are particularly relevant for settings where formal HTA pathways are less transparent or not established at all.

The proposed workshop will address specific challenges relative to the assessment and appraisal of health technologies in LMICs. Specifically, it will aim at exploring how the lack of formal HTA processes, and the existence of political, socio-economic and technological barriers may hamper the adoption and diffusion of valuable technologies. The session, will be organized as a traditional frontal lecture, and will prompt debate among participants by discussing a number of real-world case studies.

HTAi: First aid tools to the assessment of medical devices

Abstract

Dr. Iñaki Gutierrez Ibarluzea, HTAi, Canada

Health Technology Assessment international (HTAi) is the global scientific and professional society for all those who produce, use, or encounter HTA. HTAi has members from over 65 countries and embraces all stakeholders, including researchers, agencies, policy makers,

industry, academia, health service providers, and patients/consumers. We are the neutral forum for collaboration and the sharing of leading information and expertise; this means that we are a knowledge and communication hub for any stakeholder working on the assessment of the value of health technologies. The aim of the society is to support and promote the development, communication, understanding and use of HTA around the world as a scientifically-based means of informing decision making on the effective and efficient use of technologies and resources in health care.

Our members regularly participate in three main activities: Meetings, Policy Fora and Interest Groups. HTAi also provides access to a variety of Resources including the International Journal of Technology Assessment in Health Care (IJTAHC). Regarding the evaluation of medical devices, there are certain activities that are of interest to the audience such as: interest groups (Conditional Coverage/Access & Regulatory Interactions; Disinvestment; Hospital-based HTA; HTA in Developing Countries; Information Resources and Patient and Citizen Involvement among others…) and the HTAi vortal.

R554 Health economic via web: the MAFEIP tool

Abstract Dr. Francisco Lupiáñez Villanueva, University Oberta de Catalunya – Open Evidence, Spain; Leandro Pecchia, University of Warwick, United Kingdom; Ruth Vilar, Universitat Oberta de Catalunya – Open Evidence, Spain; Arnold Senn, European Commission, Belgium

Healthcare Budget is limited and in some cases scarce. Therefore, introducing a new technology may result in cutting budget for other healthcare services or interventions. Health Technology Assessment (HTA) supports policy makers in taking decisions on whether to spend public money on a new healthcare technology.

Several dimensions have to be considered in order to perform a HTA, especially when assessing medical devices or other health interventions strongly dependent from ICT (e.g., eHealth). Nonetheless, cost and health impact are the two dimensions that underlay any HTA assessment. Although several methods and case studies are available to support decision makers in performing HTA studies, but there is still a shortage of user friendly tools aiming to support decision makers in performing preliminary assessment, especially when information is not completely available.

In the past years, the European Commission financed the design and development of a web tool aiming to support health economic analyses. This tool was developed in the framework of the European Innovation Partnership on Active and Healthy Ageing (EIP on AHA), and was therefore called Monitoring and Assessment Framework for the European Innovation Partnership (MAFEIP) tool. Launched in 2012, the EIP on AHA is a European Commission led policy initiative to address the challenges of demographic change in Europe. Its overarching target is to increase the average healthy lifespan by two years by 2020 and it will pursue a "Triple Win" for European citizens:

a) Enabling EU citizens to lead healthy, active and independent lives while ageing;

b) Improving the sustainability and efficiency of social and health care systems;

c) Boosting and improving the competitiveness of the markets for innovative products and services, responding to the ageing challenge at both EU and global level, thus creating new opportunities for businesses.

The MAFEIP tool is freely accessible on line, and was designed to guide users towards the cost-utility assessment of their healthcare technologies.

This session will give a brief introduction in the theory underlying cots-utility analysis. Subsequently, thought a case study, the attendees will be guided in a practical experience designed to give then a first grasp of the kind of information that they need in order to start an assessment of healthcare technologies in their context. Finally, the attendees will be guided in a practical session aiming to train them in the use of the tool and therefore in performing a cost-utility assessment of a medical device. If possible, attendees will be spitted in small groups each facilitated by one tutor in order to maximize their learning experience in the use of this freely available too.

Regulations and Standards	
A111	Medical Device Regulations For Regulators, Manufacture, And Users
Abstract	Dr. Mary Overland, DITTA/GE Healthcare, United States; Josephina Hansen, WHO, Switzerland; Robert E. Geertsma, National Institute for Public Health and the Environment (RIVM), Netherlands This workshop will focus on the impact of medical device regulations from the perspective of regulators, manufactures, and users. The important of a medical device regulatory framework from a regulator's perspective will be explained, as well as a description of how regulators can put in place a regulatory framework. Throughout life cycle of a medical device, manufactures comply with regulations to bring products to market of consistent quality and safety. Life cycle phases of the medical devices including R&D, production, marketing authorization, distribution, use, postmarket, and disposal will be discussed. Insight as to where in the life cycle of the medical device important data is generated, where the data is used, and by whom will be discussed. Examples and explanations of the important information contained in technical dossiers and declarations of conformity and how it can be of use will be described.
Health Technology Management/Clinical Engineering	
R646	CE-HTM Education, Training, and Professional Credentialing
Abstract	Mr. John Tobey Clark, University of Vermont, United States of America; Anna Worm, THET, Benin; Mario Forjaz Secca, IFMBE, Portugal-Mozambique; Shauna Mullally, Northwest Territories Health System, Canada; Rossana Rivas, CENGETS PUCP, Peru; Yadin David, Biomedical Engineering Consultants, United States of America; Mario Medvedev, University of Zagreb, Croatia; James Wear, Consultant, United States of America The field of biomedical and clinical engineering entails formal education in engineering, technology, management, and medical areas. For biomedical equipment technicians, classroom technical training is typically combined with hands-on laboratory work or internships. Other training modalities which have been utilized are virtual including webinars, online courses, videos, and interactive discussion boards. The IFMBE/CED set forth a project to make high quality, multi-modality, training materials on medical device maintenance and management available for BME professionals in low-resource settings. The progress to date will be presented. The public expects all professional practitioners be competent in their field, exhibit ethical behaviors, and show commitment to continued education and performance throughout their careers. The biomedical and clinical engineering fields must also show these values as their responsibilities related to critical health technologies are significant. Credentialing demonstrates required education, training and experience related to their practice. IFMBE/CED embarked on a project identifying body-of-knowledge and body-of-practice that clinical engineers should have. A global assessment of credentialing programs is also in progress. This presentation will highlight the early survey results and review direction for future credentialing programs.
Report from Organizers	Growing recognition for the role of credentialing in biomedical engineering is taking place creating demand for identifying model program for local as well as for global norms.
R246	Global HTM Training and CED eCourse Project

Abstract

Mr. John Tobey Clark, University of Vermont, United States of America; Ms. Anna Worm, THET, Benin; Mario Forjaz Secca, IFMBE, Portugal-Mozambique; Shauna Mullally, Northwest Territories Health System, Canada; Rossana Rivas, CENGETS PUCP, Peru

The training of healthcare technology support staff, i.e. biomedical equipment technicians, typically includes technical training in the classroom combined with hands-on laboratory work or internships in the clinic or hospital. Other training modalities which have been utilized are virtual including webinars, online courses, videos, and interactive discussion boards. Hybrid approaches efficiently combining interactive classroom learning with dynamic virtual training have also been utilized and have been cost-effective especially if learners are at a distance from classrooms.

HTM eCourses with content, assessments, and interactive discussion boards have been successful in the WHO Region of the Americas for both healthcare technology technical and management training with over 1000 students from 40 countries taking the virtual courses over the past 10 years.

The IFMBE/CED set forth a project to make high quality, multi-modality, training materials on medical device maintenance and management available for HTM professionals in low-resource settings. Training topics planned include 80% introductory/device-specific content and 20% management content. The venture intends to combine on-line coursework completed asynchronously scheduled and live interactive Continuing Professional Development (CPD) course content. The progress to date of this multi-year training project will be presented.

A228-2 CED Role in Linking Global HT Innovation/Standards

Abstract

Dr. Yadin David, Biomedical Engineering Consultants, LLC, United States of America; Dr. Thomas Judd, IFMBE/CED, United States of America; Shauna Mullally, Northwest Territories Health System, Canada; Fred Hosea, Yachay Tech University, Ecuador

Health technology (HT) innovation positively impacts population health and wellness in hospitals, clinics, at work and in homes. From the early stage of research and trials in laboratories to successful commercialization and utilization at bedside, the path is characterized by lack of administrative and technical resources, facilities, qualified personnel, intellectual and safety regulations, national (investment) policies, and user training.

When innovation is being driven through cross-discipline incubators supported by professionals with clear regulatory guidance, and investment incentives that follow market needs, the outcome is HT that improves care and extends lives.

A key factor for safe innovation outcomes is through an HT lifecycle adverse events registry. Rising trends of unintended patient outcomes, injury or death, demonstration HT or users ill prepared for its utilization. The path of innovation from the laboratory to the bedside must avoid this and ensure appropriate and sufficient testing is conducted prior to marketing. The critical importance of clinical trials and data collection on adverse events cannot be over-emphasized.

There is a need to improve introduction of innovative technologies (products) through continuous feedback from effectiveness and unintended events collected at the bedside or home when technology utilized to promote safer and better outcomes for populations.

A241-3 Global Clinical Engineering Success Stories

Abstract

Mr. Thomas Judd, IFMBE/CED, United States of America; Yadin David, IFMBE CED Board, United States of America; Fred Hosea, Yachay Tech University, Ecuador

Health Technology (HT) is vital to the delivery of global health care and wellness. It is essential that HT be managed in the most optimal way, to better contribute to the response to the burden of disease, utilize digital care delivery tools, and confront reemerging and new

epidemics like Ebola and Zika.

At the 1st International Clinical Engineering (CE)-Health Technology Management (HTM) Congress and Summit in 2015, a resolution was adopted by the global country participants present to identify and promote CE's unique qualifications, and record many contributions of Ces to the improvement of world health.

In early 2016, a group of experts from every region collected success stories that exemplify the outcomes achieved due to interventions by Ces, with over 150 from 90 countries, grouped in six categories of impact. Each category also notes health related statistics, size of population, prominent health system, and details. Categories include: Innovation; Improved Access; Health Systems; HTM; Safety & Quality; and e-Technology. These stories were compiled into an HT Resource presented to WHO's World Health Assembly health leaders in May 2016, see http://cedglobal.org/?s=success+stories.

This session will explore the stories collected so far, lessons learned; and encourage ongoing data collection.

Report from Organizers

The global Clinical Engineering (CE) community continues to come together, led by IFMBE CE Division, see CEDGlobal.org. We are finding solutions to long-standing HTM problems in many countries, as evidenced by our CE-HTM Success Story document presented to the WHA in May 2016.

R605 Role of BMETs in health technology management

Abstract

Mr. Ismael Cordero, Gradian Health systems, United States of America; Anna Worm, THET, Benin/United Kingdom; Jocelyn Brown, 3rd Stone Design, United States of America

Despite advancements in health technology, there remain myriad challenges in designing, procuring, maintaining and using medical equipment in low- and middle-income countries (LMICs). Devices built for hospitals in the West are often repurposed for LMIC facilities that lack infrastructure to use them properly. Procurement bodies sometimes fail to account for the unique characteristics of the LMIC facilities, preventing equipment from being operated effectively. Hospitals typically lack access to local expertise and parts for repairs. And device suppliers often distribute equipment without supplying sufficient training.

One solution that could help overcome these challenges is elevating the role of local biomedical equipment technicians (BMETs). We propose a workshop to refine the ways in which BMETs can contribute to an improved health technology landscape in LMICs: from being responsible for drafting specifications for procurement to training clinical staff on basic upkeep to serving as intermediaries between suppliers and hospitals for maintenance and repairs. The workshop's goal is to highlight the role of BMETs across the healthcare technology management cycle, including planning/assessment; budgeting/financing; technology assessments/selection; procurement/logistics; installation/commissioning; training/skill development; operation/safety; maintenance/repair; and decommissioning/disposal. Following the workshop, we will produce a report summarizing participants' input and providing recommendations for the key stakeholders involved.

Report from Organizers

Gradian Health Systems and THET teamed up to lead a workshop that enlisted medical equipment experts to refine the ways in which BMETs can contribute to the various needs around medical equipment – from procurement to training to general upkeep.

When people think of "health workers," their minds tend to focus on clinical care providers who rely on medicines, supplies and equipment to deliver care, rarely extending to the technicians who often make that care possible. Because of that, BMETs are frequently overlooked in goal-setting, national policymaking and health programming, leaving a shortage of educational opportunities, funding support and professional development that would otherwise strengthen a health worker's capacity.

The workshop focused on the healthcare technology management lifecycle and the specific roles and responsibilities that BMETs could undertake to strengthen the medical equipment landscape in low-resource settings. The 22 participants from 13 countries helped chart out not

only the areas where BMETs can contribute, but also the policies and actors that could help advance these roles.

The results of the workshop are being refined and compiled and will be distributed to the participants as well as made available to the general public.

Background information on the HTM life cycle can be found at IFMBE's CED website http://cedglobal.org/ced-books/ in the ZIken "How to Manage" series.

And also on THET's website: http://www.thet.org/health-partnership-scheme/resources/medicalequipment/useful-resources-for-medical-equipment

R640	IFMBE/CED Role in Global BME/CE Recognition

Abstract Prof. James Goh, IFMBE, Singapore; Prof. Ernesto Iadanza, IFMBE, Italy; Yadin David, IFMBE/CED, United States of America

The International Federation for Medical and Biological Engineering (IFMBE), has the mission of encouraging, supporting, representing and unifying the worldwide Medical and Biological Engineering (MBE) community in order to promote health and quality of life through advancement of research, development, application and management of technology.

A key IFMBE goal is promoting the development of the MBE profession, and its recognition and awareness by the public. Its Clinical Engineering (CE) Division (IFMBE/CED) is very active in promoting the CE profession for the improvement of global healthcare delivery through the advancement of safe and effective innovation, management and deployment of healthcare technology (HT).

At the first Global CE Summit, held in China in October 2015, with representatives from the most important international institutions, a document was drafted to help reach the goal of achieving affordable, accessible, available, and high quality medical products and HT, given that the dependence on HT development and deployment by biomedical engineers and/or clinical engineers (BME/CE) is higher than ever before. The document well describes the central role of BME/CE in healthcare and has been presented to the International Labour Organization with the goal of having this profession included in the upcoming International Standard Classification of Occupations (ISCO-2018).

A228-2	IFMBE-CED & Global CE-HTM Evidence Based Advances

Abstract Prof. Ernesto Iadanza, IFMBE, Italy; Yadin David, IFMBE, United States of America

The Clinical Engineering Division (CED), an international professional group within IFMBE, focuses on global collaboration about learning, research, knowledge, deployment and communication on health technology management (HTM) within the CE community and its understanding by other stake holders. CED strategy is to promote exposure to the field and to organize scientific exchanges within and between global regions. The professional development includes characteristics of leadership, accountability, ethics, management and credentialing.

Recent major impact is evident by the volume of participation in CED events, the development of a professional development program in China, the creation of Global CE Day celebrated around the world with on-line and social media participation of over 73,000 individuals, increase in credentialing activities, the initiation of international CE-HTM global Congress, and the creation of professional societies with cross-region cooperation in Africa.

Lessons learned indicate that nurturing country/region professional societies supported by local professionals is critical, as are developing leadership skills, operation templates, and shared goals. A recent global CED project highlighted the need for academic CE programs and better recognition of the population's health benefits from this profession. Evidence will be presented about success stories collected from about 90 countries about the critical role of CE

and HTM.

Public-Private Partnership	
	Leveraging Public-Private Partnerships to Access Essential Technologies for Primary Care in Emerging Economies
Abstract	Ms. Vanessa Candeias, Peter Varnum, Jennette Leung, Arnaud Bernaert, World Economic Forum, Switzerland

The Sustainable Development Goals call for universal health coverage (UHC) by 2030, which requires strengthening primary care as a priority. Neither governments nor private organizations can address this challenge alone. Over 80% of populations in emerging markets remain without access to basic care and more than 70 countries have asked WHO to help them progress towards UHC. Every year, 100 million people fall into poverty as a result of catastrophic healthcare expenditures. The ageing population and burden of non-communicable diseases present an added challenge in reshaping health systems to deliver on UHC.

Currently, there are no stakeholders in the global health space mobilizing the private sector to provide sustainable access to primary care and universal health coverage. Aside from one-off corporate social responsibility projects, only a handful of successful, commercially viable public-private cooperation models ensure sustainable access to care in emerging economies and have yet to be scaled.

In this session we will discuss, with an emphasis on medical devices, how public-private partnerships play a key role in delivering primary care. The session will be relevant to the World Economic Forum's Primary Care Coalition project, which brings together stakeholders across sectors for the following objectives:

1. Highlight gaps and key needs in the primary care landscape particularly related to access to essential devices and technologies
2. Identify barriers and solutions in scaling initiatives public-private collaborations
3. Identify and engage partners critical to the success of the Primary Care Coalition

Report from Organizers

On barriers to delivering primary care:

Lack of the same resources in urban and rural areas; issues in delivery of devices (supply chain) and cost of delivery to rural areas

Lack of training or capacity; lack of user-friendliness

Staff turnover

Lack of funding; funding restricted to specific diseases and not given for PHC

Innovations that don't fill relevant spaces/gaps; inappropriate technologies

Lack of knowledge of local context; cultural barriers

Piloting->scaling as opposed to a pilot that is at-scale

Slow adoption rates

Policymakers prioritizing political situation over policy improvements

On solutions:

Tailored, multistakeholder capacity building

Identifying champions at all levels

International leadership and buy-in from WHO member states

Relevant needs assessments on global and local levels

Involvement of sales companies, logistics companies, professional services companies (comprehensive private sector involvement); holistic approach to delivery of devices

Better procurement

Establishing global standards that can be adopted to local context

Improved service delivery as opposed to just delivery of equipment

Relevant stakeholders:

Health workers

Regulatory groups

Patients

Tech

Business

Civil society

Ministries (of Health, Finance, Transportation, Science and Technology, etc.)

Funders (private and public)

WHO

Overall thoughts:

Access to quality primary care and the devices that assist in its delivery is crucial; this requires convening of all actors. Multistakeholder partnerships are needed at the global and local levels due to the complexity of primary healthcare.

Navigating the cycle of influence and international leadership are crucial. Ministries have to put pressure on WHO to establish and enact agenda, but other actors – civil society, private sector, international organizations – have to put pressure on Ministries to establish priorities.

Leaders of all sectors have a need to work within two health systems: the one that exists today and the one that will need to exist in 10-15 years to deliver access to affordable, quality primary care. They must continue pushing a policy agenda that transcends power dynamics and keeps as its compass quality and value of care for the patient.

	Laboratory & Pathology
R428	The mobile laboratory: bringing high-quality testing to the patient

Abstract

Ms. Susanne Andresen, International Federation of Biomedical Laboratory Science, Denmark; Pierre Bouchelouche, Zealand University Hospital Koege, Denmark

Challenge

To establish a mobile care team (the Mobile Laboratory Unit, MLU), in the form of a shared care model between the general practitioner (GP), Municipality of Koege, Denmark and home health care (Home Care), to prevent unnecessary hospitalizations and hospital readmission of senior citizens.

Patient groups

The primary target groups are chronic, elderly and frail patients who suffer from minor medical diseases, who can be assessed and treated in their own homes.

Method

When requested by the GP, the MLU drives directly to the patient's residence. The nurse makes a clinical assessment of the patient, and samples are taken and analysed directly by the biomedical laboratory scientist in the MLU. Currently, it is possible to analyze 40 of the most common analyses in less than 30 minutes. The MLU is equipped with: ABX Pentra 400 benchtop analyser (blood electrolytes, liver and kidney analyses); ABX Micros-CRP analyzer (haemotology);

Radiometer ABL 90 (blood gas), Roche Cobas h 232 (D-dimer); Roche Coaguchek XS pro (INR); Siemens Clinitek (urine) and ECG.

Conclusion

Bringing advanced testing technology and competence to the patient is lowering the number of hospitalizations, and contributing positively to higher quality and more coherent patient

care.

Report from Organizers

The mobile laboratory is a Danish project where biomedical laboratory scientist (BLS) and emergency nurse provides laboratory and nurse assistance outside the hospital.

The session had approximately 17 participants from primary high-income countries. The project was presented and afterwards questions were answered and elaborated on. There was focus on the robustness of medical devices, interfaces in cooperation between municipalities, GPs and the hospital.

One important question in the session was cost effectiveness, producing high quality at the lowest cost. The question is difficult to answer, as it would require a control group, but a statistical review, indicates that the mobile laboratory prevents unnecessary hospitalization.

The participants showed interest in the project, and the final of the workshop was about developing the mobile laboratory. Would a future possibility be a mobile laboratory being a part of a team for blood transfusion and chemotherapy in person´s own homes? Where the mobile laboratory supports the startup of blood transfusion and chemotherapy by the nurse, and is followed up with hematological parameters by the BLS.

There was an agreement, that the mobile laboratory is a project which can be adapted and developed to any context.

The workshop ended with some requests for study visits.

R244 The Evolving Role of Pathology

Abstract

Prof. Lai Meng Looi, WASPaLM, Malaysia; Dr. Roberto Verna, WASPaLM, Italy; Dr. Jagdish Butany, WASPaLm, Canada

The Evolving Role of Pathology

Workshop Sponsor: World Association of Societies of Pathology & Laboratory Medicine
Speakers: Dr(s) Roberto Verna (Rome, Italy); Lai Meng Looi (Kuala Lumpur, Malaysia), Jagdish Butany (Toronto, Canada)

Abstract:

"As is your Pathology, so is your Medicine" said Sir William Osler (1918, Toronto). Pathology continues to play a critical role in medicine and forms the basis of a physician's definitive diagnosis of disease and understanding of how disease affects the human body. Pathology covers many subdisciplines, ranging from the study of tissue and blood disorders, to testing for biochemical changes in body fluids and the detection of harmful microorganisms. Each subdiscipline has evolved over time with the incorporation of new knowledge and technology. For example, the area of tissue testing (anatomical pathology) has evolved from offering a histological diagnosis of cancer (or lack thereof) to providing prognostic and predictive information that guides choice of therapy for the patient. Together with molecular and genetic testing, detailed and accurate anatomical pathology results play an increasing and critical role in the field of personalised medicine. Pathology adds-value to rational testing of patients and has crucial roles in the timeliness and cost effectiveness of delivery of patient care.

In this workshop, we will cover some of the expanding/evolving roles played by the pathologist, roles that transcend offering of the traditional diagnosis and add value to patient management, with talks on:

(1) The introduction of new tests and the value they add (Roberto Verna)

(2) Contribution of pathology to personalised medicine (Lai-Meng Looi)

(3) The pathologist and device testing, maintaining quality and new diseases (Jagdish Butany)

Quality	
R446	Good practice in ultrasound probe cleaning
Abstract	Prof. Guy Frija, ISR, United States of America; Nicole Denjoy, DITTA, Belgium
	Ultrasound is considered one of the safest and most affordable imaging modalities at the point of care and thus widely used in global healthcare. However, the International Society of Radiology is concerned by recent publications and a European study that shows that good practices during cleaning of the probes after cutaneous or endocavitary examinations are seldom followed and thus lead to the potential development of cross-infection. The goal of this workshop is to present the European study, which showed a large diversity in protocols and practice, and to present the guidelines recently established by the World Federation of Ultrasound in Medicine and Biology to promote the safe use of ultrasound in particular in underserved areas of the world. DITTA as global industry association will present its perspectives and will introduce devices aimed at facilitating probe cleaning in order to achieve a high level of disinfection. Measures to establish and increase the use of infection control processes in ultrasound will be discussed and the importance of good medical practice in this area highlighted, following a multi-stakeholder approach based on training and awareness raising to improve patient safety.
Report from Organizers	Joint workshop of the International Society of Radiology with the Global Diagnostic Imaging, Healthcare ICT, and Radiation Therapy Trade Association (DITTA) and the World Federation for Ultrasound in Medicine and Biology (WFUMB)
	A survey performed by the European Society of Radiology was presented that showed that 10% of responding centers did not protect the probe with a cover before an examination (and 25% did not do so before an interventional procedure where body fluids could be in contact with the probe). Moreover, 10% cleaned the probe only after the list of examinations. These practices are concerning because they could induce cross-infection with germs like e.g. HIV and HPV. Recommendations for good practice coming from NHS Scotland and from the World Federation for Ultrasound in Medicine and Biology were presented and emphasised the mandatory need to protect the probe with a good quality cover before each endo-cavitary examination, to clean the probe after the removal of the cover, and to make a high level disinfection, either with chemical or physical methods (ultra-violet) before any re-use. DITTA highlighted relevant standards for disinfection and probe cleaning as well as related user recommendations.
	The WHO was called upon to raise awareness of the updated good practices guidelines by above-mentioned bodies among professionals through its program on communicable diseases.
A231	Market Dynamics: Supporting Country Decision-Making On Medical Devices; Case Study on Optimizing the Deployment of Cervical Pre-cancer Treatment Devices
Abstract	Mr. Ray Cummings, PATH, United States of America; Tara Herrick & Bhavya Gowda, PATH, United States of America
	Across various medical device and diagnostic product categories, market dynamics work is underway to: estimate product need; evaluate the appropriateness of different products for particular use cases; assess current and future product demand; quantify the supply of quality-assured products; and promote transparency and sharing of information on supply and demand across countries. These efforts are yielding global market data, market models, and other tools that can support country health authorities in product purchase and deployment decisions.
	A case study will be presented related to treatment of pre-cancerous cervical lesions. Cervical cancer is a largely preventable disease, yet still kills about 260,000 women each year, mostly in low- and middle-income countries. PATH has developed a scenario-based Excel model and data visualization mapping tools to examine optimal deployment of cervical pre-cancer treatment equipment in Uganda. These tools, which evaluate the number of women treated, associated costs, and number of units of equipment for both gas-based cryotherapy and non-

gas devices, are currently being expanded to apply to other high disease burden countries in Africa. The country-specific tools can assist decision-makers in weighing the trade-offs in balancing patient convenience and access with efficient utilization of equipment and skilled personnel.

In Vitro Diagnostics

Revised WHO guidance on procurement of IVDs and other laboratory items: tips and tricks

Abstract

Jason Williams, USAID, United States of America; Wandani Sebonego, Supply Division, UNICEF; Anita Sands, WHO, Switzerland

Background:

Poorly thought thorough procurement practices can easily lead to great misuse of funding for testing services. When procurement is not conducted in accordance with best practices, inappropriate and/or expensive products may be sourced and procured. Ten recurring challenges are likely to present including: lack of adherence to existing procurement policy, misalignment with service delivery policy, tiers of testing network not defined, effective coordinating body lacking, equipment maintenance, data availability, managing frequent shifts in technology, human resources, competing priorities, and political agendas. (Williams J. et al., 2016) Therefore, it is critical that laboratory policies, procurement policies and treatment guidelines are aligned so as to provide a responsive and appropriate service to clients.

Revised WHO/USG guidance on procurement of in vitro diagnostics (IVDs) and related laboratory items and equipment aims to provide pathways for procurement processes specific to HIV and HIV-related IVDs, laboratory items and equipment. This guidance is not intended to replace existing guidelines on basic procurement processes but rather to enhance and extend current processes to include specific issues related to diagnostics and related items/equipment that are considered essential to ensure high quality testing services.

Objectives:

1) to brief stakeholders on revised WHO guidance for procurement;

2) to conduct baseline survey to determine current status of existing WHO procurement guidance.

Target Audience:

End-users including policy makers, national HIV programme managers, managers of laboratories and other testing services, and procurement agencies.

Report from Organizers

Poorly planned and executed procurement practices can easily lead to great misuse of funding for testing and other laboratory services. Ten recurring challenges are an obstacle to procurement of the right product at the right time in the right quantities: lack of adherence to existing procurement policy, misalignment with service delivery policy, tiers of testing network not defined, effective coordinating body lacking, equipment maintenance, data availability, managing frequent shifts in technology, human resources, competing priorities, and political agendas. (Williams J. et al., 2016)

Revised WHO guidance on procurement of in vitro diagnostics (IVDs) and related laboratory items and equipment provides a structured pathway for procurement of IVDs, laboratory items and equipment. This guidance is not intended to replace existing guidelines on basic procurement processes but rather to enhance and extend current processes to include specific issues related to IVDs and laboratory items/equipment that are considered essential to ensure high quality testing services.

More information on WHO work on procurement can be found at http://www.who.int/diagnostics_laboratory/procurement/en/

WHO Guidance for procurement of in vitro diagnostics and related laboratory items and equipment can be found at http://apps.who.int/iris/bitstream/10665/255577/1/9789241512558-

eng.pdf

WHO – Prequalification of IVD

Abstract

Ms. Irina Prat, Helena Ardura, Deirdre Healy, WHO, Switzerland

The lack of regulatory oversight remains a challenge in many countries. To fill this gap, the WHO Prequalification of In Vitro Diagnostics (PQDx) undertakes an assessment of IVDs through a standardized procedure assessing their safety, quality and performance.

The prequalification process includes:

- Review of a product dossier;
- Performance evaluation; and
- Manufacturing site(s) inspection.

PQDx also conducts post-market surveillance and review of changes to prequalified products and/or the manufacturer's quality management system.

The outcomes of the prequalification process are used by WHO Member States, UN agencies and international procurement agencies to guide their procurement decisions.

Attendees will be guided through a detailed description of the different components of the process.

Report of Organziers

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The outcomes of the prequalification process are used by WHO Member States, UN agencies and international procurement agencies to guide their procurement decisions.

Attendees to the workshop were guided through a detailed description of the different components of the prequalification process, the new laboratory evaluation pathway and the new published guidance for manufacturers (Sample dossiers, Technical Guidance Series and Technical Specification Series).

The workshop was well attended, with most of the participants coming from Industry (well established manufacturers and innovators). Partner agencies and donors were also present.

Primary medical devices

WHO – Priority medical devices

Abstract

Ms. Adriana Velazquez Berumen, WHO, Switzerland; Gabriela Jimenez Moyao, Antonio Migliori & Natalia Rodriguez, WHO, Switzerland

70% of cancer incidence happens in low and middle income countries where limited infrastructure and medical technologies are available. Cancer is a complicated disease that requires performing: early diagnosis, screening, treatment, palliative care and follow up. Considering the UN declaration of NCDs and the Sustainable Development Goals, WHO initiated a project that concluded with a book that lists all the medical devices required to manage cancer. With financial support from OFID global consultations and country workshops were done to integrate all the information. The project involved management of breast, cervical, colon, lung and prostate cancers, and leukemia. The book includes the description of

the following clinical units: endoscopy, laboratory, pathology, diagnostic and interventional imaging, surgery, radiotherapy, systemic therapy and palliative care. It describes all types of medical devices required, including: single use devices, surgical instruments, medical capital equipment, laboratory equipment, reagents, software and accessories, personal protective equipment and calibration equipment. It was developed with the help of global experts, NGOs, academia and governments. This is just the first step, then the technologies and trained human resources need to be available, and finally the procedures to be affordable, accessible and appropriate for the patients wellbeing.

Nomenclature System

R254 Securing Global Supply Chain Utilizing UDI

Abstract

Mr. Ralph Ives, GMTA, Switzerland; Nicole Taylor-Smith & Lindsay Tao, GMTA, Switzerland

Securing the global medical device supply chain has never been more important to protect patients and improve healthcare systems. The unique device identifier (UDI) system provides a coordinated and globally consistent platform to achieve these goals. Utilizing bar codes and physical direct markings on certain products, the system is designed to identify medical devices throughout the global supply chain, providing precise information and location. Other public health benefits of the UDI system include, among many things, more efficient collection and better data on adverse events, comprehensive management of medical device recalls, and reduction of medical errors , reduction of supply chain cost while enhancing its efficiency. The panel of experts including regulator, industry from different regions, and regional and global harmonization organizations, will share challenges, lessons learned and best practices in implementing UDI system, and promote the understand and adoption of a global harmonized approach. If implemented globally in a harmonized way, the UDI system has the ability to transform efforts to protect patients and improve the healthcare supply chain.

GMDN: an introduction

Abstract

Mr. Mark Wasmuth, GMDN Agency, United Kingdom

The Global Medical Device Nomenclature (GMDN) has been designed to meet the exact needs of medical device regulators and over 80 countries are using or preparing to use the GMDN.

The GMDN has been chosen by the International Medical Device Regulators Forum members, including Australia, Brazil, Canada, China, the European Union, Japan, Russia, Singapore, and USA as their medical device nomenclature of choice to name and group medical devices.

There is no cost for regulators who wish to use the GMDN. The GMDN Agency has recently relaunched its multi-language website to provide additional functionality.

With the introduction of Unique Device Identification (UDI) regulation in the USA and other countries, the GMDN has been used by over 7500 medical device manufacturing companies worldwide, to identify and match to their existing product range. Manufacturers are charged for their access to the GMDN, but this as little as 120 USD. Manufacturers' benefit from using the GMDN because it reduces their costs of duplicate effort.

The GMDN is kept updated with new product groups by application from manufacturers, this ensures the GMDN is always complete.

The presentation would highlight the features and benefits of using the GMDN for medical device naming and grouping.

Report from Oragnizers

The presentation highlighted the features and benefits of using the Global Medical Device Nomenclature (GMDN) for medical device naming and grouping. Medical device regulators in over 80 countries are using the GMDN and it has been recommended by the IMDRF, as it always up to date and accurate.

The delegates that represent governments were reminded that there was no cost for using the GMDN and GMDN Agency would consider removing the cost of access for other users on the basis of hardship. The GMDN Agency has recently relaunched its multi-language website to provide additional functionality and reduce barriers to international adoption.

With the introduction of UDI regulation in the USA, the GMDN is now used by over 7500 medical device manufacturing companies worldwide. Manufacturers' support the introduction of the GMDN as the single global standard to name and group medical devices because they benefit from using the GMDN, as it removes the cost of duplicated effort.

Questions from the delegates highlighted the need for the WHO to promote the use of the GMDN as their preferred nomenclature, as recently identified in the publication 'WHO Global Model Regulatory Framework for Medical Devices'.

Tools for Health Technology Management

CMMS requirements and results

Abstract

Mr. Bill Gentles, ACCE, United States of America; Claudio Meirovich, Meirovich Consulting, Spain; Martin Raab, Swiss Tropical Institute, Switzerland; Jitendar Kumar Sharma, AP MedTech Zone, India

Introduction

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. This workshop will discuss the options for implementing a CMMS in low resource settings.

What "Open Source" CMMS programs are in current use?

A comparison of available open source CMMS programs with live demonstrations will be presented. The strengths and weaknesses of existing open source CMMS software as well as misconceptions about the meaning of "open source" will be discussed.

Why Is a CMMS a useful Tool?

A CMMS provides a powerful means of enabling strategic investment planning, managing the maintenance of the devices and the crucial link to the management of health facilities and health systems. Evidence has demonstrated that enormous amounts of money is wasted because of underperforming maintenance systems

Challenges in collecting Inventory data

Setting up a CMMS and maintaining inventory data is time consuming work. In many cases, there are simply not the staff resources to accomplish this important task. A discussion of strategies to collect and track inventory data will be discussed.

Challenges in implementing Planned Preventive Maintenance

Methods of implementing planned maintenance in a CMMS will be discussed.

Report from Organizer

Introduction

This workshop discussed the options and challenges in implementing a CMMS in low resource settings.

Audience comments/requests

At the start of the workshop, the audience was asked for input on what topics they thought were most important to discuss. Suggestions included: usability, supportability, costs, performance indicators available in the software and questions to ask when selecting a CMMS.

Results of a survey

Data was presented from a survey conducted via the Infratech email discussion group relating to the current practices for managing equipment in low resource settings. Forty-two responses were received, 14 from developed economies, and 28 from developing economies. Of 24 public organizations, 63% were using spreadsheets or open source or free software. Of 17 private organizations, 59% were using a commercial CMMS product. Other details of the survey results have been circulated on Infratech.

Costs of implementing a CMMS

Data was presented from India showing that the cost of implementing a CMMS could be 0.5% to 2.0 % of the asset value in the inventory, depending upon characteristics desired.

An Overview of some Free/Open Source systems

Three freely available CMMS systems were presented.

OpenMedis, http://openmedis.scih.ch

BMEMS, http://www.bmems.co.in/home/

TaskMaster, http://www.ebme.co.uk/downloads/category/10-miscellaneous

Features of each program were briefly discussed.

Conclusions: Workload implications of implementing a CMMS

It was emphasized that implementing a CMMS has cost implications, even if the software is "free". It will always result in increased workload. A major workload obstacle is the collecting of inventory data, a time-consuming task. Another challenge is to train users and change the culture of the staff who will use the system.

The HTM/ medical devices community (with focus on LMIC) identifies, evaluates and recommends CMMS systems that are truly adapted to the needs of LMIC's. Once a system(s) is identified it should appropriately be promoted and supported for implementation. Ideally in the format of an openSource project community (such as DHIS2).

R552	A reality check on biomedical engineering education

Abstract

James Goh, International Federation of Medical and Biological Engineering, Singapore; Kingping Lin, IFMBE, Singapore; Shankar Krishnan, Wentworth Institute of Technology, United States of America; Ratko Magjarević, IFMBE/University of Zagreb, Croatia

The medical devices industry sector is projected to grow rapidly which means that there is a need to invest in human capital development to achieve sustainable growth. In support of this, education and training programs to strengthen the manpower capabilities for the medical devices industry have been developed over the years at a rapid rate. The question is: how relevant are these biomedical engineering educational programs in training students with skills to understand real world complex issues in medical and healthcare problems? Furthermore, the wide career opportunities open to graduates in biomedical engineering seems to be expanding. Are we providing adequate training to handle these jobs? Should internships, overseas exchange programs, and involvement in leadership-type activities be made compulsory so as to develop their marketability to employers? Should curriculum be designed with biomedical innovation in mind and ensure relevance to the industry? It is timely that a reality check on biomedical engineering education be carried out and consensus reached to create an educational and training program that is truly professional.

Report from Organizers

Presence of innovative thinking for health care is present in European space for a number of years: the number of patents in biotechnology submitted to the European Pattent Office is far the largest in engineering. This statistics is closely related to biomedical engineering education and it reflects the ongoing activities within more than 300 biomedical engineering programs in Europe. We want to present and discuss methods in high education that lead to innovation and may have impact in health care, such as problem based learning, design competitions etc.

Regulatory Framework

	WHO model regulatory framework medical devices workshop

Abstract

Ms. Josephina Hansen, WHO, Switzerland; Adham Ismael Abdel, WHO EMRO, Egypt; Johanna Koh, Singapore

In 2014 the World Health Assembly adopted Resolution 67.20 on Regulatory system strengthening for medical products. The Resolution states that "effective regulatory systems are an essential component of health system strengthening and contribute to better public health outcomes, that regulators are an essential part of the health workforce, and that inefficient regulatory systems themselves can be a barrier to access to safe, effective and quality medical products". It states that "Recognizing also that effective regulatory systems are necessary for implementing universal health coverage".

In the context of Resolution 67.20, the growing interest in medical devices in the global health community and thelack of regulatory systems for medical devices in many countries, WHO

decided to develop the WHO Global Model Regulatory Framework for medical devices including in vitro diagnostic medical devices ('the Model') . It is intended to provide guidance to WHO Member States that have yet to develop and implement regulatory controls relating to medical devices, as well as to jurisdictions that are continuing to improve their regulatory frameworks. The Model recommends guiding principles and harmonized definitions. Its main elements refer to international harmonization guidance documents developed by the Global Harmonization Task Force (GHTF) and its successor, the International Medical Device Regulators Forum (IMDRF). These main principles and elements are also reflected in other publications like the Asian Harmonization Working Party Playbook for implementation of medical device regulatory frameworks and the WHO Regional Publications, Eastern Mediterranean Series Regulation of medical devices A step-by-step guide and in the recent revised European Regulations.

Appendix 3

Oral Parallel Session

Parallel sessions - Thursday 11 May 2017	
Innovation of medical devices	
	Session Chair: Dr. Gaby Vercauteren, WHO, Switzerland Session Co-Chair: Fred Hosea, Yachay Tech University, Ecuador
Chair's key point	· For innovative medical devices to be successful in a sustainable manner, a comprehensive approach is required. That is the initial plan already needs to consider: the customer needs assessment, the appropriate design, R&D costs, the transfer to scale up, regulatory requirements, the business plan and commercialization, post market surveillance. · Governments do play a critical role in fostering access/or not to innovative medical devices, either through national stimulation/ incentive plans or by imposing too high taxes on imported medical devices, that could have a positive health impact for their population. · The audience recommended discussion roundtables on particular topics and also that time would be allocated during the conference for channeled interaction between participants.
A180.2	Engineering innovations for clinical applications
	Prof. James Cho Hong Goh, Chwee-Teck Lim, International Federation of Medical and Biological Engineering, Singapore
R270	Medical device reforms & the landscape in India
	Dr. Madhur Gupta, World Health Organization Country Office, India
A63	Collaborative open design for safer medical devices
	Ms. Alice Ravizza, Arti Ahluwalia, Carmelo De Maria, Licia Di Pietro, Jacopo Ferretti, Andrés Díaz Lantada , Mannan Mridha, Philippa Ngaju Makobore, June Madete, Albo Aabloo, Arni Leibovits
R490	Designing high quality global health technologies
	Dr. John Langell, Bernhard Fassl, Tyson Schwab, Dean Wallace, Roger Altizer, Tomasz Petelenz, Walter Prendiville, University of Utah, United States of America
A151	Designing global health technology for commercial scale
	Ms. Jocelyn Brown, Robert Miros, 3rd Stone Design/Hadleigh Health Technologies, United States of America; Adam Lewis, Gradian Health Systems, United States of America
R259	Temperature protocol that minimises early neonatal deaths
	Prof. Hippolite Amadi, Imo State University Nigeria & Imperial College London, United Kingdom; Olateju Eyinade K., Adesina Temilade C., University of Abuja Teaching Hospital, Nigeria
Regulation of medical devices	
	Session Chair: Ms. Thangavelu Sasikala Devi, Medical Device Authority, Malaysia Session Co-Chair: Ms. Josephina Hansen, WHO, Switzerland
R609	Actions of medical device post-market surveillance
	Prof. Kangping Lin, International Federation of Medical and Biological Engineering, Singapore; Yueh-Tzu Hung, Shiu-Huei Yeh, Yu-Wen Huang, Pei-Weng Tu, Food and Drug Administration, Ministry of Health and Welfare, Chinese Taipei

R611	A new academic program for MD regulatory affairs professionals
	Prof. Folker Spitzenberger, Heike Wachenhausen, University of Applied Sciences Luebeck, Germany
R619	Medical device competency regulatory program in Malaysia
	Ms. Sasikala Devi Thangavelu, Medical Device Authority, Malaysia
R539	Validation and verification of IVDs in Kenya
	Ms. Bintiomar Tsala, Kenya Medical Laboratory Technicians and Technologists Board, Kenya
	Collaborating Centre PAHO/WHO for the Regulation on Health Technology (Medical Devices). Impact in regional regulatory work.
	Ms. Dulce María Martínez Pereira, State Center of Medicine and medical Devices, Cuba
	Assessment of medical devices Session Chair: Dr Iñaki Gutierrez, HTAi, Spain Session Co-Chair: Ms. Mirella Marlow, NICE, United Kingdom
R468	INAHTA perspective of assessment of medical devices
	Dr. Sophie Wörko, INAHTA; Gino De Angelis, CADTH, Canada
R561	Assessment of medical devices in low-income settings
	Dr. Leandro Pecchia, IFMBE, United Kingdom; Nicolas Pallikarakis, University of Patras, Greece
R315	Horizon scanning to ensure timely HTA
	Dr. Vigdis Lauvrak, The Norwegian Institute of Public Health; Ellen Nilsen, Norwegian Directorate of Health, Norway
A87	Using other's HTAs: adopt or adapt?
	Dr. Katrine Bjørnebek Frønsdal, Lauvrak V, Skår Å, Giske L, Sœterdal I, Fure B, Norwegian Institute of Public Health, Norway
R468	Implementation considerations in a HTA of dialysis
	Mr. Gino De Angelis, Eftyhia Helis, Janet Crain, Kristen Moulton, Laura Weeks, CADTH, Canada
	Management of medical devices Session Chair: Ms. Vanessa Candeias, World Economic Forum , Switzerland Session Co-Chair: Mr. Tom Judd, IFMBE CED, United States of America
Chair's key point	1. Need of a global web-based database for nomenclature and managment of Medical devices. 2. Gather all together CMMS from different countries to standarize and define key elements and indicators for guidance on appropriate management of medical devices.
R96	Medical equipment management
	Prof. Nikolaos Pallikarakis, Institute of Biomedical Technology (NIBIT), Greece
A73	HTM implementation in Saint George hospital Lebanon
	Mr. Riad Farah, Lebanon
R173	Good governance of equipment in public sector
	Dr. Pamphile Thierry Houngbo, Ministry of Health, Benin; Prof. Joske. F. G. Bunders-Aelen, Vrije Universiteit Amsterdam, The Netherlands
R46	Strengthening utility and maintenance of medical devices
	Mr. Demeru Yeshitla Desta; Ismael Cordero, Gradian Health System, United States of America; Ayalew Firew, Kibwana Sharon, JHpiego-Ethiopia.

	Human resources and medical devices
	Session Chair: Prof James Goh, IFMBE, Singapore
A243	The involvement of IFMBE in developing countries
	Prof. Mario Forjaz Secca, IFMBE
R622	IOMP initiatives on equipment related professional capacities
	Prof. Magdalena Stoeva, International Organization for Medical Physics (IOMP), United Kingdom
A179-1	Clinical engineering in China
	Prof. Bao Jiali, Zhu Chaoyang, Zhejiang University, China
R653	Apprenticeship model for clinical engineering workforce development
	Mr. Abdul Basit, Malcolm Birch, Barts Health NHS Trust, United Kingdom
A198-1	Biomedical engineering education: studies harmonisation
	Prof. Nikolaos Pallikarakis, Institute of Biomedical Technology (NIBIT), Greece
	Assistive devices
	Session Chair: Prof. Shankar Mutukrishnan, Wentworth Institute of Technology, United States of America Session Co-Chair: Dr. Emma Tebbutt, WHO, Switzerland
R197	A novel device to screen newborns for hearing loss in resource constrained settings to prevent speech loss
	Mr. Nitin Sisodia, Gopinathan, Karthikeyan, Sohum Innovation Lab, India
R529	Evaluation of performance leads to better products?
	Mr. Jesper Nordlinder, SCA Hygiene Products, Sweden
A249	Dynamical orthostatic chair
	Mr. Walef Robert Ivo Carvalho, Instituto Nacional de Telecomunicações, ; Ana Letícia Goncalves, National Institute of Telecomunications (Inatel), Brazil
R651	Hand orthosis for radial or cubital injury
	Ms. Rosa Itzel Flores Luna, Ruben Valenzuela-Montes, Hanna L. Garcia-Guerra, David de Jesus-Cruz, Mariano Garcia del Gállego, Alvaro Ayala-Ruiz, National Autonomous University of Mexico (UNAM), Mexico
R217	Disrupting the barriers to uncorrected refractive errors
	Dr. Shivang R. Dave, Nicholas J. Durr, Daryl Lim, Eduardo Lage, PlenOptika, Inc.; Department of Biomedical Engineering, Johns Hopkins University, United States of America; Ramakrishnan Mahadevan, Sriram Ravilla, Aurolab, India; Department of Biochemistry, Universidad Autonoma de Madrid, Medical School, Spain; Sanil Joseph, Thulasiraj D. Ravilla, Aravind Eye Care System, India
	eHealth
	Session Chair: Dr. Abdelbaset Khalaf, Tshwane University of Technology, South Africa
Chair's key points	It was noted that eHealth space is growing and it has the potential to address gaps and shortages of skills in particular in LMIC. Data Mining and the Medical Internet of Things was seen as a promising field and a concern was raised on data security. The use of Artificial Intelligence has been used occasionally and more attention should be given to its application in the development of expert systems that support health workers in LMIC in CDSS.

A10	Medical internet of things and embedded intelligence in healthcare
	Dr. Abdelbaset Khalaf, Tshwane University of Technology, South Africa
R68	Development of innovative tools for improving rural health care and safety
	Dr. Mannan Mridha, The Royal Institute of Technology, Sweden; Hashem. Md. Abul, Department of Soil Science, Bangladesh Agricultural University, Mymensingh, Bangladesh
A248	Conquering the leprosy last mile: the role of mobile-phones!
	Prof. Phillip Olla, Audacia Bioscience, Canada
R655	Non-invasive and minimally invasive medical devices
	Prof. Ratko Magjarević, IFMBE / University of Zagreb, Croatia
	Health service delivery: Oxygen supply systems (round-table)
	Session Chair: Dr. Dino Rech, Bill and Melinda Gates Foundation, United States of America
	Availability and use in small hospitals
	Dr. Wilson Were, WHO, Switzerland
A194	Methods for strengthening the market for safe oxygen delivery
	Ms. Lisa Smith, PATH, United States of America
R140	Medical device ownership models and maintenance contracting approaches
	Ms. Lisa Smith, Michael Ruffo, PATH, United States of America
R574	Quantifying gaps in access using medical device census information
	Mr. Michael Ruffo, Lisa Smith, PATH, United States of America; Prabhat, Anjaney, National Health System Resource Center, India
A195	Multi-country suitability assessment for available pulse oximeters
	Mr. Michael Ruffo, Ben Creelman, Gene Saxon, Lisa Smith, PATH, United States of America
R307	Strengthening policy advocacy for medical devices
	Ms. Jaclyn Delarosa, PATH, United States of America
R595	Oxygen system technologies
	Mr. Kristoffer Gandrup-Marino, UNICEF, Denmark
	Personal Protective Equipment (PPE) for Ebola [Special Session]
	Session Chair: Dr. Nahoko Shindo, WHO, Switzerland Session Co-Chair: Dr. May Chu, Colorado School of Public Health, United States
Chair's key points	1. The Special Session was chaired by Dr. Nahoko SHINDO. The session brought together experts who serve as members of the WHO Advisory Committees for Innovative Personal Protective Equipment (PPE) who have been charged in collecting, reviewing and assessing evidence for the protective effects of PPE for healthcare workers who were on the frontline in West Africa during the 2014 Ebola epidemic. Many challenges were associated with the types of PPE used, they were hot and uncomfortable and limited the workers from delivery of good clinical care to Ebola patients. A high number of health workers were infected with Ebola due to inconsistent PPE, practices and physical constraints.

	2. We had an audience interested in the reports from the Advisory Committees and learned of the problems and potential solutions. A key goal of this is to produce a se of Preferred Product Characteristics (PPC) as part of the WHO compendium of product profiles to publish the document for designers, engineers and industry to use as guide to create a PPE of the future that will be more comfortable and safe for healthcare workers in tropical climates
	Laboratory Evidence and Research
	Prof. Daniel Bausch, UK Public Health Rapid Support Team, United Kingdom
	End Users Perspectives
	Dr. Andrew Hall, Mosoka Fallah, United Kingdom
	Occupational Health and Infection Protection Control
	Dr. Trish Perl, University of Texas Southwestern Medical Center, United States of America
	Technical Specifications and Logistics and Procurement
	Dr. Fatma Selcen Kilinc-Balci, John McGhie, International Procurement Agency, Netherlands
	Preparing the preferred product characteristics (PPC) for innovative PPE
	Dr. May Chu, Colorado School of Public Health, United States of America; Adriana Velazquez, WHO, Switzerland
	Innovation of medical devices Session Chair: Dr. Prashant Jha, All India Institute of Medical Sciences, India Session Co-Chair: Prof. Kathleen Sienko, University of Michigan, United States of America
Chair's key point	· Several systematic efforts have produced compendia and inventories of medical devices and digital health tools · Preferred product characteristics and technology product profiles are increasingly available to guide product innovation process · Funding mechanisms exist to support early-stage innovations · Market shaping is important for supporting scaling of innovations · There is a need for non-financial support to navigate regulatory and commercialization processes
R591	How UNICEF supply has driven innovation within medical devices
	Mr. Kristoffer Gandrup-Marino, UNICEF, Denmark
R562	Small team medical device innovation for low-resource settings
	Dr. Ryan Lewis, Megadyne a Johnson & Johnson Family of Companies, United States of America
R430	Designing solutions to global health challenges: the Johns Hopkins CBID model
	Prof. Youseph Yazdi, Acharya Soumya, Johns Hopkins University, United States of America
R625	Design for real-world device evaluation
	Prof. David Matchar, Bibhas Chakraborty, Duke-NUS Medical School, Singapore
R106	Transfer of medical devices manufacturing technology
	Dr. Luca Passaggio, LP Medical Consulting Sagl, Switzerland

	Regulation of medical devices Session Chair: Dr. Maura Linda Sitanggang, Ministry of Health, Indonesia Session Co-Chair: Ms. Josephina Hansen, WHO, Switzerland
Participants' opinions	Feedback on session Unifying efforts against counterfitting and forging documents WHO: Regulators combating counterfeited Medical Devices What: Register at Medical Device Watch Website Where: https://eportals.sfda.gov.sa
R577	Global medical device regulatory harmonization
	Mr. Eugene Saxon, PATH, United States of America
A78	Voluntary certification for medical devices
	Mr. Mohammad Ameel, National Health Systems Resource Centre, India
R231	Unifying efforts against counterfitting and forging documents
	Dr. Nazeeh Alothmany, Saudi Food and Drugs Authority, Saudi Arabia
	Human factors engineering Session Chair: Dr. John Langell, University of Utah, United States of America
A234	Teaching appropriate medical device design to engineers
	Prof. Walter Karlen, ETH Zürich, Switzerland
R343	Applying human centered design for medical devices
	Ms. Jennifer Fluder, Marissa Leffler, Avery Waite, USAID, United States of America
R496	Human-centered design of medical devices for global users
	Prof. Beth Kolko, University of Washington/Shift Labs, United States of America
R647	Student-based maternal needs assessment for Sub-Saharan Africa
	Prof. Kathleen Sienko, Timothy Johnson, Ibrahim Mohedas, Maria Young, University of Michigan, United States of America; Elsie Effah Kaufmann, University of Ghana, Ghana; Samuel Obed, Korle Bu Teaching Hospital, Ghana; Kwabena Danso, Thomas Konney, Tawiah Odoi, Henry Opare-Addo, Cornelius Turpin, Komfo Anokye Teaching Hospital, Ghana; Zerihun Abebe, St. Paul's Hospital Millennium Medical College, Ethiopia
	Human resources and medical devices Session Chair: Dr. James Goh, IFMBE, Singapore Session Co-Chair: Mr. Andrew Jones, THET, United Kingdom
R49	Networking from Colombian clinical engineers
	Ms. Andrea Rocio Garcia Ibarra, Biomedical engineer-MoH consultant, Colombia
A155	Biomedical and clinical engineering development in Bangladesh
	Dr. Md Ashrafuzzaman, Military Institute of Science and technology, Bangladesh
R172	Roles of CE in medical device development
	Mr. Hiroki Igeta, Japan Association for Clinical Engineers / Aso Iizuka Hospital, Japan
R724	Addressing challenges in educating biomedical engineers to meet the global needs

	Prof. Shankar Muthukrishnan, Wentworth Institute of Technology, United States
	Health service delivery: Oxygen supply systems Session Chair: Mr. Ismael Cordero, PATH, United States of America Session Co-Chair: Dr. Lisa Stroux, Independent, United Kingdom
Chair's key points	Oxygen is an essential medicine that is finally getting the attention it deserves mainly due to recent efforts in combating childhood pneumonia, but the truth is that oxygen is essential for all aspects of healthcare including anesthesia, intensive care, emergency care, etc. In many low income countries oxygen is very expensive and difficult to obtain so it is very encouraging to see several organizations and companies exploring low cost creative solutions for the local production, storage and delivery of oxygen. WHO and its partners should continue raising awareness and providing guidance on this issue.
R319	Automating the diagnosis of childhood pneumonia
	Ms. Elina Naydenova, University of Oxford, United Kingdom
A42	Triaging infection and pneumonia among <5 children
	Dr. Mohammad Shah, Save the Children US, United States of America; Walter Karlen, ETH Zürich, Switzerland
R523	Validation study of an electricity-free oxygen concentrator
	Prof. Roger Rassool, David Peake, Jim Black, FREO2 Foundation, Australia; Bryn Sobott, The University of Melbourne, Australia
R481	An oxygen storage system
	Dr. James Black, Roger Rassool, Bryn Sobott, David Peake, FREO2 Foundation, Australia; Sheila Bagayana Mutetire, Mbarara Regional Referral Hospital, Uganda; Peter Moschovis, Massachusetts General Hospital/Harvard Medical School, United States of America
R510	Transitioning from improvised to safer BCPAP therapy
	Mr. Michael Eisenstein, Mr. Eugene Saxon, PATH, United States of America
	Management of medical devices Session Chair: Mr. Paolo Lago, IRCCS San Matteo Hospital Foundation, Italy
R295	Value based procurement (panel)
	Mr. Joseph Gatewood, Global Medical Technology Alliance, Switzerland
R589	Procurement of complex medical equipment and the considerations for product selection, installation, training, after sales service and maintenance
	Mr. Paul Labarre, UNICEF Supply Division, Denmark
R385	Developing compendium of generic specification for public health procurement
	Dr. Shashi Sinha, National Health System Resource Centre, India; Ameel Mohammad , Ajai Basil, Anjney Shahi, P.V Vigneshwaran, Consultants, NHSRC, Ministry of Health & Family Welfare, India
R39	The status of medical equipment in Sub-Sahara Africa
	Ms. Anna Worm, THET, Benin; Theogene Namahungu, Minister of Health, Rwanda; Harold Chimphepo, Minister of Health, Malawi; Charles P. Soroheye, DIEM, Benin

	Assessment of medical devices Session Chair: Prof. Panagiotis Kanavos, London School of Economics, United Kingdom Session Co-Chair: Dr. Adham Ismail Abdel Moneim, EMRO, WHO
R194	ISPOR international initiatives on the assessment of the value of medical technologies (Round table)
	Oyvind Melien, Norwegian Directorate of Health, Norway; Mirella Marlow, The National Institute for Health and Care Excellence (NICE), United Kingdom; Katharina Hawlik, Ludwig Boltzmann Institute for Health Technology Assessment (LBI-HTA), Austria; Yves Verboven, MedTech Europe, Belgium
R255	Justification of new types of practices involving medical exposure (Round table)
	Ms. Eva Godske Friberg, Norwegian Radiation Protection Authority, Norway; Ritva Bly, Radiation and Nuclear Safety Authority, Finland; Torsten Cederlund, Swedish Radiation Safety Authority, Sweden; Nellý Pétursdóttir, Icelandic Radiation Safety Authority, Iceland; Hanne Waltenburg, Danish Health Authority, Radiation Protection, Denmark
R556	How to involve citizens and patients in HTA
	Dr. Francesca Moccia, Cittadinanzattiva, Italy
	WHO - Medical Devices and Digital Tools for Reproductive Health and Research (Round-table) Session Chair: Dr. Garrett Mehl, WHO, Switzerland Session Co-Chair: Mr. Mario Festin, WHO, Switzerland
	Electronic MEC and Postpartum FP compendium
	Dr. Mary Lynn Gaffield, WHO, Switzerland
	RHR Task sharing guidelines interactive tool
	Dr. Joshua Vogel, WHO, Switzerland
	DMPA self injection and subcutaneous syringe
	Dr. Caron Kim, WHO, Switzerland
	Management of Victims of Sexual Assault
	Dr. Claudia Garcia Moreno and Avni Amin, WHO, Switzerland
	Dual HIV and syphilis testing
	Dr. Melanie Taylor, WHO, Switzerland
	Odon Device
	Dr. Mercedes Bonet Semenas, WHO, Switzerland

Parallel session - Friday 12 May 2017	
Innovation of medical devices Session Chair: Dr. Yadin David, IFMBE, United States of America Session Co-Chair: Dr. Caridad Borras, IUPESM, China	
R487	Effectiveness of aerospace technology and methodology of transfer of class 2 medical devices: safety and safeguard achievements
	Dr. Renato Giordano, EasyDial Inc., United States
A180-1	Silk-based scaffolds for tissue engineering applications
	Prof. James Cho Hong Goh, IFMBE, Singapore
R644	Enabling local production of medical devices
	Dr. Jitendar Sharma, Nitin Bharadwaj, Rohit Chhabra, Andhra Pradesh MedTech Zone, India
R50	A shared determination to drive sustainable healthcare solutions ... a technology perspective
	Mr. Vikram Damodaran, GE Healthcare India; Lee Sally, GE Healthcare, Singapore
R583	GANDHI: global affordable need driven health innovations
	Dr. Prashant Jha, All India Institute of Medical Sciences, India
Assessment of medical devices Session Chair: Dr. Sophie Werkö, INAHTA, Sweden Session Co-Chair: Mr. Alexandre Lemgruber, PAHO-WHO, United States of America	
A197	Incorporating patient perspectives in Canadian HTAs
	Mr. Gino De Angelis, Laura Weeks, CADTH Canada
	Health technology assessment of innovative medical devices
	Dr. Iñaki Gutierrez Ibarluzea, HTAi, Spain
R149	Role of HTA in open innovation (round table)
	Debjani Mueller, CMeRC, South Africa; Marco Marchetti, Andrea Urbani, Policlinico A. Gemelli, Catholic University of the "Sacred Heart", Italy; Valentino Megale, Open Biomedical Initiative; PG Kanavos, LSE, UK; Paolo Morgese, European Research for Deerfeld Institute
Priority medical devices by healthcare facility Session Chair: Prof. Mario Forja Secca, IFMBE, Mozambique Session Co-Chair: Ms. Susan Wilburn, Health Care Without Harm, Argentina	
R593-2	Oxygen generators type PSA: solution for the supply of oxygen in Senegal
	Awa Ndiaye Ep Diouf, Ministère de la Santé et de l'Action sociale, Senegal
A8-1	Equipment planning synchronised with hospital design and construction
	Mr. Claudio Meirovich, Spain

A171	Developing and advancing freeze-preventive vaccine carriers
	Mr. Steven Diesburg, PATH, United States of America
R659	Strategic operation processes to scale a high specialty hospital from a general hospital
	Ms. Claudia Cardenas Alanis, Escala Biomédica; Leila Dib Fajer, University Iberoamericana; Sandra Rocha Nava, National Institute of Cancerology, Mexico
	Medical Devices for Emergencies and Disasters Session Chair: Ms. Alejandra Velez, Independent, Mexico Session Co-Chair: Dr. Teri Reynolds, WHO, Switzerland
Chair's key point	Innovative technologies have a critical role in emergency preparedness (eg, innovative online trainings) and response (eg, innovations in PPE, water treatment, portable treatment spaces, mobile clinics and ambulances). Both incorporation of end-user input and implementation of performance standards (such as the recent WHO testing framework for water-treatment devices) is critical to developing effective devices. Iterative use and design cycles helps products evolve, and understanding manufacturer production path constraints is essential. Innovating during a crisis for the next crisis can ensure that products are safer, more effective, more appropriate for end users, and able to meet real-world demands.
Participants' opinion	Although content about emergency preparation for facilities and systems exists, there is a lack of access to training opportunities especially in rural locations and WHO is encouraged to adopt on-line eLearning programs (like those available at PAHO) to improve access to content in such remote locations.
A228-3	Improving emergency preparedness through hybrid interactive training
	Dr. David Yadin, IFMBE, United States; Rossana Rivas, UPCH/PUCP/CENGETS PUCP, Peru; Tobey Clark, University of Vermont, United States
A112	Accelerating innovation during a global health crisis
	Mr. Vikas Meka, Marissa Leffler, Jennifer Fluder, Avery Waite, USAID, United States of America
R645	Medecins Sans Frontieres medical equipement framework
	Ms. Gabriela Jimenez Moyao, Oscar Rodriguez, Tom Lauwaert, Jean Claude Tewa, Medecins sans frontieres (MSF), Belgium; Benoit Pierre Ligot, Paul Damien Chateau, MSF, France; Hugues Gaertner, MSF, Spain; Malcom Townsend, MSF, Switzerland; Lizette Van De Kamp, Sean King, MSF, Netherlands
R465	Choosing a product that works: household water treatment in emergencies
	Dr. Batsirai Majuru, WHO, Switzerland
R593	Proposed acquisition of 162 ambulances and 4 mobile units
	Ms. Awa Ndiaye Ep Diouf, Ministère de la Santé et de l'Action sociale Senegal; Amad Diouf, Division Etudes et Programmation, Direction des Infrastructures des Equipements et de la Maintenance, Senegal

	eHealth Session Chair: Prof. Marc Nyssen, IFMBE, Belgium
Participants' opinions	A session on citizen processed (checking for errors, using the record to self manage, contributing results and events to the record) health and medical records on the ionternet and on mobile phones would be useful.
A11-2	Telecom innovation in mobile health units
	Prof. Leonardo Melo, Diagnext, Brazil; Alessandro Melo, Universidade Federal Fluminense, Brazil
R168	Disabled patient correcting medical records online
	Dr. Richard Fitton, Tameside and Glossop Clinical Commissioning Group; Edna Davies UK Patient's mother, United Kingdom
A176	The use of expert systems and artificial intelligence to prevent disease around the world: an experience in Mexico
	Prof. Alvaro Rios, Rafael Bueno, Medical High Technologies, Mexico
R749	Medical informatics in low resource settings
	Prof. Marc Nyssen, IFMBE, Belgium
	Tools to support medical device management Session Chair: Mr. Paolo Lago, IRCCS San Matteo Hospital Foundation, Italy Session Co-Chair: Ms. Maria Eugenia Moreno, Starmedica Hospital, Mexico
Chair's key points	1. Need of a global web-based database for nomenclature and managment of Medical devices. 2. Gather all together CMMS from different countries to standarize and define key elements and indicatorS for guidance on appropiate managment of Medical devices.
R152	Appropriate CMMS systems – potential for health systems development
	Mr. Martin Raab, David Huser, Alexandre Vanobbhergen, Swiss Topical and Public Health Institute, Switzerland
A198-2	Web-based medical equipment management system
	Prof. Nikolaos Pallikarakis, Panayiotis Malataras, Institute of Biomedical Technology (INBIT), Aris Dermitzakis, University of Patras/Biomedical Technology Unit, Patras, Greece
R511	Proposal: WHO nomenclatures for medical devices
	Mr. Murilo Contó, PAHO / WHO; Leandro Safatle, ANVISA, Brazil; Vania Canuto, Ministry of Health, Brazil
	Injection Safety Symposium Session Chair: Dr. Edward Kelley, WHO, Switzerland Session Co-Chair: Prof. Benedetta Allegranzi, WHO, Switzerland
	Overview of the WHO Injection Safety Policy and Implementation Strategy
	Dr. Edward Kelley, Benedetta Allegranzi, WHO
	Working together with industry under POPS Injection Safety
	Ms. Lisa Hedman, WHO, Switzerland

	Achievements and challenges in Egypt
	Dr. Alaa Hashish, WHO, Egypt
	Sustaining progress achieved in injection safety
	Dr. Evelyn McKnight, HonoReform Foundation, United States
	Launch of POPS IS and closing remarks by Assistant Director General
	Dr. Marie Paule Kieny, WHO, Switzerland
	Innovation of medical devices for newborn and children care Session Chair: Dr. Mohammad Shah, Save the Children US, United States of America Session Co-Chair: Dr. Wilson Were, WHO, Switzerland
Chair's key point	Innovations with new, effective, and robust diagnostic tools must follow a holistic approach not leave the community component behind. Going beyond the end-users, it is critically important to connect the community, incorporate counseling and educating the community and engaging local MOH as well as governing bodies, and civil society are key elements in the path to reach the sustainable solution using the innovations.
R238	Groundbreaking devices to save lives at birth
	Mr. Vinesh Kapil, Karen Clune, U.S. Agency for International Development, United States of America
R648	Newborn essential solutions and technologies
	Dr. Megan Heenan, Queen Dube, Josephine Langton, Robert Miros, Jocelyn Brown, Megan Heenan, Elizabeth Molyneux, Maria Oden, Rebecca Richards-Kortum, Rice 360 Institute for Global Health, United States of America
R634	Phototherapy to reduce exchange transfusions
	Mr. Luciano Moccia, Firetree Asia Foundation, China; Arnolda Gaston,University of Sydney, Australia; Trevisanuto Daniele,Padua University Hospital, Italy
R310	Premature breathing system
	Prof. Anjelica Gonzalez, Yale University, United States of America
	Quality and safety of Medical Devices Session Chair: Prof. Shankar Mutukrishnan, Wentworth Institute of Technology, United States of America Session Co-Chair: Dr. Caridad Borras, IUPESM, China
R641	Non-ionizing radiation for diagnostic and cosmetic purposes
	Prof. Adele C. Green, ICNIRP, International Commission on Non-Ionizing Radiation Protection, Germany; Jacques S. Abramowicz, World Federation for Ultrasound in Medicine and Biology (WFUMB), United States of America; Emilie Van Deventer, World Health Organization (WHO), Switzerland
A190-2	The single-use reuse problem in low-income settings
	Dr. Ryan Lewis, Megadyne a Johnson & Johnson Family of Companies, United States of America

R215	Equipments for safer anaesthesia for everybody today
	Dr. Philippe Mavoungou, WFSA, United Kingdom
R513	Neonatal resuscitation equipment maintenance to prevent infection
	Dr. Manjari Quintanar Solares, Siobhan Brown, PATH, United States of America
A116	Is ultrasound safe for my baby?
	Prof. Jacques Abramowicz, WFUMB and University of Chicago, United States of America
	Radiation for diagnostic and treatment Session Chair: Prof. Magdalena Stoeva, IOMP, United Kingdom Session Co-Chair: Ms. Maria del Rosario Perez, WHO, Switzerland
Chair's key points	Radiation in medical imaging and radiotherapy are essential for achieving Universal Health Coverage, and all the resources invested timely in radiation technology and education & training will pay back later. We need to build bridges between stakeholders: international organizations, professional societies and governmental bodies, and promote partnerships with industry to ensure that THE RIGHT RADIATION TECHNOLOGY AND THE RIGHT SKILLS ARE AVAILABLE AT THE RIGHT PLACES.
R695	Innovations in multimodality imaging devices
	Prof. Habib Zaidi, Geneva University Hospital, Switzerland
R317	Diagnostic imaging: vital role in management of non- communicable diseases
	Dr. Miriam Mikhail, RAD-AID International, diagnostic radiologist, consultant, Switzerland; Nikita Consul, Columbia University chapter of RAD-AID International, United States of America; Elise Desperito, Melissa Culp, RAD-AID International, United States of America
A91	Improving universal health coverage : Kenya PPP example
	Ms. Gisela Abbam, Farid Fezoua, GE Healthcare Africa, Ministry of Health, Kenya
R453	Status of radiological equipment used in Nepal
	Dr. Kanchan P. Adhikari, National Academy of Medical Sciences, Bir Hospital, Nepal
A110	Ensuring Radiological Security in the Context of Cancer Treatment
	Ms. Kristina Hatcher, U.S. Department of Energy, United States
	IAEA perspective on radiotherapy
	Mr. Rajiv Prasad, IAEA, Austria
	Innovation for in vitro diagnostics Session Chair: Prof. Francis Moussy, WHO, Switzerland Session Co-Chair: Dr. Gaby Vercauteren, WHO, Switzerland
Chair's key point	1. Multiplex assays are an important tool to effectively address symptoms that require a differential diagnosis. 2. Innovative diagnostics how to implement them strategically at each level of the health care system. 3. More research is required on cost effectiveness of new diagnostics, to guide their implementation at country level.

A173	A new point-of-care diagnostic test for sickle cell disease
	Ms. Mutsumi Metzler, Patricia Coffey, Mercy Mvundura, Jeanette Lim, PATH, United States of America
R701	Key considerations in implementing point-of-care in Kenya
	Ms. Nancy Bowen, Ministry of Health, Kanya; Wafula, Rose, Nascop, Kenya
R305	Integrated human diagnostics and vector control towards OneHealth
	Dr. Konstantinos Mitsakakis, University of Freiburg & Hahn-Schickard, Germany
	Prequalification for in vitro diagnostics
	Ms. Deirdre Healy, WHO, Switzerland
Affordability, Appropriateness, Acceptability, Availability and Accessibility of Medical Devices	
	Session Chair: Ms. Jacqueline Cahill, the Canadian Continence Foundation, Canada Session Co-Chair: Dr. Mario Medvedec, University Hospital Centre Zagreb, Croatia
Chair's key point	During the Oral Parallel Session 4 'Affordability, Appropriateness, Acceptability, Availability and Accessibility of Medical Devices' which had been held on Friday, May 12, 2017, 13:30 – 15:00 only two out of five authors/presenters showed up and presented their work (R463 Appropriate digital X-ray system with eHealth services, Mr. Romain Sahli, Ecole Polytechnique Fédérale de Lausanne, Switzerland; A99-2 Skill development for growth in emerging markets, Ms. Gisela Abbam, GE Healthcare, Marut Setia, Head of Education and Professional Services Lists). However, the 5 A's session succeeded to addressed two important sides of the problem: 5 A's of medical devices and 5 A's of education/training of medical device users. Presented examples were illustrated by: 1) a spin-off company, PRISTEM SA, incorporated in December 2015 for the industrialization and the deployment stages of the GlobalDiagnostiX project to develop a robust and low-cost digital x-ray system, raising strong interest from investors, and 2) GE Healthcare in the process of establishing and expanding India's programs from 2014 onwards (new skill development & upskilling) to other countries in South Asia, Africa and ASEAN at disruptive costs to enable delivery of superior healthcare services across the region, all in cooperation with local/national/regional authorities.
R46	Appropriate digital X-ray system with eHealth services
	Mr. Romain Sahli, Ecole Polytechnique Fédérale de Lausanne, Switzerland
A99-2	Skill development for growth in emerging markets
	Ms. Gisela Abbam, GE Healthcare; Marut Setia, Head of Education and Professional Services
List of medical devices, nomenclature & pricing (round-table)	
	Session Chair: Prof. Renato Garcia Ojeda, IEB-UFSC, Brazil Session Co-Chair: Prof. Nicolas Pallikarakis, IFMBE, Greece
	National List of medical devices by country, global nomenclature for medical devices and medical devices pricing
	Mr. Alexandre Lemgruber, WHO, AMRO, United States of America; Adham Ismail Abdel Moneim, WHO EMRO, Egypt; Adriana Velazquez, WHO, Switzerland; Murillo Conto, PAHO, United States of America

Parallel Sessions	
Innovation of medical devices	
A180.2	Engineering innovations for clinical applications
	Prof. James Cho Hong Goh, Chwee-Teck Lim, International Federation of Medical and Biological Engineering, Singapore With the advances in technology, multi-scale bioengineering solutions can be honed and developed to aid in the understanding of cellular and molecular processes in pathology, and in the integration of computational modeling and in-vivo experimentations to address issues in tissue remodeling, injury risk prediction and prosthetics design. Research at the micro level includes injury biomechanics. The focus is attuned towards tissue remodeling and instability analysis, particularly in tumour. Research at the nano level involves the use of highly sophisticated instrumentation, such as the laser 'tweezers' used to stretch red blood cells to study the stiffness of Malaria-infected cells. While microfluidic channels were developed to investigate the clogging mechanism of these 'stiff and sticky' infected cells flowing through blood vessels and capillaries. Furthermore, atomic force microscopy was used to determine how the cellular and molecular structures within the cells change with the advancing stages of infection. Clearly, this research will allow us to understand and develop ways to interfere with these changes and perhaps reduce the disease's virulence. This new knowledge will bring us closer to our goal of developing potential treatments and applications for a wide range of clinical problems.
R270	Medical device reforms & the landscape in India
	Dr. Madhur Gupta, World Health Organization Country Office, India The Government of India (GoI) has taken various steps to ensure that medical device sector gets its due recognition. Make in India and other policy changes have created the right environment for India to take this leap. Some of the most significant 'medical device' highlights were revisions in the regulations and delinking of medical devices from schedule M III of pharmaceuticals, creation of medical device parks, removal of duty anomalies in the sector, launch of Materiovigilance programme of India, designation of WHO Collaborating centre for priority medical devices, approval of 100% FDI in medical devices, notification of medical devices rules 2017, among others. There is also the link to Universal Health Coverage, the underlying theme being access to affordable and quality medical devices. A joint report on the Medical Device Manufacturing in India- A Sunrise Sector, produced by WHO India Country Office, was recently released. On the lines of being a pharmacy of the world, India is preparing to emerge as a global player in manufacturing accessible, affordable and quality medical devices and be known as 'medical device hub of the world'. The presenter would detail the integration of the policy reforms and regulatory landscape of medical devices in India.
A63	Collaborative open design for safer medical devices
	Ms. Alice Ravizza, Arti Ahluwalia, Carmelo De Maria, Licia Di Pietro, Jacopo Ferretti, Andrés Díaz Lantada , Mannan Mridha, Philippa Ngaju Makobore, June Madete, Albo Aabloo, Arni Leibovits UBORA ("excellence" in Swahili), a project funded by European Union, brings together European and African Universities and their associated technological hubs to create an e-Infrastructure for the co-design of open source biomedical devices to address current and future global healthcare challenges with particular attention to local needs and constraints. The e-Infrastructure will be aimed at stimulating innovation in the field of BME through knowledge distribution, promoting harmonization of biomedical device requirements with subsequent impacts on healthcare services and ultimately on patient safety. This e-infrastructure enables a peer-to-peer evaluation before submitting the documentation to the regulatory authorities, if a company wants to transform the project into a product: this double check of the design might then lead to safer medical devices. Quality and safety guidelines for biomedical device, under the guidance of ISO standards and European Medical Device Directive, are at the foundation of the project, which will be spread to other institutions through partnerships and linkages embedded in the e-infrastructure 's

architecture. UBORA will help also the sharing of open data on devices' statistics (performance, field tests, quality control), promoting the research on the highest priority medical devices backed with research on current disease burdens.

R490 Designing high quality global health technologies

Dr. John Langell, Bernhard Fassl, Tyson Schwab, Dean Wallace, Roger Altizer, Tomasz Petelenz, Walter Prendiville, University of Utah, United States of America

The design of global medical technology solutions requires a thoughtful approach to device design and development. All to often globally focused innovators develop low-cost and lower quality solutions to address emerging markets healthcare delivery needs when what is needed is a single high quality solution with a regionally tailored and sustainable business model. Accurately capturing marketing requirements, user needs, and design specifications for medical device innovation is multifactorial and challenging. Through intensive on-site ethnographic research, environmental resource assessment and design validation, innovators may develop high quality solutions to better solve unmet medical needs and provide a product with tremendous clinical and market potential.

We have developed a successful and scalable approach to global medical device design using our Design-Box methodology. Design-Box provides an effective and standardized process for conducting global medical device design that meets end-user requirements and provides high-quality solutions that meet regional healthcare delivery constraints. Using our Design-Box approach we have created new global device solutions for laparoscopic surgery, cervical cancer prevention, non-invasive anemia monitoring, vital sign monitoring and the treatment of postpartum hemorrhage.

The Design-Box workshop will provide attendees the knowledge and tools necessary to develop well designed and high quality global medical technology solutions. Attendees will gain a strong understanding of environmental resource analysis, ethnographic investigation of clinical needs, user-centered design processes and design validation tools.

A151 Designing global health technology for commercial scale

Ms. Jocelyn Brown, Robert Miros, 3rd Stone Design/Hadleigh Health Technologies, United States of America; Adam Lewis, Gradian Health Systems, United States of America

While global health technologies are increasingly being designed and developed by multinational corporations, early-stage start-up companies, and engineering programs in university settings, there are few technologies that actually make it to commercial scale in emerging markets. Although emphasis on human-centered design in the medical device design process is key, accounting for regulatory, manufacturing, and commercialization strategies early in the design process is critical for successful medical device work.

We will present two case studies of global health technologies that have successfully been brought to market: an anesthesia machine and a low-cost neonatal respiratory device. These technologies have not only been designed with and for end users over a long-term, iterative process, but they have also been designed to meet international regulatory approvals, to be manufactured at both minimal cost and in accordance with ISO standards, and have been marketed and sold in emerging markets for several years. We aim to present lessons learned during this process and continuing challenges faced by technology developers who aim to commercialize medical devices in emerging markets.

R259 Temperature protocol that minimises early neonatal deaths

Prof. Hippolite Amadi, Imo State University Nigeria & Imperial College London, United Kingdom; Olateju Eyinade K., Adesina Temilade C., University of Abuja Teaching Hospital, Nigeria

Introduction: Nigeria has about the highest record of neonatal mortality (NNMR) globally. Half of deaths before age of five are neonatal. NNMR increases sharply with decreasing birthweight and postnatal age. Over 90% of extremely low birthweight (LBW) neonates in most Nigerian newborn centres would not survive, hence contributing to Nigeria's 79% early deaths as documented by

the W.H.O. We consistently observed across Nigerian centres, excessive long periods of time before neonate attained thermal stability within acceptable physiological range of 36.5 – 37.4 Celsius. We considered this extreme inadequacy that could partly be responsible for early mortalities (within first week of life), hence sought to devise a protocol to reverse this.

Methods: We developed the initial setpoint algorithm (ISA) temperature protocol and applied this to extremely-LBW (600g – 1200g) in a cohort comparative study involving 29 TEST cases over 13 months, and 105 CONTROL (without ISA) cases.

Results: ISA ensured Test cases attained normotherm within average 0.47hrs post-presenting while this took 12.4hrs in Control. NNMR in Control was 63% of which 71% died early. For ISA group, NNMR was 7% without any early death.

Conclusions: ISA protocol coincidently eliminated early mortality in this study, hence could be the game-changer in high NNMR countries.

R591 How UNICEF supply has driven innovation within medical devices

Mr. Kristoffer Gandrup-Marino, UNICEF, Denmark

In 2016, UNICEF procured approximately $3.6 billion worth of supplies and services for children in more than 190 countries making it the largest UN procurement agency. Some 86 per cent of UNICEF's procurement is done in partnership with other UN organizations, NGOs, and governments, which is critical for leveraging broad demand for essential products for children.

The UNICEF Supply Division Innovation Unit in collaboration with relevant procurement centers drives development of fit-for-purpose and value-for-money supplies to address unmet product needs. This session will illustrate the product innovation process in stimulating R&D for medical devices and diagnostics using push and pull mechanisms through case studies such as the Zika Virus diagnostics and the Acute Respiratory Infection Diagnostic Aid (ARIDA) developments. Push mechanisms as well as pull mechanisms such as working with donors to accumulate funding for scale through modalities such as Advance Procurement Commitments, will be discussed. The intent is to enable a dialogue from the audience any of the following topics:

1. R&D of fit-for-purpose products
2. The future of medical devices, short and long-term solutions?
3. Market assurance mechanisms, driving force or roadblock?
4. Regulatory Landscape and Policy
5. Sustainable procurement and innovation in contracting

R562 Small team medical device innovation for low-resource settings

Dr. Ryan Lewis, Megadyne a Johnson & Johnson Family of Companies, United States of America

Creating medical devices for low-resource settings requires a different approach and mindset than found in traditional R&D groups. Freedom to explore and think outside the mainstream product development pathways is needed to address some of the global surgical healthcare needs. Small teams can be agile and produce iterative solutions more rapidly than larger teams. Taught from the perspective of a medical device industry executive and expert.

R430 Designing solutions to global health challenges: the Johns Hopkins CBID model

Prof. Youseph Yazdi, Acharya Soumya, Johns Hopkins University, United States of America

Following good design principles and methods is increasingly critical to the success of efforts to create and develop new solutions to major global health challenges. While traditional discovery-based translational research has yielded many promising breakthroughs, good design processes are needed to ensure that great ideas are translated into solutions that have a high potential to work on the ground and deliver real-world impact.

Such principles include: starting with the development of a deep understanding of the perspectives of a wide range of stakeholders affected; understanding the landscape of existing solutions and why they are lacking; exploring a wide range potential new and better solutions; selecting the most promising solutions and exploring them in depth thru repeated prototyping, evaluation, and refinement.

The Johns Hopkins Center for BioEngineering Innovation & Design (CBID) designs devices, apps, tools, training materials and related solutions to healthcare challenges of both advanced and lower-resourced healthcare systems worldwide. To do so, CBID implements a common design methodology for both, and one that incorporates best practices from academia and industry. The CBID method starts with tool that ensures 2 key principles are implemented: First, that all key stakeholders in and influencers of the success a solution are considered early on, and Second, that team grows their understanding of this wide range of factors gradually and iteratively, as they develop and grow their solution.

This presentation will describe the CBID process and method and outcomes from the first 6 years of our Global Health Innovation Program.

R625 Design for real-world device evaluation

Prof. David Matchar, Bibhas Chakraborty, Duke-NUS Medical School, Singapore

There has been a surge in the availability of devices to extend health services to the community or home settings (i.e., telehealth, TH), particularly for Low and middle income countries. Motivating this availability is an expectation that TH will allow people to receive services that are better -- otherwise unavailable (e.g., regular blood pressure monitoring) or are more effective than otherwise available (e.g., portable sonogram) – or cheaper (e.g., smart pill dispensers).

Two challenges to acceptance of TH are: (1) establishing usability in the context of site (e.g., shanty housing) and in the context of need (the medical and social factors in which the device offers a potential for a health benefit or cost saving relative to alternatives); and (2) identifying which of several TH interventions may apply to which context.

In this workshop, we address both challenges. We illustrate how to identify the contextual factors that can be used to define "needs segments". Further, we introduce the cutting-edge sequential multiple-assignment randomized trial ("SMART") research design which permits a practical yet rigorous approach to evaluate portfolios of TH in ways that allow us to identify which mix of services best satisfy individuals in each needs segment – to find the "sweet spot."

R106 Transfer of medical devices manufacturing technology

Dr. Luca Passaggio, LP Medical Consulting Sagl, Switzerland

Technology is a key element in industrial development, it also has an essential role in the economic and social development of a country. The general definition of technology transfer is the capacity of one country or organization to adopt and replicate the technology, knowledge and skills from another, with the aim to improve, modify and expand further.

The term technology transfer is related to the methods used in transferring the technology from one country or organization to another. It is not only related to establishing new industries, but especially to develop human resources, services and the standard of living, while improving existing science and technology to achieve self-reliance.

The first step of a technology transfer is the choice of the best possible channel: this depends upon many factors, the main issues being the availability of local financial and human resources, the presence of local raw materials and services and the choice of what degree of control is acceptable for the recipient country or organization. There are three main accepted channels of transfer of manufacturing technology: joint-venture agreements, licensing agreements and turn-key plants. Another channel is to establish foreign subsidiaries, but this is usually controlled by the donor and not by the recipient country or organization.

The transfer of manufacturing technology within the domain of medical devices involves other concepts and algorithms, as the initial export of the device to the recipient country; a feasibility study needs to be carried out, involving a market study, the analysis of the economic environment, capital outlays, production costs, financial analysis and a strategic marketing plan.

There is no successful industrial investment without the right strategic marketing plan

R487 Effectiveness of aerospace technology and methodology of transfer of class 2 medical devices: safety and safeguard achievements

Dr. Renato Giordano, EasyDial Inc., United States of America

Increased presence of kidney Chronical disease with increase degradation of patient life due to lack of modern technology into the actual equipment, exhaustive use of precious media like water not transportability of the existing equipment, necessity of huge infrastructure network with the existing technologies and or equipment First and unique application for Hemodialysis, with state of the art miniaturized aerospace used state of the art technology enhancing performance safety redundancy miniaturization, low weight, low power consumption, enhanced efficiency with optimization and reduction of treatment time and cost.

Conclusion: Worldwide enhancement of Hemodialysis treatments with patients safety and quality of life in mind.

A180-1 Silk-based scaffolds for tissue engineering applications

Prof. James Cho Hong Goh, IFMBE, Singapore

Innovative approaches to different fields within biomedical engineering and life sciences have largely been biologically inspired. This is especially so in the field of tissue engineering and regenerative medicine, whereby researchers have looked upon nature for inspiration in strategies and design parameters for scaffold materials and architectures for specific tissues. Biopolymers have been largely studied and silk fibroin has shown to be an excellent example due to its unique molecular and supra-molecular structure, its customizable ligands-based bioactivity, its ability to self-assemble and its ability to be manipulated into various forms and structures. There exist an array of techniques to process silk fibroin into various forms with tailored mechanical and biological properties, to provide the necessary cellular, architectural and chemical cues for the specific tissue types. The material can be processed into powders, films, gels, sponges, foams, yarns, knitted and woven mats for various interesting tissue engineering applications. Numerous researches have looked into applying the material in regeneration of tissues such as bone, cartilage, tendon/ligament, intervertebral discs, skin and cardiovascular tissues. However, limitations persist in its widespread use due to source-based variations and lack in standardization of processing protocols.

R644 Enabling local production of medical devices

Dr. Jitendar Sharma, Nitin Bharadwaj, Rohit Chhabra, Andhra Pradesh MedTech Zone, India

Lack of domestic manufacturing of medical devices in India has resulted into significant import dependency (of the total market size of USD3.9 billion in 2015, 75% accounted for imports) and high cost of medical products and services. To address this, Andhra Pradesh MedTech Zone Ltd. (AMTZ), comprising of 200-250 manufacturing units and a set of common manufacturing and scientific facilities for manufacturing of electro-medical, radiological, and biomaterial medical devices, is being established. AMTZ will create state of the art civil and electrical infrastructure for industry to walk-in and establish their units in shortest possible time. Following the principle of public-private partnership (PPP), the manufacturing units will be leased out at rents as low as 10 US cents per square feet per month and common facilities will be created on user fee model. AMTZ will also include offices for export promotion body, regulators, and health technology and policy institute, aimed at assisting manufacturers in promoting their products. These efforts will foster domestic production of medical devices and bring down their cost by about 40-50%. AMTZ, India's first dedicated medical device park, is being developed in the eastern port city of Visakhapatnam under the aegis of Government of Andhra Pradesh

R50	A shared determination to drive sustainable healthcare solutions ... a technology perspective

Mr. Vikram Damodaran, GE Healthcare, India; Lee Sally, GE Healthcare, Singapore

Over 5.8 billion people across the world represent the underserved population with respect to key clinical care areas such as cardiology, oncology, surgery and maternal and child health. The presentation makes a case for understanding primary needs, translating needs to barriers to adoption of potential solutions and finally building holistic offerings that can scale sustainably should be an integrated approach rather than a point intervention. Using maternal and child health as an example and the implementation of a holistic offering in Ethiopia the presentation will make the case in support of driving better outcomes through an integrated approach. The presentation also makes the case of an "ecosystem" approach to delivering an integrated solution as opposed to a "box" based implementation. Finally, the presentation will aim to present the future of healthcare systems transformation with DIGITAL interventions and how the role that the DIGITAL FABRIC will play for better outcomes for a given investment.

R583	GANDHI: global affordable need driven health innovations

Dr. Prashant Jha, All India Institute of Medical Sciences, India

Inventions from the current MedTech leaders from the west are expensive misfits for 80% of the global citizens. Is there a way to solve the problems of the developing and underdeveloped world? Can clever solutions for developing world problems help the developed world save healthcare costs? Guided by the philosophy of GANDHI (Global Affordable Need Driven Health Innovations), the Biodesign School is connecting resources to create frugal solutions for the global healthcare challenges. The innovation Fellowship from Government of India is creating MedTech leaders who are creating low cost, high impact medical devices with a global appeal.

Regulation of medical devices

R609	Actions of medical devices post-market surveillance

Prof. Kangping Lin, International Federation of Medical and Biological Engineering, Singapore; Yu-Wen Huang, Pei-Weng Tu, Food and Drug Administration, Ministry of Health and Welfare, Chinese Taipei

Regulatory authorities worldwide are committed to fostering the post-market surveillance of medical device safety in order to complement their premarket review. As more attention has been placed on post-market issues of medical devices over the years, reactive and proactive mechanisms including adverse event reporting, periodic safety reporting, vigilance monitoring, re-evaluation, sampling/testing, and for-cause inspection, have gradually emerged to become the key elements in post-market surveillance. It has been observed that awareness of adverse event reporting system by medical device users and healthcare providers can be promoted to improve the collection of post-market data which are meaningful and useful for evaluation. To this end, regulatory agencies strive to encourage and increase the reporting of medical device problems from all stakeholders, with the intent to formulate timely post-market safety measures for the protection of public health. The information from a functional post-market surveillance system is therefore crucial, and may provide potential cues for improvement in the premarket review of medical devices. While regulators utilize the Safety Alert Dissemination System (SADS) of Asian Harmonization Working Party (AHWP) to communicate surveillance or vigilance information, convergent efforts are currently underway in the Asia-Pacific region to further enhance the safety, performance, and quality of medical devices.

R611	A new academic program for MD regulatory affairs professionals

Prof. Folker Spitzenberger, Heike Wachenhausen, University of Applied Sciences Luebeck, Germany

As emphasized by WHA resolution WHA 67.20, effective regulatory systems for medical products are an essential component of health system strengthening.

Considering the variety and application types of medical devices, the regulatory framework for these products is of decisive relevance for the contribution to health standards. However,

stakeholders of the medical device sector are challenged by the increasing complexities of medical product development and supply chains accompanied by increasing regulatory requirements.

Professional competencies in the medical device regulatory field are therefore needed and should be developed as integral part of the international health workforce.

The University of Applied Sciences Luebeck has a long tradition in the field of Biomedical Engineering and related sciences. Among others, an international Master study program for Biomedical Engineeering was introduced in cooperation with the University of Luebeck that attracts students from all-over the world. However, a professional education in the field of medical device regulatory affairs was lacking so far.

To close this gap, the Master study program „Regulatory affairs for medical devices" was recently developed with the support of the German Federal Ministry of Education and Research and as part of the joint project of regional universities – LINAVO.

With the expected start of the 2-year Master study program in October 2017, students will be enabled to acquire the degree „Master of Science – Regulatory Affairs" and will be qualified as academic medical device regulatory affairs professionals.

R619 Medical device competency regulatory program in Malaysia

Ms. Sasikala Devi Thangavelu, Medical Device Authority, Malaysia

Unfamiliarity with a certain technology or operating procedure, and the use of a device for clinical indications outside its scope can cause medical device failure even in the absence of inherent design or manufacturing defects. In addition, the use of devices not in accordance with the instructions, and without proper control or precautions for minimizing associated risks, can be detrimental. Certain categories of medical devices require proper installation (including testing and commissioning) prior to usage and scheduled maintenance or calibration to ensure the devices continue to function properly. The lack of, or inappropriate testing, maintenance and calibration may jeopardize safety and performance of such devices. As such there is a need to have competent personnel to ensure the safe operation and performance of medical device.

This paper outlines the development of competency regulatory program for the user and technical personnel based MS2058 standard and the Medical Device Act 2012. The aim of this program is to ensure only competent personnel with appropriate qualification and competency shall use, test, commission, maintain and dispose medical device. The implementation of this regulatory program shall ensure the safety and performance of the medical device throughout the life span of the device.

R539 Validation and verification of IVDs in Kenya

Ms. Bintiomar Tsala, Kenya Medical Laboratory Technicians and Technologists Board, Kenya

Background: The Kenya Medical Laboratory Technicians and Technologist Board(KMLTTB) is mandated by law to regulate all IVDs intended for use in Kenya as a measure to ensure quality of laboratory services. However, the path to regulatory approvals of IVDs has been marred with several challenges with the most critical one being lack of a standardized method to conduct validation, certification and registration of all products intended for laboratory use. As a result, most manufacturers approached relevant programs directly, a field evaluation would be conducted and based on the outcome, the program would deploy the device without involving KMLTTB. In view of this, only 3 IVDs were registered through the board by 2014. This report highlights on strides made by KMLTTB in an effort to accelerate approvals.

Methods: Review of regulatory policies and procedures to have an all-inclusive IVD validation and verification plan to be used by various equipment vendors.

Outcome: Remarked increase in number of IVDs from 3 in 2014 to 29 by December 2016 duly registered and certified by KMLTTB.

Conclusion: The new IVD regulation plan developed by KMLTTB is the surest way to accelerate equipment validation and enhance access to laboratory test services.

Collaborating Centre PAHO/WHO for the Regulation on Health Technology (Medical Devices). Impact in regional regulatory work.

Ms. Dulce María Martíney Pereira, State Center of Medicine and medical Devices, Cuba

In July 2014, the Pan American Health Organization / World Health Organization (PAHO/WHO) designated the Medical Devices Sub direction of the Center for State Control of Medicines, and Medical Devices (CECMED) as a Collaborating Center (CC) for Health Technology Regulation. The designation of this CC marked a new stage in the regulatory program for medical devices in Cuba that already had experience and prestige in the American Region. The work plan have been related to the terms of reference agreed with the PAHO. Impact results have been obtained regarding the mapping of opportunities and needs for capacity building on regulation of medical devices in the region; the first edition of regional virtual course on regulation of medical devices; the Program of Exchange of Reports of Adverse Events in the Americas (REDMA Program) as part of activities of mirror regional working group of NCAR; and the regional tool of evaluation of regulatory authorities with scope to medical devices. In these two years have been carried out activities closely related to the strategic projection of CECMED and the priorities PAHO/WHO, considering that regulatory functions of medical devices are aimed at strengthening the regulatory capacity, and the contribution to regulatory convergence both regional and global levels.

R577 Global medical device regulatory harmonization

Mr. Eugene Saxon, PATH, United States of America

A key challenge when seeking marketing authorization for medical devices in low- and middle-income countries is the uncertainty regarding regulatory requirements applicable to medical devices. Although a growing number of countries are implementing regulatory frameworks for medical devices, a significant number of countries in Africa and Asia still lack device regulation altogether, while others have regulations that can differ in their definitions, nomenclature, risk classifications, and conformity assessment procedures. Efforts are ongoing to facilitate regional regulatory harmonization and convergence, generally based on guidance documents first published by the Global Harmonization Task Force. To further facilitate this effort, the World Health Organization is in the final stages of drafting a global model regulatory framework anticipated for publication in 2017. PATH will present an overview of current harmonization efforts including those within the Association of South East Asian Nations and the East African Community. A comparison of medical device regulations in Ethiopia, India, Indonesia, and Kenya will be presented in order to highlight similarities and differences. Updates regarding anticipated changes to European medical device regulations will also be given, as well as implications of more open access to the European Database for Medical Devices.

A78 Voluntary certification for medical devices

Mr. Mohammad Ameel, National Health Systems Resource Centre, India

To fill the regulatory vacuum in quality certification space for medical devices in the country, the Association of Indian Medical Device Industry (AIMED) in collaboration with the Quality Council of India (QCI) and technical support from National Health Systems Resource Centre (NHSRC) has rolled out a voluntary quality certification scheme for medical devices. The Scheme is intended to enhance patient safety, and provide enhanced consumer protection along with much needed product credentials to manufacturers for instilling confidence among buyers. This move is also intended to significantly eliminate trading of sub-standard products or devices of doubtful origins, a widespread and injurious phenomenon in the Indian market.

R231 Unifying efforts against counterfitting and forging documents

Dr. Nazeeh Alothmany, Saudi Food and Drugs Authority, Saudi Arabia

The objective of Regulatory bodies is to ensure the safety and efficacy of medical devices entering the market. This is achieved by verifying proofs of product conformity with the regulation that is submitted by the manufactures or suppliers prior to putting the device in the market.

In 2012, SFDA began to enforce regulations on medical devices entering into the Saudi Market. All international manufacturers were required to appoint an authorized representative in Saudi who is responsible for submitting the technical documentation for SFDA to obtain market authorization for their devices before entering the Saudi market.

SFDA noticed that many of the submitted document were forged; some international entities pretend to be manufacturers of devices when in reality they are not. Furthermore, counterfeiting is also a challenge that we constantly face.

The presentation shows many such examples captured by SFDA to show how far some suppliers/manufacturers can go. The objective is to show the importance of having a strong infra-structure to tackle these challenges and the need for a harmonized and unified effort by the regulators to work together in ways that would enhance the overall regulatory framework.

	Assessment of medical devices
R468	INAHTA perspective of assessment of medical devices
	Dr. Sophie Wörko, INAHTA; Gino De Angelis, CADTH, Canada
R561	Assessment of medical devices in low-income settings
	Dr. Leandro Pecchia, IFMBE, United Kingdom; Nicolas Pallikarakis, University of Patras, Greece

Health Technology Assessment (HTA) on Medical Devices (MDs) remains an open challenge in particular for Low and Middle Income Countries (LMICs) and settings. Extensive literature investigated how economical constrains affect HTA in LMICs. Much less has been done in analyzing systematically how MDs safety and efficacy depend from environmental and operational conditions.

The majority of MDs are designed for higher income countries, where there are clear standards and harmonized regulations on minimum requirements for design and maintenance of medical-location plants (i.e., electric, air and water plants in surgical theatres, ambulatory etc.). These standards and regulations allow transferring MDs among hospitals/countries maintaining the same level of safety and efficacy. In many LMICs those minimum requirements are not homogenously guaranteed (and will not in the short term) and there is no evidence on how this effects patient safety, medical device efficacy and therefore the HTA of MDs.

This contribution aims to shares preliminary results and experience from an empirical study, aiming to contribute to ongoing discussion on this topic.

R315	Horizon scanning to ensure timely HTA
	Dr. Vigdis Lauvrak, The Norwegian Institute of Public Health; Ellen Nilsen, Norwegian Directorate of Health, Norway

A major objection to health technology assessment (HTA) is that it may delay the introduction of important technologies. To ensure a timely HTA process, Horizon scanning has since 2015 been part of a National system for Managed Introduction of New Health Technologies within the Specialist Health Service in Norway.

The output of the Horizon scanning process is short two page alerts that serve as proposals for national HTA. The HTAs are used to inform national decisions on whether to offer a technology in Norwegian public hospitals. Between January 2015 and December 2017 we produced 120 alerts, 41 of these were on non-pharmaceuticals, mostly devices.

As, in most cases devices are introduced to the European marked with limited clinical documentation, we find it challenging to predict the right time to perform an HTA for devices.

Whether an HTA should wait for a reasonable level of evidence to be available, or whether an (early) HTA may promote better clinical evidence is disputable. Either way, we consider that timeliness of HTA for devices may benefit from a more systematic international collaboration on horizon scanning.

Information on the national system: https://nyemetoder.no/english

A87 Using other's HTAs: adopt or adapt?

Dr. Katrine Bjørnebek Frønsdal, Lauvrak V, Skår Å, Giske L, Sæterdal I, Fure B, Norwegian Institute of Public Health, Norway

The very first step when conducting an HTA is to look for what others have already done, because "reusing" relevant, timely and high quality HTA information avoids work duplication and wasting resources. Indeed, in cases where others have performed an updated systematic literature search for studies relevant to our own research question, done a proper quality assessment, graded and summarized the evidence appropriately using validated tools, we can – and should– reuse the assessment. We are so-called "adopting" and/or "adapting" the HTA in question into our "local setting". So far, the Norwegian Institute of Public Health has fruitfully taken advantage of three EUnetHTA-produced HTAs for carrying out own assessments. Two of these were commissioned directly by Norwegian Health Authorities, and one by Norwegian clinicians. In most cases, HTA information from the European HTAs could be transferred directly including numericals and calculations. However, there were differences in reporting and formats, and in interpreting results. Hence, interpretations and sometimes conclusions had to be reformulated for some effectiveness outcomes, and especially for outcomes related to safety. Our experience with using these three HTAs have been positive, and has allowed to define key factors hampering and facilitating reuse of other's HTA assessments in general.

R468 Implementation considerations in a HTA of dialysis

Mr. Gino De Angelis, Eftyhia Helis, Janet Crain, Kristen Moulton, Laura Weeks, CADTH, Canada

BACKGROUND

In Canada, traditional hemodialysis (HD), offered in a clinical setting, remains the most frequently used dialysis option for patients with end stage kidney disease. Despite available evidence suggesting that non-traditional modalities such as peritoneal dialysis and home HD may achieve similar clinical outcomes for eligible patients, these options are less frequently used.

OBJECTIVE

To describe CADTH's process of incorporating implementation considerations for the uptake of non-traditional dialysis modalities in a recent HTA.

METHODS

The HTA methodology included a review of implementation considerations to determine barriers and facilitators that influence decision-making around the choice of dialysis modalities. An Environmental Scan, which comprised of two surveys and a literature review, gathered information from Canadian dialysis stakeholders on implementation processes, barriers, facilitators and funding availability for dialysis.

RESULTS

The review identified a number of current issues and needs as well as strategies that may support effective implementation of non-traditional dialysis modalities such as education for clinicians, patients and caregivers, administration support, sharing information on successful models, and relevant policies.

CONCLUSIONS

Integrating implementation considerations in the HTA process systematically provided an effective platform for understanding the context in which the HTA findings can be applied to facilitate real-

world decision-making in dialysis treatment.

R194 ISPOR international initiatives on the assessment of the value of medical technologies (Round table)

Oyvind Melien, Norwegian Directorate of Health, Norway; Mirella Marlow, The National Institute for Health and Care Excellence (NICE), United Kingdom; Katharina Hawlik, Ludwig Boltzman Institute for Health Technology Assessment (LBI-HTA), Austria; Yves Verboven, MedTech Europe, Belgium

OBJECTIVE: Identify current and future roles of Health Technology Assessments (HTA) compared to other tools and initiatives used to assess the value of medical technologies throughout their life cycles to inform decisions and reach healthcare policies.

BACKGROUND: Over the recent decades, HTAs increasingly have been adopted in order to evaluate various interventions in health care with reference to their benefits for the patients, safety, cost-effectiveness and consequences for health systems.

In recent years initiatives are taken towards a value based healthcare and new instruments are being considered to measure the benefits for patients, health system performance and the value of medical technologies.

METHOD: Several international organizations will cooperate to approach these challenges with the following focal points:

- Perform a gap analysis
- Analyze the role of evidence generation
- Study future roles of HTA for medical technologies
- Give inputs to capacity building and international collaboration
- Collect perspectives from stakeholders

CONCLUSION: There is a need to explore more closely how to utilize and adapt HTA as a supportive tool in the life cycle of medical technologies to benefit patients, health systems and society, and consider the value of other tools and initiatives on novel value frameworks to inform decisions and reach policy objectives

R255 Justification of new types of practices involving medical exposure (Round table)

Ms. Eva Godske Friberg, Norwegian Radiation Protection Authority, Norway; Ritva Bly, Radiation and Nuclear Safety Authority, Finland; Torsten Cederlund, Swedish Radiation Safety Authority, Sweden; Nellý Pétursdóttir, Icelandic Radiation Safety Authority, Iceland; Hanne Waltenburg, Danish Health Authority, Radiation Protection, Denmark

Medical exposure is an essential tool in diagnosis and treatment of different conditions and diseases. However, ionizing radiation is associated with cancer induction and for some high-dose procedures also acute tissue reactions are reported. To ensure safe introduction of new health technologies, it is important to properly address and evaluate the radiation detriment associated with medical exposure. This is the rationale behind the requirement for generic justification of medical exposure in the international and European Basic Safety Standards (BSS) on radiation protection. The Nordic radiation protection authorities recommend the integration of generic justification into established methods for assessments of new health technologies as one approach to strengthen the justification process. One of the advantages with this approach is that radiation protection and the concept of generic justification is part of the total assessment and decision-making processes and not evaluated in a separate and isolated system. Health technology assessment (HTA) and other similar methods are recognized as valuable tools in promoting generic justification of medical exposure. These assessments may also have an important role in assessing the impact on the public health economics and resources related to the introduction of screening programmes and individual health assessments of asymptomatic persons. A closer cooperation between national radiation protection authorities and relevant national bodies, like competent HTA bodies, is essential to succeed with the development of this approach.

R556 How to involve citizens and patients in HTA

Dr. Francesca Moccia, Cittadinanzattiva, Italy

Involvement of citizens and patients in processes of HTA is raising interest in public health policies, although barriers to participation still exist. In Italy despite an existing national system on HTA, there isn't yet a solid experience in involving citizens/patients in HTA.

To fill this gap Cittadinanzattiva since 2012 organised 4 training initiatives. Main features of the last edition: focus on patients' involvement; de-centralization of the training; purposely mixed target (in the Autumn School 2016 the target included not only leaders of patients'/citizens' associations, but also operators of healthcare service; a project work (example of a "citizens'/patients' involvement Plan") for which participants were divided into 3 groups with the task of discuss the project with institutional interlocutors. The topic was "citizens', patients' and users' involvement" in the following issues, choosed by the groups: purchasing process of medical devices, introduction of beds for intermediate care, design of a Path Diagnostic Therapeutic Care for ADHD.

Results: the project works could be implemented in the areas concerned; as recommendations on patients' involvement addressed to administrations, we adopted "Values and quality standards for patient involvement in HTA" by HTA International, integrated with elements from the School; emerged the need of involving smaller patients' associations.

A197 Incorporating patient perspectives in Canadian HTAs

Mr. Gino De Angelis, Laura Weeks, CADTH, Canada

BACKGROUND
HTA agencies worldwide are increasingly incorporating patient perspectives into the HTA process to enhance legitimacy in public decision making, and ensure decisions that impact patients appropriately consider their perspectives.

OBJECTIVE
To describe CADTH's process of systematically reviewing literature, often qualitative, relevant to patient perspectives and experiences, along with lessons learned.

METHODS
Research questions explore perspectives and experiences of people who could be impacted by resultant health policy recommendations and are answered following best practices in systematic review methods. Results of included studies are analyzed through thematic synthesis—a form of meta-aggregation appropriate for synthesis of qualitative and other descriptive research. Regular team discussions provide opportunities to evaluate strengths and challenges and help ensure an efficient and rigorous process.

RESULTS
Five reviews have been completed to date, which will be used to illustrate the process as well as lessons learned. The use of standard systematic review methods has facilitated integration with corresponding clinical and economic reviews, and acceptance of this process within the broader HTA.

CONCLUSIONS
The integration of a systematic review of literature relevant to patient perspectives and experiences into the HTA process is novel in Canada, and is helping to generate more meaningful and patient-centred evidence.

Health technology assessment of innovative medical devices

Dr. Iñaki Gutierrez Ibarluzea, HTAi, Spain

Technology is the use of human intelligence to resolve problems or needs. In the case of health technology we refer to different kind of solutions to address the needs related to pathologies or conditions. This embraces drugs, medical devices, vaccines, public health interventions and programmes.

In the case of drugs and vaccines, the introduction and access to the market is regulated somehow, in the case of medical devices, this regulation is mainly devoted to ensure the safety and performance of the device, especially in the case of devices that will be implanted in human bodies and thus certain evidence is produced even on efficacy.

The main difference in comparison to drugs is that technologies that will be incorporated in medical devices have been previously tested or applied in other economic sectors (energy, transportation or information), while drugs are mainly designed to address health problems. That's why the egg is before the hen in the case of medical devices. The solution is in the market before addressing a real need. How Health Technology Assessment could act in this case in a constructive way. Three main actions should be performed: early advice to innovators, inform systems on technologies developed and inform decision makers (whoever they are) on the best information/evidence available at the moment of decision.

R149 Role of HTA in open innovation (round table)

Debjani Mueller, CMeRC, South Africa; Marco Marchetti, Andrea Urbani, Policlinico A. Gemelli, Catholic University of the "Sacred Heart", Italy; Valentino Megale, Open Biomedical Initiative; PG Kanavos, LSE, United Kingdom; Paolo Morgese, European Research for Deerfeld Institute

Innovation has arisen from the combination of tools and expertise from previously unrelated sectors. Traditional internal knowledge competences in combination with external knowledge partnerships and networks can lead to generative practice of interaction. Open-source partnerships between different contributors including active patient input to healthcare, has allowed research and development to move towards affordable technologies keeping in mind that there is a danger of intellectual property spillover. Nevertheless, these processes could have a positive impact on effectiveness and affordability.

Health Technology Assessment has been found to play a key role in the identification of most innovative technologies by active use of the information by health authorities in making decisions in the areas of pricing and financing health products, licensing, etc. Similarly, it can support health systems throughout the developing and developed world in the adoption of open-source and low-cost health technologies resulting from open innovation initiatives.

The workshop will present the challenges and opportunities that arise with the increasing adoption of these technologies, the key role of HTA in this process and follow up with an interactive session on the pros and cons of open innovation.

Management of medical devices	
R96	Medical equipment management

Prof. Nikolaos Pallikarakis, Institute of Biomedical Technology (NIBIT), Greece

The constantly increasing number and complexity of MD during the last decades, have made clear since the end of the 80's that for the efficient management of MDs, software tools are of necessary. During the last 10 years, given the impressive progress in the fields of computer sciences and information & communication technologies (internet, mobile devices, etc.) led to the development of new software tools and platforms with new programming capabilities and better infrastructures, have altered the way such computerized management systems operate. A web based version of Medical Equipment Management System (MEMS) provides today great assistance to Clinical Engineering Departments (CEDs) in order to assure safety, effectiveness, and efficiency in the use of medical equipment. These systems are today modular, and support all main tasks, such as: Inventory, Corrective Maintenance, Preventive Maintenance, Contract and Spare Part Management, Statistics/Reports and Assigned Work Scheduler. These modules are interrelated in a logical manner to support all clinical engineering services and are distance accessible, thus facilitating their use.

A73	HTM implementation in Saint George hospital Lebanon

Mr. Riad Farah, Lebanon

Saint George University Hospital in Lebanon is more than 135 years old, with more than 25 Million $ of medical devices serving all specialties. The Biomedical Engineering Department services were based essentially on repairing the devices at best quality/ lower cost possible, but this offer no more a solution to the ever growing yearly expenditure on technology. Medical Devices budget rises up to 3 Million $ a year. Health Technology Management HTM and HTA technology assessment offer the tool for the administration to draw the map of the needed technologies for patients. After being HTM certified by ACI, I lead a gap analysis project with the commitment of all the medical engineers, and came out with list of improvements to be implemented within 3 years-time, to transform the services from Biomedical to Technology Management. This presentation shall demonstrate the projects done, like: Preventive Maintenance plan reduced by adopting Reliability Centered Maintenance and Failure Mode and Effect Analysis, Replacement of medical devices, medical equipment management plan, capital budget, technology planning, needs assessment, acceptance testing, continuous training, and safety. The HTM project started paying off through reduction in budgets and promising savings in replacement of medical equipment.

R173	Good governance of equipment in public sector

Dr. Pamphile Thierry Houngbo, Ministry of Health, Benin; Prof. Joske. F. G. Bunders-Aelen , Vrije Universiteit Amsterdam, The Netherlands

A Model for Good Governance of Management and Maintenance of Healthcare Technology in the Public Sectors: Learning from Evidence-Informed Policy Development and Implementation in Benin

The main research question this PhD thesis addresses is: How can evidence-informed policy be developed that incorporates principles of good governance to realise the effective and efficient management and maintenance of healthcare technologies in Benin?

Principles of both good governance and the Interactive Learning and Action approaches based on qualitative and quantitative research methods (e.g. desk research, observation, questionnaires, interviews, workshops, and expert meetings) were used.

Five published or accepted articles present the details of the findings. The first paper is entitled: Policy and management of medical devices for the public health care sector in Benin. The second: The effect of Benin's first public procurement code and its amendment on healthcare equipment acquisition prices. The third: Ineffective healthcare technology management in Benin's public health sector: the perceptions of key actors and their ability to address the main problems. The fourth: The root causes of ineffective and inefficient healthcare technology management in

Benin public health sector. The fifth: A model for good governance of healthcare technology management in the public sector: learning from evidence-informed policy development and implementation in Benin.

The conclusion and discussion assessed the policy and its development process for their realization of good governance principles to answer the guiding research question.

R46 Strengthening utility and maintenance of medical devices

Mr. Demeru Yeshitla Desta; Ismael Cordero, Gradian Health System, United States of America; Ayalew Firew, Kibwana Sharon, JHpiego-Ethiopia

Background: A significant number of medical equipment and devices used in Ethiopian public health facilities are imported. The health sector faces challenges in ensuring that the equipment is adequately maintained and serviced during the warranty period, affecting utility of the equipment and therefore service provision.

Objective: The objective of the assessment is to share evidence of best practice in management of medical devices

Method and findings: Jhpiego Ethiopia procured 14 anesthesia machines from Gradian Health System, which were then donated to 14 public hospitals across Ethiopia. Preventive Maintenance visits were conducted for each machine twice a year, for a total of 28 total visits. We conducted oral interviews with 10 biomedical Engineers, 15 Technicians and 25 anesthesia preceptors from July 2016 – February 2017. Findings suggest that spare part availability is improved by 92 %, the down time of the anesthesia machine decreases by 78.6 % and service provision maximized at each hospital by 78.6%.

Next step: The findings will be shared with key stakeholders nationally, to inform and guide future approaches and strategies to ensure medical equipment is appropriately maintained and managed during the warranty period.

R295 Value based procurement (panel)

Mr. Joseph Gatewood, Global Medical Technology Alliance, Switzerland

Description:

Increasing demand for healthcare services worldwide has placed unprecedented pressure on both emerging and developed economies to spend resources in more efficient and effective ways. Value based procurement is a key part of the solution to addressing these issues. Our session will focus on some innovative policies around value based procurement as applied to the uniquely complex area of health care. We will examine in detail systems that are currently being utilized and/or considered to be utilized as mechanisms to both foster innovation and obtain value for money spent. Examples will be offered from health care systems in different geographies that focus on innovation and a redesigned procurement paradigm to achieve greater value. The session will also provide an in-depth discussion of the World Bank's once in a generation reform to move to a value based procurement model in the medical technology arena.

R589 Procurement of complex medical equipment and the considerations for product selection, installation, training, after sales service and maintenance

Mr. Paul Labarre, UNICEF Supply Division, Denmark

Since 1990, significant improvements in child health have been made. The under-five mortality rate has decreased by 49%, from 90 deaths per 1,000 live births in 1990 to 46 per 1,000 in 2013. However progress is hindered in many low- and middle-income countries by weak health systems and poor access to life-saving medical equipment commonly found in neonatal intensive care units (NICUs).

Access to these technologies requires a foundation of basic infrastructure including availability of

medical gasses and clean, reliable electricity. Proper selection of fit-for-purpose and high value-for-money equipment is essential. This requires ensuring products meet minimum specifications and manufacturers have the proper certifications demonstrating a robust quality management system. Clinical training, installation, and after sales service are also essential to ensuring the equipment is safe and effective. Finally, health technology management requires a cadre of well-trained clinical engineers who are knowledgeable and skilled at preventative and corrective maintenance and who maintain a robust spare parts supply to support this maintenance.

The presentation outlines UNICEF Supply's role in procurement of Essential Medical Equipment and the considerations for product selection, installation, training, after sales service and maintenance of complex capital equipment associated with the NICU environment.

R385 Developing compendium of generic specification for public health procurement

Dr. Shashi Sinha, National Health System Resource Centre, India; Ameel Mohammad , Ajai Basil, Anjney Shahi, P.V Vigneshwaran, Consultants, NHSRC, Ministry of Health & Family Welfare, India

With many complex items of equipment available in the market and healthcare professionals being so dependent upon them it is always a time consuming exercise to set up committees for preparing clear specifications for medical equipment. The Ministry of Health and Family Welfare of the Government of India decided to develop a database of specifications. Committees of experts were set up to frame the basic specifications. Generic technical speciation is prepared by the Healthcare technology Division of NHSRC to enable fair procurement of medical devices and maintain quality and uniformity of medical devices across the states. Currently 157 medical devices technical specifications are drafted on WHO template with GMDN nomenclature. It Involves consultation meetings and large technical document resources. The Division now plans to prepare Generic Specifications for 468 Medical Devices covering the entire scope of Indian Public Health Standards- Revised 2012. So far the domain of Neonatology, Pediatrics, Emergency care, Clinical laboratory, skill laboratory, radiology and Operation theatres have been covered. Due to this work savings amounts to hundreds of Crore which is proposed to be displayed during the global forum.

R39 The status of medical equipment in Sub-Sahara Africa

Ms. Anna Worm, THET, Benin; Theogene Namahungu, Minister of Health, Rwanda; Harold Chimphepo, Minister of Health, Malawi; Charles P. Soroheye, DIEM, Benin

Data on medical equipment in sub-Sahara Africa are limited and not always a good representation of today's situation. P. Howitt mentions that at least 40% of medical equipment is out of service[1]; other studies cite 50-80%[2].

Based on inventories made in Rwanda, Malawi, DRC and Benin, we see that about 70% of medical equipment is functional. The 30% of equipment that's out of service is mostly due to equipment being obsolete, difficulties in acquiring spare parts and a lack of skilled (technical) staff.

The Clinical Engineering handbook[3] indicates that up to 80% of medical equipment in many sub-Saharan African countries is donated or funded by foreign sources[3]. A limited research (questionnaires) with the participation of 6 Francophone ministries of health shows that an average of 44% of the equipment is donated or (partly) financed with external funds (preliminary data, Anglophone countries to be analysed).

New insights in the status of medical equipment in sub-Sahara Africa confirm the need of better understanding and quantifying the current situation to find ways to leverage the available resources (e.g. human, financial) to maximise the impact of medical equipment in healthcare delivery. This is a task for both African nations and partners.

1 The Lancet Commission: Technologies for Global Health, P. Howitt et al., Aug 2012

2 EMRO Technical discussions, "The role of medical devices and equipment in contemporary health care systems and services", June 2006

3 T. Judd, J. Dyro, and J. Wear, "Advanced health technology management workshop," in Clinical Engineering Handbook, J. Dyro, Ed. Elsevier, 2004

Human resources and medical devices	
A243	The involvement of IFMBE in developing countries

Prof. Mario Forjaz Secca, IFMBE

The International Federation of Medical and Biological Engineering (IFMBE) has the mission of encouraging, supporting, representing and unifying the Biomedical Engineering community to promote health and quality of life through medical devices, with the developing countries in strong need of this support. With this in mind the Federation has a Developing Countries Working Group (WG), focusing on the specific problems of Low and Middle Income Countries (LMIC) that lack the resources available to the richer countries and do not have enough qualified personnel to manage and maintain the Medical Devices used.

Working with other IFMBE Divisions and Groups, and WHO, we concentrate on supporting and developing BMET training programs, on supporting the managing and servicing of donations, on promoting the profession and on supporting the creation of national professional groups.

We are now working on the creation of a WG on African Activities, to act as an attractor for different African countries, in order to concentrate on specific problems and share experiences.

As a pilot project we are working on the implementation of a Biomedical Engineer consultancy program within the Ministry of Health in Mozambique, hoping to extend it to other countries.

R622	IOMP initiatives on equipment related professional capacities

Prof. Magdalena Stoeva, International Organization for Medical Physics (IOMP), United Kingdom

The International Organization for Medical Physics (IOMP) represents c.24,000 medical physicists in 86 countries. An important aspect of IOMP's mission is to advance medical physics practice worldwide by disseminating scientific and technical information. Achieving this mission is an on-going challenge associated with initiatives conducted on a global level.

IOMP's strategy on this topic involves support for various workshops on medical equipment quality control and topics on equipment selection and management.

IOMP supports various publications dedicated to medical equipment management and related radiation safety issues. The newest addition to IOMP's publication is the free on-line IOMP Journal Medical Physics International (MPI), which includes publications from medical equipment industry. The dedicated MPI Technology and Innovations section focuses on presenting the leading medical technology achievements to medical physicists.

An important part of these activities is IOMP's collaboration with world leading organizations as IAEA and WHO in developing guides and activities related to safe and effective use of medical technology. Some of these are the regular participation in various IAEA projects and in WHO's Global Forums on Medical Equipment.

IOMP's initiatives on Equipment Related Professional Capacities are focused on building sustainable relations between medical physicists, the industry and the relevant international organizations worldwide.

A179-1	Clinical engineering in China

Prof. Bao Jiali, Zhu Chaoyang, Zhejiang University, China

Clinical engineering originated in the 1970's in China, when with the medical device in hospital, the Chinese hospital successively established the Department of Equipment. At that time, the role of the department is to repair the medical equipment. So far the main tasks in the department consist of the quality and risk management, health technology assessment, compliance with regulations and standards, configuration and procurement, preventive maintenance and repair,

education and training for medical device in use. At present, clinical engineering staff in China is of 100,000 approximately who has doctor degree in 0.5%, master's degree 7.6%, undergraduate 43.8% from major in Biomedical Engineering 21.9% and Electronic 16%. The social communities in clinical engineering have Chinese Medical Association Medical Engineering Section, the Biomedical Engineering Society of China Clinical Medical Engineering Branch, the Chinese Medical Doctor Association Clinical Engineers Branch and the China Association of Medical Equipment.

R653 Apprenticeship model for clinical engineering workforce development

Mr. Abdul Basit, Malcolm Birch, Barts Health NHS Trust, United Kingdom

Hospitals in England are facing a skills gap in the technical workforce for maintaining electro-medical equipment. This study was carried out in the Clinical Engineering (CE) department of a major public London hospital.

An interview based engagement process was deployed to identify outcomes and benefits that stakeholders would like to see in an ideal format of a CE apprenticeship programme to address multiple challenges including the skills gap. Interviews were transcribed and themes identified, such as Motivation, Training Curriculum and Recruitment. This resulted into a four-layer CE Apprenticeship Model.

The model was implemented in September 2016 through the launch of a CE apprenticeship programme that provides equal opportunities to bright and talented 16-19 years old GCSE or A-level graduates to pursue a career in CE regardless of their ability to pay university fees. We received 87 applications, shortlisted 11, accepted 4 and currently 4 are enrolled in the programme. The current apprentices are expected to graduate in 2018 and be able to maintain low to medium risk medical devices ensuring their safely provision for patients and clinicians.

Through this case study we want to share our experiences so far in creating and implementing the model.

A198-1 Biomedical engineering education: studies harmonisation

Prof. Nikolaos Pallikarakis, Institute of Biomedical Technology (NIBIT), Greece

Medical technology radically reshaped the way healthcare is delivered today and continues to improve it in an accelerated pace. Biomedical Engineering (BME) is a multidisciplinary field lying in the cross-section of medical/biological sciences and engineering. Healthcare today is technology-driven and delivered by teams rather than individuals. Biomedical Engineers (BMEs) as professionals are playing a vital role in these developments, being behind the recent advances and involved during the whole life cycle of Medical Devices (MDs), from the innovative idea to their final use. However, this rapid evolution creates a constant pressure for new knowledge and skills for the BMEs and therefore for continuous curriculum updates in order to meet R&D and market demands, but also harmonisation of studies worldwide that will facilitate staff and students' mobility and collaboration. A wide acceptance of a generic core curriculum that would be part of a great number of BME programs, based in the Bologna approach, will promote employability, competitiveness as well as staff and student mobility through the use of the European Credit Transfer System (ECTS) and will facilitate a worldwide opening of the BME job market, through mutual recognition of the competencies acquired.

R49 Networking from Colombian clinical engineers

Ms. Andrea Rocio Garcia Ibarra, Ministry of Health and Social Protection, Colombia

In 2015, Direction of Drugs and Health Technologies of the Ministry of Health (MoH) of Colombia launched an initiative for establishing a "Clinical Engineering Network" oriented to improve Medical Equipment Management (MEM) countrywide. The Network, which covers 40% of the national territory, is divided into six nodes/regions, includes 120 hospital and 10 universities.

In order to prepare projects on MEM and share information and experiences, the Network members meet every two months in each node. Key accomplishment of these meetings includes:

- Continuous training in Colombian regulations.
- Positioning the Biomedical Engineers as MEM key stakeholders.
- Institutional strengthening of the MoH in Health Technology field.

The interaction among the members has facilitated a successful knowledge and best practices transfers in MEM from the eight high-complexity hospitals to almost 120 regional and local hospital with limited access to resources. The Network has contributed to improve the efficiency in MEM process. The outcome is a better service to the population.

Currently, the Network is collaborating with the MoH in the validation of the Equipment Maintenance Manual and Obsolescence Assessment.

Next steps are:

- Strengthening of the network
- Increasing the membership and the motivation of institutions
- Interacting with professional engineering societies and health technology organizations worldwide.

A155 Biomedical and clinical engineering development in Bangladesh

Dr. Md Ashrafuzzaman, Military Institute of Science and technology, Bangladesh

Healthcare Delivery Systems in Bangladesh lack the biomedical and clinical engineering professionals that are capable to manage effectively the healthcare technology. The National Sustainable Development Strategy (NSDS) 2010 has been prepared to meet the major challenge of health sector by identifying the diverse health care needs of a growing population which will reach 177 million in 2021 along with improvement in quality of services to achieve vision 2021 target of the government. The strategies include increasing the number of doctors, nurses and health technicians, ensuring strong health education program but to fulfil the requirements of skilled biomedical and clinical engineers for the safe and cost effective health care management is yet to be developed.

To produce numerous skilled professionals, government has started medical physics and technology, biomedical and clinical engineering education program in various universities, technical and vocational training institutes to strengthen the local capability for the efficient delivery of healthcare services and for the advancement of methods used for diagnosis, therapy and rehabilitation. With the establishment of national technical committee for medical devices through Directorate General of Drug Administration (DGDA) and the Ministry of Health and Family Welfare, Bangladesh, strengthening quality management, local capacity enhancement, develop skilled professionals, is supporting innovation through educational initiatives, and encouraging the inclusion of expert professionals from various electro-medical industries. Such sustainable development integrating biomedical and clinical engineering into collaborative efforts through university-industry-hospital partnerships, is significant to accelerate progress and work towards a healthier future for ensuring quality management of health care systems in Bangladesh. Thus, a draft guideline can be proposed for establishment of quality, certification and training centre for medical device where biomedical and clinical engineers will be trained with advanced technology aiming to perform the following activities:

1. Academic leadership training program through collaboration with foreign universities/institutions to produce skilled engineers.

2. Ensure the quality control and management of medical equipment at high standard through the support and monitoring policy from the developed country nominated by WHO.

3. Establishment of a common platform for biomedical and clinical engineering professionals to ensure the effective health care management systems nationwide by organizing seminar, conference, workshop and symposiums for disseminating the knowledge of relevant fields.

R172 Roles of CE in medical device development

Mr. Hiroki Igeta, Japan Association for Clinical Engineers / Aso Iizuka Hospital, Japan

The role of the Japan Association for Clinical Engineers (JACE) is to contribute to the promotion and development of the nation's medical care and welfare through the raising of professional ethics of CEs, enhancement of their professional knowledge and skills, and improvement of reliability of equipment-based medical care and welfare, including life-support systems. JACE has more than 40 committees in a variety of domains of expertise relating to clinical engineering and the each committee conducts many types of activities.

Recently, collaboration project between medicine and industry has been gathering public attention as the Japanese government adopts policies of extension of healthy life expectancy and of applying Japanese high-technology to medical devices. JACE believes the collaboration project could be a new field to use CEs' engineering skills and their medical knowledge gained through experience in practical clinical fields. CEs can be developers, consultants, evaluators, etc.

JACE established a "clinical-industrial-academic collaboration committee" in 2016. The committee has been preparing an environment for members to be active in this new field and also takes many actions such as displaying and introducing devices which were developed by CEs under the framework of collaboration projects at major exhibitions or related conferences.

R724 Addressing challenges in educating biomedical engineers to meet the global needs

Prof. Shankar Muthukrishnan, Wentworth Institute of Technology, United States

The healthcare delivery needs have been increasing world-wide, which triggers a corresponding increase in all associated healthcare disciplines, including in biomedical engineering. The field of biomedical engineering has grown significantly due to proliferation of technological advances and applications to the BME field. Resources available for training in different regions and in different countries vary widely posing severe challenges to the BME educators. In resource-poor countries, the challenges are magnified. The objective the presentation is to determine the challenges and to explore solution approaches at varying levels of BME education.

Biomedical engineers are needed at the healthcare delivery sites including primary, secondary and tertiary care facilities, as well as in medtech industries, research centers and regulatory government agencies. The expertise required spans across a wide spectrum of support ranging from bench to bedside. While several well organized undergraduate programs exist at sites with adequate resources, they cannot be emulated in resource-poor settings. The time available for training, the faculty, labs and support staff pose complex challenges. Multi-tiered education solutions from associate degree to master's level with proper ratios will address the challenges. Properly planned, technology-assisted pedagogies can facilitate effective training and lead to capability building across different levels of resource settings.

Assistive Devices

R197 A novel device to screen newborns for hearing loss in resource constrained settings to prevent speech loss

Mr. Nitin Sisodia, Gopinathan, Karthikeyan, Sohum Innovation Lab, India

In most advanced healthcare systems, universal screening is mandatory at the time of birth. 800,000 hearing impaired babies are born every year all over the world, of which ~100,000 are in India and 90% in developing countries. In resource constrained settings, such as India, hearing impairment goes undiagnosed till the child is about 4 years. By then, it is too late for the care cycle to be effective. This leads to speech loss, impaired communication skills, possible mental illness and unemployment. Sohum provides early screening, that leads to timely treatment and rehabilitation, as well as savings in healthcare expenses to the system. Sohum is a noninvasive safe gold standard technology to screen neonates for hearing impairment with high sensitivity and specificity. Sohum uses automated Brainstem Evoked Response Audiometry (BERA) technology in an innovative way with an easy-to-use interface which gives results as 'Pass' or 'Refer'. Sohum technology can perform in noisy settings, doesn't require expensive disposables, designed to be used by a healthcare worker, and is tele-medicine enabled with an audiologist verifying every result to

ensure high sensitivity and specificity and provide timely intervention (hearing aid, cochlear implant, rehabilitation) to every baby tested positive.

R529 Evaluation of performance leads to better products?

Mr. Jesper Nordlinder, SCA Hygiene Products, Sweden

Introduction: Incontinence is a heavily stigmatizing set of diseases affecting almost 400 million people worldwide, with growing prevalence in ageing population. Despite its high prevalence, tough psychosocial and economic implications, it is still a taboo. Cure rates are low, but still there is very little specific information and guidance on how good continence care should look like.

Urine absorbing incontinence products are widely used and there is a need to be able to evaluate their performance to drive further innovations.

Evaluation of urine absorbing products: A good performing product that meets the specific need of the user is an important part of a good continence care. The standard, IS0-15621 identifies factors to consider when evaluating a product and they are divided into three areas (product, user and usage). It highlights the importance of the interaction of the 3 areas to achieve a good performance. Today most of these factors are not included in the evaluation of products instead parameters such as rewet, acquisition speed and total capacity are measured. Important parameters but doesn´t answer how the product performs in use.

Workshop discussion:

How can the performance of absorbing product in use be measured in a comparable and effective way?

A249 Dynamical orthostatic chair

Mr. Walef Robert Ivo Carvalho, Instituto Nacional de Telecomunicações, ; Ana Letícia Goncalves, National Institute of Telecomunications (Inatel), Brazil

There are currently about 24.6 million physically disabled living in Brazil. This special group of people constantly faces mobility difficulties in their day-to-day living. Hence to ease their problems and improve the accessibility of the disabled, this research proposes an application of electronic concepts to develop mobile equipment capable of letting disabled in upright position and enable the locomotion to the place wanted. The equipment meets the difficulties faced by those affected spinal cord injury, assisting them in the process of locomotion in any enclosure, providing independence. Thus, it is possible to recover the self-efficacy, within the limits imposed by disability, promoting social reintegration. The prototype is controlled via remote control and a joystick. The user presses a button and an iron mechanical arm is directed to the patient's chest. Done that step, one performs security procedures, coupling to equipment. The control unit moves motors located inside the mechanical structure. The equipment provides the chance to wheelchairs users to be in standing position, offering the locomotion possibility again. Electronic circuits allow the movement of the structure when the user performs a control commands. The equipment was tested with people with disabilities and the results of the recovery were satisfactory.

R651 Hand orthosis for radial or cubital injury

Ms. Rosa Itzel Flores Luna, Ruben Valenzuela-Montes, Hanna L. Garcia-Guerra, David de Jesus-Cruz, Mariano Garcia del Gállego, Alvaro Ayala-Ruiz, National Autonomous University of Mexico (UNAM), Mexico

Peripheral nerve injuries are common, and there is no treatment that can successfully restore the hand movement, only 50% of the patients regains useful function after surgery. A semi active hand orthosis to recover the mobility on paralyzed hand because of peripheral nerve injuries is presented. The orthosis is based on a six bar mechanism and a circular slide, using the hand as a part of the mechanism. Many other orthosis or exoskeletons have been developed around the world, nevertheless this design is has no need for an actuator, and can be powered like a mechanical hand prosthesis. As result, a mechanism and a pilot test with users are presented, the users can hold different objects with their hand using the orthosis.

R217 Disrupting the barriers to uncorrected refractive errors

Dr. Shivang R. Dave, Nicholas J. Durr, Daryl Lim, Eduardo Lage, PlenOptika, Inc.; Department of Biomedical Engineering, Johns Hopkins University, United States of America; Ramakrishnan Mahadevan, Sriram Ravilla, Aurolab, India; Department of Biochemistry, Universidad Autonoma de Madrid, Medical School, Spain; Sanil Joseph, Thulasiraj D. Ravilla, Aravind Eye Care System, India

Uncorrected refractive errors, a leading cause of DALYs, affect more than 1 billion people worldwide. Since the insufficient number of refractionists in resource-constrained areas contributes to this problem, new technologies are needed that hold promise to extend the productivity of existing refractionists and increase the accuracy and reliability of technicians. We assessed the best-corrected visual acuity (VA) and patient preference for eyeglasses prescribed by a novel autorefractor (LAR) and an experienced ophthalmic technician with over four years of subjective refraction experience (LSR). Participants, aged 15-70 with refractive error -6D to 10D, were recruited from patients scheduled for a general refraction at Aravind Eye Hospital (N=506) and satellite vision center (N=202). The autorefractor was a low-cost, handheld, binocular, open-view, wavefront aberrometer prototype that was operated by a technician with no formal eye care training. The VA and prescription preferences for trial lenses set to LSR and LAR were evaluated by a refractionist blinded to the prescription source. Our study shows a total of 47%, 91%, and 85% of patients had 20/20 vision or better, before correction, with LSR, and with LAR, respectively. The difference in VA between LAR and SAR was one-letter, however, autorefraction required considerably less training than subjective refraction.

eHealth

A10 Medical internet of things and embedded intelligence in healthcare

Dr. Abdelbaset Khalaf, Tshwane University of Technology, South Africa

eHealth and Artificial intelligence (AI) hold great promise in computational medicine and considered as an ultimate goal to prevent and treat diseases. Although (AI) has been developed for screening and assisted decision-making in diseases prevention and management as part of Clinical Decision Support System (CDSS), it has a greater potential if integrated with medical internet of things (MIOT) and embedded intelligence in medical systems. This may reshape the future of healthcare, which lies in building cognitive action derived from the intelligent medical devices that provide sensing, data integration, analysis of things and cognitive action.

This presentation will focus on the embedded intelligence in healthcare and the application of medical internet of things coupled with Fog and Cloud computing infrastructures.

R68 Development of innovative tools for improving rural health care and safety

Dr. Mannan Mridha, The Royal Institute of Technology, Sweden; Hashem. Md. Abul, Department of Soil Science, Bangladesh Agricultural University, Mymensingh, Bangladesh

Health workers and village doctors are largely responsible for rural medical care, because qualified medical doctors are not available, although, 75% of the population lives there. This leads to wrong diagnosis, inappropriate medication and often cause serious suffering that is preventable. In order to improve rural health care and achieve health equity and patient safety, we set up model centers for empowering the village doctors and female health workers for training them to use smart and affordable medical devices and appropriate ICT tools, to address some of the most serious health problems. Our e-Health initiatives in rural settings in India & Bangladesh have shown potentials for improving village doctors' performance. Our work included: i) identifying the problems, ii) creating access to reliable, essential and cost effective medical devices, iii) developing program for safe use of diagnostic devices and ICT tools, iv) providing reliable connectivity to the medical experts, v) developing appropriate e-Learning content on health education for disease prevention. Our e-Health work, addressing the local needs and conditions, are gaining acceptability among rural people for illness management, disease detection, disease prevention, health awareness improvement, and all that can lead to poverty reduction, and sustainable socioeconomic development.

A248 Conquering the leprosy last mile: the role of mobile-phones!

Prof. Phillip Olla, Audacia Bioscience, Canada

Over the past three decades, there has been a successful concerted effort to reduce the incidence of leprosy by adopting: multidrug therapy (MDT), clinical staff education, and public awareness campaigns. Notwithstanding, leprosy persist as an atrocious health concern in many regions. Normally, diagnosis is conducted by a combination of clinical, histopathological, and bacteriological assessments, all present significant barriers to early and rapid diagnosis.

Leprosy dedicated research has revealed promising results when a mobile phone was incorporated into the study for diagnosing, monitoring or educational purposes. This presentation will highlight the important aspects of the mobile phones as a medical device, and provide a demonstration of a leprosy mHealth solution. Our goal is to scale-up a regional early diagnosis network that identifies infected people quick before deformities begin. Our approach involves 3 important components. First, deploying an easy to smart Rapid Diagnostic Test (RDT) that has the capability to diagnose before symptoms deform the patient. The second component is a mobile RDT reader, referral and telemedicine network to connect the rural areas with the leprosy centers to monitor epidemics. The third is phone enabled education content highlighting the fact that the disease being a curable bacterial infection.

R655 Non-invasive and minimally invasive medical devices

Prof. Ratko Magjarević, IFMBE / University of Zagreb, Croatia

Non-invasive and minimally invasive medical devices are preferred in clinical practice since they present a lot of benefits for patients, accelerate the recovery and reduce the costs of medical treatments. We would like to present some new trends in their research and development as well as their potential for providing medical care in resource limited regions. Accessibility to information and communication technologies (ICT) provides an opportunity to facilitate acquisition of health data from wide populations, their use in research, analytics and finally in improving the outcomes of health care. Internet of Things (IoT), as one of results in increased implementation of ICT in health care, turns out to be dominantly intended for applications in health care and Internet of Medical Things (IoMT) opens a lot of possibilities for improving health care.

A11-2 Telecom innovation in mobile health units

Prof. Leonardo Melo, Diagnext, Brazil; Alessandro Melo, Universidade Federal Fluminense, Brazil

Telemedicine was developed to cross borders, bringing medical knowledge, actions and practices to wherever it might be needed. However, the global's reality context doesn't help - infrastructure capable of transmitting the amount of data needed for telemedicine doesn't exist exactly where they are most needed.

After years of engineering and medical studies, a set of protocols, practices, technologies and patents have been developed that are capable of perfecting the infrastructure that supports teleradiology and brings it to a new level - being able to overcome technological barriers and transmit big data volume.

This newest technology was made available to the Amazonas's State, and implemented in 51 forest's hospitals, overcoming all dificults and knowns barriers. It transmits more than 100,000 x-ray and mammography tests per year, 20 times more fast than the conventional technology. Finally, all this made the evaluation of a medical examination of up to 6 months to little more than a minute using a slow and unstable satelites communications system.

The major specialty of this technology in this context is in the detection of breast cancer, which has been able to increase patient care, periodic examinations and drastically reduce the incidence of the maladies of the disease to controllable levels.

R168 Disabled patient correcting medical records online

Dr. Richard Fitton, Tameside and Glossop Clinical Commissioning Group; Edna Davies UK Patient's mother, United Kingdom

Using the on line access view of the primary care GP record from home, a paper print out, and a shared view with the GP at the surgery/office the mother of a daughter with multiple disabilities checked the accuracy and completeness of her daughter's GP medical record. Discussions and examination of the record took place at the doctor's surgery with Abigail and Edna and a more accurate and complete record was achieved.

The paper discusses the background and technological and cultural solutions that were involved in on line access to a record of a disabled patient and the verification of its contents.

A176 The use of expert systems and artificial intelligence to prevent disease around the world: an experience in Mexico

Prof. Alvaro Rios, Rafael Bueno, Medical High Technologies, Mexico

Purpose: This work is part of a research project, to determinate the comparative effectiveness of Automated DR Screening System (expert system) with traditional survillance methods for detect diabetic retinopathy (DR) This paper show The first stage of the project, that was developed to provide preliminary information regarding the prevalence of eye diseases in Mexico, and to measure the impact of non-mydriatic cameras and Expert System on preventing blindness from DR

Methods: Diabetic patients who underwent free DR screening with diferent kind of mydriatic fundus camera were given the recommendation to have an ophthalmic visit, in a time frame suited to the DR stage or in case abnormalities in the macula, the optic nerve. The photographs were performed by trained technicians and the images was process through the expert system developed by MedicalHightech.

Results: A total of 500 persons participated in the screening program across sites, with 24.91% having DR in at least 1 eye. The most common type of DR was non proliferative DR, which was present in 48.55% of all participants with DR. Almost one therd (33.97%) of the sample screened had ocular findings other than DR; 30.7% of the other ocular findings were cataract.

Conclusions: In a DR telemedicine screening program in urban hospital settings in Mexico serving predominantly low income populations, DR was identified on screening in approximately 2.5 in 10 persons with diabetes. The vast majority of DR was chronic, indicating low public health potential for intervention in the earliest phases of DR when treatment can prevent vision loss. The csot of the DR screening was reduced in more than 95%, using the expert system.

R749 Medical informatics in low resource settings

Prof. Marc Nyssen, IFMBE, Belgium

Evidence abunds that in Africa, paper medical records cannot be handled well and the probability that a medical record will be recovered, when a patient returns to a hospital after 1 year is just a few percent. Electronically kept records however, can offer far better results to the benefit of the patients (and professional satisfaction for the care providers). Moreover, excellent « open source » systems are available and they provide cost-effective solutions.

A study in Ghana has shown that a very large task force (mostly nurses) are involved in monthly reporting ; also here, very high gains can be obtained by well-kept electronic medical records, potentially resulting in reporting in « a mouse-click » and thus releasing thousands of nurses from this periodic administrative burden.

Finally, ICT will be inevitable to enable handling of the data, necessary for the multiple insurance schemes applied today, with « universal coverage » as ultimate aim.

	Health service delivery: Oxygen systems (round table)
	Availability and oxygen use in small hospitals
	Dr. Wilson Were, WHO, Switzerland
A194	Methods for strengthening the market for safe oxygen delivery
	Ms. Lisa Smith, PATH, United States of America
	Oxygen is an essential treatment for multiple health indications. Hypoxemia, or low levels of oxygen in the blood, is observed in a variety of diseases, both respiratory and non-respiratory, often disproportionately impacting maternal, neonatal and child health. However, despite the inherent risks of hypoxemia and the direct benefits of oxygen, surveys conducted in LMIC have found less than half of health facilities have uninterrupted access to oxygen. In 2016, PATH conducted a market assessment to understand the factors that contribute to poor availability of oxygen delivery devices and pulse oximeters in LMIC markets. This assessment included consultations with representatives from the manufacturing industry, global health partners and financiers, as well as key in-country stakeholders responsible for programmatic and policy implementation, medical device regulation, procurement and maintenance in Ethiopia, India, Indonesia and Kenya. PATH categorized findings according to characteristics of market access as awareness, affordability, availability, assured quality and appropriate design. PATH then tailored appropriate interventions by country archetypes (e.g., countries with similar attributes such as centralized or decentralized health care decision-making). The result of this work is an evaluation of common challenges and overarching recommendations for addressing barriers based on common country attributes.
R140	Medical device ownership models and maintenance contracting approaches
	Ms. Lisa Smith, Michael Ruffo, PATH, United States of America
	Maintenance and after-sales service is a consistent challenge across many developing countries. Traditional warranties have not been as effective at maintaining device functionality in these settings due to limited terms and conditions of warranties, non-transparent sharing of warranty information to the end-users (e.g., health care workers), complex supply chains, and poor accountability of suppliers. Without the capability to ensure effective device operation, both suppliers and end users face the risk of failed implementation. The result of this is wasted financial resources and negative experiences with life-saving equipment, which may adversely affect future procurement decisions. To understand challenges and successes in the current market, PATH conducted an assessment of existing maintenance approaches for medical devices in select low- and middle-income countries. We evaluated maintenance approaches that are most appropriate for different categories of durable medical devices, ownership models for device procurement and maintenance, contracting terms with distributors (and/or manufacturers), and opportunities for leveraging analogous maintenance approaches from other device industries. This assessment concludes with key considerations and recommended approaches for improving medical device functionality through after-sales service models that are appropriate in developing countries. It also outlines remaining questions and future areas of work to best tailor implementation by country.
R574	Quantifying gaps in access using medical device census information
	Mr. Michael Ruffo, Lisa Smith, PATH, United States of America; Prabhat, Anjaney, National Health System Resource Center, India
	Decentralized procurement decision-making and sporadic device donations have made it challenging for many low- and middle-income countries (LMIC) to monitor, maintain, and replace essential medical devices. To address this challenge in India, the Ministry of health and family welfare (MOHFW) commissioned a national census of medical devices to identify existing devices, repair or replace non-functioning devices, and quantify the remaining gap in medical devices. Systematically tracking devices across the country provided the foundation to ensure device functionality and determine when and how to optimally outfit health facilities.

The census includes over 600,000 data entries and captured information from 21 states and territories. Leveraging work from MHOFW and WHO collaborating Centre for Priority Medical Devices & Health Technology Policy, PATH conducted an analysis of two essential medical devices - oxygen concentrators and pulse oximeters - which further illustrates the utility of information obtained through this census. PATH's work quantified the gap in availability as compared to national guidelines for device deployment and the budgetary allocation required to fill the gap at different scale-up rates. The analysis provides practical information for procurers and outlines an approach for medical device management that may be useful for managing supply systems in other LMIC markets.

A195 Multi-country suitability assessment for available pulse oximeters

Mr. Michael Ruffo, Ben Creelman, Gene Saxon, Lisa Smith, PATH, United States of America

Many health care decision-makers acknowledge the importance of pulse oximeters to identify and monitor treatment of patients with hypoxemia, however availability of appropriate devices remains limited in most low- and middle-income country (LMIC) health systems. PATH conducted a preliminary assessment of pulse oximeter availability in four countries (India, Indonesia, Ethiopia and Kenya) and found that (1) clear guidance on selecting an appropriate pulse oximeter for use in LMICs is limited, and (2) the global market for pulse oximeters contains a number of manufacturers with wide-ranging device quality and pricing.

Once identified, pulse oximeters in the four countries were assessed using a suitability assessment matrix (SAM) developed internally at PATH. The SAM compared common pulse oximeter use cases against international standards, tender documentation, and key stakeholder interviews. The goal of the SAM was to understand the appropriateness of currently available pulse oximeters and to inform procurement recommendations for these devices by identifying a simplified set of essential performance characteristics and functional device features. In the future, the SAM may contribute insights into a formal technical specification for pulse oximeters and support other countries in completing effective assessments of available pulse oximeters.

R307 Strengthening policy advocacy for medical devices

Ms. Jaclyn Delarosa, PATH, United States of America

Availability of medical devices in low- and middle-income countries (LMIC) is often limited by a lack of appropriate policies and strategies to guide medical device selection, procurement, distribution, and related maintenance and provider training. National medical devices policies are often non-existent, outdated, misaligned with national medicines policies, and/or poorly disseminated or implemented. Evidence-based policy advocacy, including consensus building among key decision-makers, is critical to ensuring the development and implementation of national policies that support the introduction and scale-up of medical devices in LMIC. PATH has extensive experience applying its unique evidence-based policy advocacy approach to support increased availability of and access to essential medicines, and will examine how this strategic approach can be applied to medical devices. We discuss the nuances of evidence-based policy advocacy, essential advocacy tactics to engage decision-makers, monitoring the success of policy advocacy, and our experience translating global normative guidance to national policies and strategies. Examples will include an examination of current global and national policies related to the provision of oxygen therapy and their influence on quality of care and access to relevant medical devices and diagnostics in LMIC.

R595 Oxygen system technologies

Mr. Kristoffer Gandrup-Marino, UNICEF, Denmark

Pneumonia is the single largest infectious cause of death in children worldwide killing over 900,000 children in 2015. Hypoxeamia increases the risk of death by 5 times and the number of children with pneumonia and other respiratory diseases needing access to oxygen systems is overwhelming. Although there are affordable, commercially available technologies that can be used at most levels of the health system to identify and treat hypoxemia, there are inherent complexities in the procurement of appropriate equipment and utilization thereof.

The roundtable discussion seeks to convene relevant stakeholders to find solutions for creating

impact within O2 therapy projects. Objectives are:

1. Map current and planned O2 therapy projects and stakeholders on a world map
2. Explore synergies in information sharing tools for O2 therapy gap analysis and strategies for upgrading capacity
3. Share lessons learned
4. Map barriers to progress and key priorities for future engagement
5. Clarity on the highest priority products needed to deliver oxygen to neonates and children such as pulse oximetry, anaesthesia and oxygen therapies

R319 Automating the diagnosis of childhood pneumonia

Ms. Elina Naydenova, University of Oxford, United Kingdom

Pneumonia is the number one killer of children under the age of 5 worldwide, with 99% of mortality in low-resource settings. Accurate and timely diagnosis has been seen to reduce mortality by more than 40%. However, diagnostic complexity and shortage of clinical expertise cause critical delays in the identification of disease and administration of treatment. To alleviate this, we have developed data mining algorithms that automate: (1) the extraction of essential symptoms from medical signals, e.g. lung sounds; (2) the interpretation of a wide range of symptoms to derive an evidence-based diagnosis. The former was developed on a dataset collected in the Gambia and the latter on a dataset collected in Peru. Building upon this, we designed a mobile health toolkit, including a set of existing affordable point-of-care tools, that can be used by minimally trained health workers to deliver diagnosis in the community. A study validating this approach on 1000 children in Mumbai, India is running between February and June 2017. Our work demonstrates that carefully designed digital tools powered by smart algorithms could mitigate the lack of clinical expertise in low-resource set

tings and empower minimally trained users to deliver evidence-based diagnosis for childhood pneumonia.

A42 Triaging infection and pneumonia among <5 children

Dr. Mohammad Shah, Save the Children US, United States; Walter Karlen, ETH Zürich, Switzerland

In response to increasing global demand for easy-to-use diagnostics in low resource settings, we proposed an automated device for accurate measurement and interpretation of key vital signs [oxygen saturation (SpO2), respiration, pulse, and temperature) and thereby for triaging possible severe bacterial infections and pneumonia among <5 years old children. We developed and validated an automated breath counting device for children <5 years, named "ChARM" (Children's Automated Respiration Monitor), which can classify childhood pneumonia according to WHO guidelines. Now, with support from Saving Lives at Birth (SL@B), we are including additional sensors for SpO2, pulse rate, temperature, and also a decision support layer to guide the interpretation of the combined vital signs following IMCI guidelines. Our proposed device compensates for motion artifacts; the SpO2 sensor comes with a single universal probe usable for all <5 children; and has an integrated infra-red sensor for measuring temperature. One rechargeable unit could run several days with normal use (~10 measurements/day) before it needs to recharge. The device will be made to withstand the environmental conditions in rural areas, but also ensure long-term use. We envision this device will help ensuring accurate diagnosis and reducing unnecessary referrals by community health workers, and rationing limited antibiotics.

R523 Validation study of an electricity-free oxygen concentrator

Prof. Roger Rassool, David Peake, Jim Black, FREO2 Foundation, Australia; Bryn Sobott, The University of Melbourne, Australia

The scarcity of oxygen available to neonates in sub-Saharan Africa leads to preventable deaths from conditions such as birth asphyxia and pneumonia. To address this need we have developed an electricity free oxygen concentrator and will conduct a validation study in Western Uganda.

The FREO2 Siphon system relies on exploiting the reduction in pressure created by water flowing through a raised siphon to create a vacuum. This vacuum is used to power a customized vacuum-

pressure-swing-adsorption system and produce medical grade oxygen. It is independent of water quality and ideally suited for deployment in tropical or mountainous regions with proximity to flowing creeks. Importantly, the oxygen generating capacity of FREO2 rises with the increased demand commonly observed during the rainy season in such climates. By having no fuel requirements, FREO2 is independent of supply chains, independent of transport infrastructure and has negligible environmental impact.

I will present peer-reviewed results confirming the production of 4 LPM of 90% oxygen without electricity. To the best of our knowledge this is a world first. Preparations for a validation study later this year examining the technical, clinical and economic considerations will also be presented.

R481 An oxygen storage system

Dr. James Black, Roger Rassool, Bryn Sobott, David Peake, FREO2 Foundation, Australia; Sheila Bagayana Mutetire, Mbarara Regional Referral Hospital, Uganda; Peter Moschovis, Massachusetts General Hospital/Harvard Medical School, United States of America

Introduction
Widespread access to oxygen would reduce global pneumonia mortality. Oxygen concentrators are one solution but have limitations: vulnerability to electricity fluctuations and failure during blackouts. The Low-Pressure Oxygen Storage (LPOS) system addresses these in low-resource settings.

We report system testing in Australia, and non-clinical field testing in Uganda.

Methods
The system included a power-conditioner, a concentrator, and a low-pressure oxygen store. In Australia pressure and flows were monitored during cycles of filling/emptying, with forced voltage fluctuations. The bladders were pressure-tested until they ruptured.

In Uganda, the system was tested by accelerated cycles of filling/emptying, then monitored on grid power for thirty days.

Results
The LPOS performed well, including sustaining a pressure twice the working pressure before rupture of the outer bag. Flow of 1.2 litre/minute was maintained to a simulated 'patient' during 30 days, despite power failures totalling 2.9% of the time, with durations of 1-176 minutes (mean 36.2, median 18.5).

Discussion
LPOS is robust and durable, with testing equivalent to two years' operation revealing no sign of imminent failure. Despite power cuts LPOS provided oxygen, equivalent to the treatment of one child, for thirty days under typical African power conditions. The LPOS system is ready for clinical trials.

R510 Transitioning from improvised to safer BCPAP therapy

Mr. Michael Eisenstein, Mr. Eugene Saxon, PATH, United States of America

Each year, millions of preterm infants are born with immature lungs, which often leads to respiratory distress syndrome, a major cause of chronic illness and death. Many facilities in low-resource settings (LRS) have limited financial resources, unreliable electricity, and/or no source of compressed air. These barriers for facilities in LRS often prevent the use of commercially available existing continuous positive airway pressure (CPAP) devices. Therefore, providers in these settings often resort to improvising bubble continuous positive airway pressure (bCPAP) therapy by taping together scavenged medical tubing and bottles. These improvised devices do not blend air with tank-supplied oxygen, thereby providing 100% oxygen, which can cause blindness, chronic lung disease, and brain damage in preterm infants. To address this, PATH designed, developed, and optimized: (1) an appropriate and affordable bCPAP device that does not require electricity, batteries, or a source of compressed air to operate, and (2) an innovative oxygen blender that works by blending room air with oxygen. Together these two integrated device innovations provide facilities in LRS access to safer bCPAP delivery while minimizing equipment costs. At an estimated price of less than

US$20, our device will enable increased access to safe bCPAP therapy for preterm infants.

Personal Protective Equipment (PPE) for Ebola

Laboratory Evidence and Research	Prof. Daniel Bausch, UK Public Health Rapid Support Team, United Kingdom
End Users Perspectives	Dr. Andrew Hall, Mosoka Fallah, United Kingdom
Occupational Health and Infection Protection Control	Dr. Trish Perl, University of Texas Southwestern Medical Center, United States of America
Technical Specifications and Logistics and Procurement	Dr. Fatma Selcen Kilinc-Balci, John McGhie, International Procurement Agency, Netherlands
Preparing the preferred product characteristics (PPC) for innovative PPE	Dr. May Chu, Colorado School of Public Health, United States of America; Adriana Velazquez, WHO, Switzerland

Frontline health workers (FHW) worked under stifling and stressful conditions during the 2014 Ebola epidemic. Central to protecting FHW from Ebola were personal protective equipment (PPE) and infection prevention control practices. While PPE was meant to protect them, FHW were provided with a variety of PPE components that caused confusion especially during the donning and doffing process. This might have led to usually high number of Ebola infections in FHW but, in reality, PPE design, use and its protective effects has not been systematically addressed. The WHO invited FHW, researchers, clinicians, technical standards experts and logisticians and procurement specialists to review the scientific evidence on the protective effects of PPE for clinical management and high risk activities associated with high-threat pathogens. WHO has also engaged with innovators and PPE manufacturers to examine and elicit their comment on new designs and innovations for PPE. Through the recommendations of the specialists, WHO will produce a Preferred Product Characteristics document as guidance for industry and innovators to refine improvements to current PPE and for a new PPE to be designed, tested and standardized for the FHW working in tropical conditions when taking care of patients infected with high threat pathogens.

Human factors engineering

A234 Teaching appropriate medical device design to engineers

Prof. Walter Karlen, ETH Zürich, Switzerland

Since the introduction of the Sustainable Development Goals in 2015, it became clear that many of the 17 ambitious goals could not be reached without the support of technology. These health goals to reduce mortality rates from communicable and non-communicable diseases require better tools for accurate diagnosis, monitoring, treatment, and prevention. Although the concepts of appropriate health technologies have been promoted by the WHO since the late 1970's (C.A. Lomax 1980), there is still a mismatch in medical devices that can provide effective and efficacious performance within an economic, cultural and environmental context (WHO 2010).

At ETH Zurich we offer since Spring 2016 an appropriate health system design course to sensitize engineering and health science students to the challenges of developing user- and application-centered medical technologies. The students develop in flipped classrooms the concepts of system costs, performance, usage, and durability. Projection upon an unfamiliar persona is used from the beginning to practice empathetic design approaches, while shifting the focus from technology innovation to system assessment and management. The course not only promotes the principles of appropriate technology, but also application to and evaluation of current priority medical devices, training a new generation of biomedical device developers.

R343 Applying human centered design for medical devices

Mr. Vikas Meka, Marissa Leffler, Jennifer Fluder, Avery Waite, USAID, United States of America

Designing medical devices for low resource settings is challenging for a myriad of reasons, from the complexities of navigating multi-stakeholder ecosystems, to changing user behavior, to striking the right balance between affordability and business sustainability. Human-centered design (HCD), which places the end users and key stakeholders influencing user decisions at the center of the solution design process, can be critical to surmounting these hurdles.

Through several of the United States Agency for International Development's global health initiatives, including the Fighting Ebola Grand Challenge, HCD has been successfully applied to improve product design and space configurations, drive demand for services, and increase efficiency of systems. Specific to the medical device field, HCD was essential to the design of improved personal protective equipment for healthcare workers during the 2014 Ebola outbreak, as well as a low-cost, battery-powered infusion monitor for tracking flow rate and volume when administering IV medications, the DripAssist. In this presentation, we will share how HCD accelerated the evolution of these products, helped inform design decisions and increased the likelihood of adoption. At the end of this presentation the audience will appreciate the ways in which HCD can be used to support the development of successful global health innovations.

R496 Human-centered design of medical devices for global users

Prof. Beth Kolko, University of Washington/Shift Labs, United States of America

As a professor of Human Centered Design and Engineering, I have worked on healthcare technology development projects for over a decade. In that time, our teams have deployed prototypes on three continents, and across a range of health priorities. The academic literature on how to design from a human centered perspective is robust and covers key themes like appropriateness, affordability, and sustainability. However, what is less well understood is how to move medical device innovation from prototype or pilot into full, sustainable commercialization.

Commercialization challenges, sometimes referred to as the Trough of Sorrow, remain an intractable problem in ensuring innovations reach a wide audience. Achieving healthcare equity will depend on solving exactly that problem. In this presentation, I will discuss how Human Centered Design (HCD) can contribute to the additional challenges of scaling medical device innovation. In particular, HCD can be a method or framework for medical device entrepreneurship. Users and business models can be analyzed using the same methodologies as human centered product design in order to craft appropriate and sustainable approaches. Closing healthcare gaps requires attention not just to the devices we build, but how we share them with patients and clinicians around the world.

R647 Student-based maternal needs assessment for Sub-Saharan Africa

Prof. Kathleen Sienko, Timothy Johnson, Ibrahim Mohedas, Maria Young, University of Michigan, United States of America; Elsie Effah Kaufmann, University of Ghana, Ghana; Samuel Obed, Korle Bu Teaching Hospital, Ghana; Kwabena Danso, Thomas Konney, Tawiah Odoi, Henry Opare-Addo, Cornelius Turpin, Komfo Anokye Teaching Hospital, Ghana; Zerihun Abebe, St. Paul's Hospital Millennium Medical College, Ethiopia

We have developed an engaged-learning medical device design program that emphasizes direct interactions with stakeholders and firsthand exposure to the contexts in which solutions will be implemented. Students in the program gain practical hands-on experience identifying and defining unmet maternal health needs in low-income countries, and apply human-centered and co-creative design approaches. Device designs that incorporate rigorously collected and analyzed first-hand data from diverse users and stakeholders rather than anecdotal or poorly represented information are more effective at meeting true needs. To date, approximately 100 undergraduate student participants have identified hundreds of needs in collaboration with sub-Saharan healthcare providers. More than 350 students from the U.S., Ghana, and Ethiopia have contributed to the generation of medical device concept solutions to address these needs. Program outcomes include more than 70 student design projects completed at multiple institutions, student-led design-based conference publications and journal articles, device commercialization, and peer-to-peer mentoring within traditional capstone design courses.

WHO – Medical Devices and Digital Tools for Reproductive Health and Research (Round-table)	
Electronic MEC and Postpartum FP compendium	Mary Lynn Gaffield, WHO, Switzerland
RHR Task sharing guidelines interactive tool	Joshua Vogel, WHO, Switzerland
DMPA self injection and subcutaneous syringe	Caron Kim, WHO, Switzerland

The Department of Reproductive Health and Research at WHO RHR has produced some digital products and tools (either online or on an electronic drive) that can be used on computers, tablets, or smart phones, to enhance the use of information from the various guidelines and documents from the department. The session will include a short description of the product, providing links to the tool for some audience participation, and followed by discussions. Among the various tools to be presented would be: Electronic MEC wheel and Postpartum FP compendium, the Family Planning Training Resource Package (fptraining.org), Maternal Mortality Rate Country Progress Calculator, and the RMNH and Safe Abortion Task sharing guidelines interactive tool.

Management of Victims of Sexual Assault	Claudio Morenao Garcia, Avni Amin, WHO, Switzerland
Dual HIV and syphilis testing	TBD
Odon Device	Mercedes Bonet Semenas

The Special Programme for Research, Development and Research Training in Human Reproduction (HRP) hosted by the Department of Reproductive Health and Research (RHR) at WHO, has produced research on drugs and devices to improve the health of men and women for over 40 years. Past products include contraceptive vaginal rings, emergency contraception, and others. This session will describe recent products that have developed and the latest evidence on ongoing or completed research. The topics include the Odon device (an innovative tool to manage prolonged labor), evidence for self injection of hormonal injectable contraception by women, test packages for acute management of victims of sexual assault (rape kits), and evidence for dual testing of HIV and syphilis. Short presentations will be followed by open discussions.

Priority medical devices by healthcare facility

R593-2 Oxygen generators type PSA: solution for the supply of oxygen in Senegal

Awa Ndiaye Ep Diouf, Ministère de la Santé et de l'Action sociale, Senegal

Oxygen supply is a crucial problem in hospitals in developing countries. Today, we continue to die in certain structures or operative programs are canceled due to lack of oxygen, while solutions exist that are financially viable and adapted to the PED.

At present, the on-site generator oxygen generator (PSA) system provides an alternative to oxygen for traditional medical applications adapted to healthcare facilities with particular constraints, in particular supply difficulties.

Like most Developing Countries, Senegal has long been confronted with an oxygen problem due to a lack of financing for the purchase of gaseous oxygen in bottles, which was not always reliable. The indebtedness of our hospitals is decried across the country: oxygen supply is at the forefront. In some facilities, O 2 consumption represents the second largest item of competition for medicines.

To address this problem, in 2014, the Ministry of Health and Social Welfare undertook an oxygen autonomy project for hospitals in Senegal by installing oxygen generators such as PSA. Today, twenty-two (22) hospitals (all Public Health Establishments (EPS) Levels 3 and 2) are equipped with these types of generators.

And an acquisition procedure for mobile power stations for the ten Tier 1 EPS is expected in the second half of 2017 to cover all hospitals in Senegal.

The technology of oxygen generators type PSA (Pressure Swing Adsorption) is based on the

separation of gases from the air that uses the ambient air connecting raw material. The PSA process involves passing compressed air previously filtered through a column containing a molecular sieve called a zeolite.

A8-1 Equipment planning synchronised with hospital design and construction

Mr. Claudio Meirovich

New Hospital projects are expected to be completed in 18-24 months. Delays up to 18 months are most common. One of the main reasons for such delays is the lack of synchronization between construction works and "planning, procurement and installation of the new equipment".

The value of the equipment may be 30-40% of the total investment (new hospital) or up to 80% (rehabilitations). Why equipment it is not then synchronized with the construction?

The classic construction and equipment methodology does not consider any link between the equipment and the infrastructure and assumed no special works for the equipment to be installed. It is a very simple workflow where construction and equipment run in parallel without interaction or even as consecutive activities. Such model is destined to fail and comes along with several problems that in the end will impact the total construction time as well as in the total expenditure.

We propose a hospital project methodology including equipment as an integral part of the project allocating resources to plan equipment at the same time the building is designed and synchronizing the procurement and installation with construction and installations works. Final Result = Reduced costs and better implementation in time.

A171 Developing and advancing freeze-preventive vaccine carriers

Mr. Steven Diesburg, PATH, United States of America

Freezing of freeze-sensitive vaccines has been identified and confirmed as a pervasive issue in vaccine cold chains over the last couple of decades. However, technology solutions to consistently avoid freezing during vaccine transport and "last mile" outreach have not been available. PATH has been working with multiple partners to facilitate the availability, prequalification, and introduction of freeze-preventive vaccine carriers to immunization programs in developing countries. The effort has included:

- Analysis of multiple technical approaches to the problem as part of a multiagency working group.
- Research and design of a protective liner for existing vaccine carriers as well as testing to prove the concept and de-risk the new technology for potential manufacturers.

- Ensuring access to the protective liner concept for all vaccine carrier manufacturers.

- Technical support to the World Health Organization (WHO) to help create the required specifications and protocols for WHO prequalification of freeze-preventive vaccine carriers.

- Design, engineering, and market support to multiple manufacturers to encourage and accelerate introduction of one device meeting the necessary requirements.

This multifaceted approach to advance a new category of solutions has helped to inclusively encourage, enable, and support multiple stakeholders. Multiple devices in the category are now moving toward production.

R659 Strategic operation processes to scale a high specialty hospital from a general hospital

Ms. Claudia Cardenas Alanis, Escala Biomédica; Leila Dib Fajer, University Iberoamericana; Sandra Rocha Nava, National Institute of Cancerology, Mexico

Strategic change is an important process for hospitals. The planning phase of a change management project was realized to assist the Hospital General Naval de Alta Especialidad in

Mexico City towards change. This hospital will have two additional buildings, and the objectives of this project include: planning the change of the clinical services that will be operating in the first new building, and planning the preparation of health personnel for this first change.

As a result, the processes of the mentioned services were identified, the connections between services of the three buildings were studied and prioritized, and strategies were proposed.

Medical Devices for Emergency and Disasters

A228-3 Improving emergency preparedness through hybrid interactive training

Dr. David Yadin, IFMBE, United States; Rossana Rivas, UPCH/PUCP/CENGETS PUCP, Peru; Tobey Clark, University of Vermont, United States

Continuing provisioning of public health services in a safe, accessible, effective and efficient environment is critical for healthcare facilities during disasters, especially when in the disaster area. Emergency preparedness (EP) programs provide sustained operations consistent with needs, fostering protection, safety and well-being of community patients, employees, and staff with adherence to social responsibility. An EP plan based on a comprehensive vulnerabilities assessment, completed prior to unpredictable events, focuses on protection of systems and training.

The recent traumatic flooding disaster in Peru has created acute and longer term issues in population health, especially for children. Health centers were affected. To maximize the value of EP education and training - especially, where learners are at a distance from classrooms - hybrid interactive EP programs can be valuable.

This session describes methodology for hybrid training, achieved by combining strategic classroom sessions with ongoing webinars and online courses, preparing personnel to effectively respond to disaster challenges such as infectious and respiratory diseases and malnutrition. Learning objectives include application of knowledge to relevant case studies via a collaborative team approach to solutions; this approach for public health in Peru is a valuable and pertinent evidence for other global health sectors who face similar health challenges.

A112 Accelerating innovation during a global health crisis

Mr. Vikas Meka, Marissa Leffler, Jennifer Fluder, Avery Waite, USAID, United States of America

As the global response to contain the 2014 Ebola epidemic in West Africa unfolded, clear gaps in the health systems emerged. In order to end the outbreak the global community was challenged to think differently about the most efficient ways to work in an epidemic. In an effort to promote new ways of working and fill some of these system gaps, the United States Agency for International Development (USAID) funded 14 innovations to fight Ebola. In less than two years, seven of the innovations were market ready. This presentation will highlight lessons learned from innovating in the midst of an infectious disease outbreak. We will share how innovators focused their design efforts on the needs of healthcare workers by spending time in Ebola treatment centers during the midst of the outbreak; and, later, balancing the design changes made to meet the care workers' needs with manufacturer capabilities. We will showcase this dynamic with two case studies, which will investigate the tension between developing medical devices to meet end users' needs and ensuring commercial viability. This session will illustrate USAID's unique approach to accelerate the development and sustainability of health innovations, and how this model is being applied to combat Zika.

R645 Medecins Sans Frontieres medical equipement framework

Ms. Gabriela Jimenez Moyao, Oscar Rodriguez, Tom Lauwaert, Jean Claude Tewa, Medecins sans frontieres (MSF), Belgium; Benoit Pierre Ligot, Paul Damien Chateau, MSF, France; Hugues Gaertner, MSF, Spain; Malcom Townsend, MSF, Switzerland; Lizette Van De Kamp, Sean King, MSF, Netherlands

MSF is an International Medical Organization that delivers humanitarian medical assistance to people affected by conflict, natural disasters, epidemics or healthcare exclusion. Medical equipment is a vital part to deliver and perform the medical interventions since a refrigerator for a

vaccination campaign, a microscope for malaria diagnosis, an anesthesia machine for a mobile surgical unit or the basic oxygen concentrator. MSF have an internal setup of human resources in the field and at the headquarter that takes care of the equipment during all its life cycle, planning, budget, technical assessment and selection, procurement, commissioning, training, safe operation, maintenance etc. Until now more than 300 documents have been developed to support each of our projects in terms of medical equipment considering the evident particular contextual characteristics: remoteness, insecurity, volatility and also important to cope with challenges such as shortage of skilled human resources, lack of support of distributors or manufacturers on site, difficult accessibility to spare parts and tools etc. Everything is done with the objective to increase the availability of medical devices in such contexts.

R465 Choosing a product that works: household water treatment in emergencies

Dr. Batsirai Majuru, WHO, Switzerland

Household water treatment (HWT) and safe storage is an important public health intervention to improve the quality of drinking-water and prevent water-borne disease. When effective methods are used correctly and consistently, HWT and safe storage can reduce diarrhoeal disease by as much as 45 %. The International Scheme to Evaluate Household Water Treatment Technologies (the Scheme), was established by the World Health Organization (WHO) to independently and consistently evaluate the performance of HWT technologies in removing pathogens from drinking-water. The results of these health-based evaluations are intended to guide governments, procuring agencies and users at large in product selection. Through an open call for submissions, a range of products representing filtration, solar, ultraviolet (UV) and chemical disinfection methods have been evaluated under the Scheme.

The session will present the results from this first ever global evaluation of HWT technologies, and seeks to stimulate discussion on key needs to support application of these results in HWT product selection, and strengthen implementation of HWT in humanitarian and emergency relief contexts. The expected outcomes from the session are: increased awareness of WHO performance recommendations for HWT, and increased understanding of their application in product selection and humanitarian emergency response.

R593 Proposed acquisition of 162 ambulances and 4 mobile units

Ms. Awa Ndiaye Ep Diouf, Ministère de la Santé et de l'Action sociale Senegal; Amad Diouf, Division Etudes et Programmation, Direction des Infrastructures des Equipements et de la Maintenance, Senegal

The project is part of the strategic programs of the MSAS, namely:

- The emergency plan for the improvement of the curative care system in which it is planned to acquire four hundred and four (483) medical ambulances and mobile units;
- The Strategic Plan for the Development of the Supply of Surgical Care, of which mobile units are a component;
- The Strategic Plan of the Medical and Emergency Assistance Service (SAMU).

Therefore, the realization of this project remains a priority for my department in accordance with the instructions of the President of the Republic.

MSAS initiated a procurement consultation through an international competitive bidding process.

The contract is for an amount of seven billion five hundred forty million eight hundred eighty eighty five hundred and eighty-four (7,540,881,584) CFA Francs for the supply of one hundred and sixty-two (162) ambulances and four (04) mobile units
The Convention is signed and the conditions of the loan contracted with the Banco BIP of Portugal for the supply of these ambulances and mobile units.

The ambulances and mobile units will be linked by a geolocation system whose server will be at

Samu National and the Directorate of Infrastructures of Equipment and Maintenance (DIEM) which will be able to control the position of each ambulance throughout the national territory.

An equipped repair vehicle will also be provided and assigned to the MSAS central garage for vehicle tracking.

Therefore, the realization of this project remains a priority for the health department in.

Tools to support medical device management	
R152	Appropriate CMMS systems – potential for health systems development

Mr. Martin Raab, David Huser, Alexandre Vanobbhergen, Swiss Topical and Public Health Instititute, Switzerland

The availability of appropriate, safe and efficient medical equipment is vital for any health system to perform. But there is plenty of evidence that investments in medical equipment are not based on rational planning and underperforming procurement procedures. Not adequate equipment management capacities further lead to the non-availability of clinical devices for crucial health interventions.

CMMS's provide a powerful means of enabling strategic investment planning, the guidance for the maintenance of the devices and the crucial link to the management of health facilities and health systems.

Why do we observe still a wide scale failure of CMMS's working properly in Low and middle income countries? The lecture builds on more than 10 years of experience in implementing medical equipment management systems in Eastern Europe, the Middle East and African countries. This experience has led also to the development of an openSource CMMS' that is available to the biomedical community. The lecture will cover issues such as good implementation practices, nomenclature, essential equipment lists, pathways of capacity building and technical themes ranging from mobile solutions to data security.

A198-2	Web-based medical equipment management system

Prof. Nicholaos Pallikarakis, Panayiotis Malataras, Institute of Biomedical Technology (INBIT), Aris Dermitzakis, University of Patras/Biomedical Technology Unit, Patras, Greece

The constantly increasing number and complexity of MD during the last decades, have made clear since the end of the 80's that for the efficient management of MDs, software tools are of necessary. During the last 10 years, given the impressive progress in the fields of computer sciences and information & communication technologies (internet, mobile devices, etc.) led to the development of new software tools and platforms with new programming capabilities and better infrastructures, have altered the way such computerized management systems operate. A web based version of Medical Equipment Management System (MEMS) provides today great assistance to Clinical Engineering Departments (CEDs) in order to assure safety, effectiveness, and efficiency in the use of medical equipment. These systems are today modular, and support all main tasks, such as: Inventory, Corrective Maintenance, Preventive Maintenance, Contract and Spare Part Management, Statistics/Reports and Assigned Work Scheduler. These modules are interrelated in a logical manner to support all clinical engineering services and are distance accessible, thus facilitating their use.

R511	Proposal: WHO nomenclatures for medical devices

Mr. Murilo Contó, PAHO / WHO; Leandro Safatle, ANVISA, Brazil; Vania Canuto, Ministry of Health, Brazil

Countries invariably adopt medical device nomenclatures from private bases or create their own standard because they understand that such bases do not fully meet their needs. The result is often

operational difficulties related to financial issues or the lack of comparability with other standards.

The adoption of nomenclatures is usually associated with regulatory issues for techno-surveillance purposes, where only a generic name identifying the device is sufficient. However, when it comes to issues related to the financing, reimbursement or economic monitoring of the market, where there is a need for comparisons and parameterizations, there is a need for greater detail in the nomenclature in order to promote a differentiation between devices of the same nature, but with different values added.

A strategy for establishing a standard of classification organized and managed by WHO and its regional offices can meet the needs of member countries, both from the standpoint of regulation and also from the technical-economic monitoring of the market.

With a WHO standard of nomenclatures, countries can easily exchange technical-economic information on medical devices, increasing the power of comparability and the subsidies for decision-making. In Brazil, the Ministry of Health and ANVISA support this initiative.

Injection Safety Symposium

Overview of the WHO Injection Safety Policy and Implementation Strategy	Edward Kelly, Benedetta Allegranzi, WHO
Working together with industry under POPS Injection Safety	Lisa Hedman, WHO, Switzerland
Achievements and challenges in Egypt	Alaa Hashish, WHO, Egypt
Sustaining progress achieved in injection safety	Evelyn McKnight, HonoReform Foundation, United States of America
Launch of POPS IS and closing remarks by Assistant Director General	Marie Paule Kieny, WHO, Switzerland

To address the global problem of injection safety WHO introduced guidelines in 2015 which recommended that all Member States should switch to exclusive use of safety engineered syringes for intramuscular, intradermal and subcutaneous injections in health care settings. The recommendations include syringes with reuse prevention (RUP) feature and syringes with sharp injury protection (SIP) feature. Global IPC Unit which is where injection safety is housed has embarked on a global campaign in three pilot countries which include India, Egypt and Uganda. The intervention is designed on a standard set of key process indicators which are followed in the three countries. As the first step Ministries of Health, WHO Country Offices and other stakeholders have been taken on board. One of the key process indicators in the intervention was a comprehensive baselines assessment of injection safety using WHO Tool C which has been successfully completed in two countries. The results of the assessment will be used to formulate national policy of injection safety and a community and health care provider targeted communication campaign. The presentation will highlight the achievements and challenges in continuing the intervention and lessons learned for future projects.

Innovation of medical devices for newborn and children care

R238 Groundbreaking devices to save lives at birth

Mr. Vinesh Kapil, Karen Clune, U.S. Agency for International Development, United States of America

An estimated 2.6 million stillbirths, 2.7 million neonatal deaths and 303,000 maternal deaths occur globally each year, signaling a major gap in interventions specifically around childbirth and the early postnatal period – a time when mothers and babies are most vulnerable. Innovative ideas that can leapfrog conventional approaches to address inequities and inequalities of care are critical in surmounting this gap.

Since 2011, the Saving Lives at Birth Grand Challenge Partnership – the U.S. Agency for International Development, the Bill & Melinda Gates Foundation, the Government of Norway, Grand Challenges Canada, the UK's Department of International Development, and the Korea International Cooperation Agency – have sought groundbreaking prevention and treatment approaches for

pregnant women and newborns in underserved communities around the time of birth. Over seven years, the Partners sourced a robust pipeline of 107 potentially gamechanging innovations. In this session, participants will learn about this exciting crowd-sourcing model for development and some of the innovative devices in the portfolio. Highlights will include a low-cost uterine balloon tamponade, which has shown a nearly 95% survival rate against postpartum hemorrhage; the Pumani bubble Continuous Positive Airway Pressure (bCPAP) system to reduce newborn deaths from respiratory distress; and PharmaChk, a substandard drug detection device.

R648 Newborn essential solutions and technologies

Dr. Megan Heenan, Queen Dube, Josephine Langton, Robert Miros, Jocelyn Brown, Megan Heenan, Elizabeth Molyneux, Maria Oden, Rebecca Richards-Kortum, Rice 360 Institute for Global Health, United States of America

Complications of preterm birth cause the deaths of 1.09 million children each year. As many as 85% of these babies could be treated using technologies which are effective in high-resource settings but which fail in Africa due to harsh environmental conditions, complex maintenance requirements, and lack of stable infrastructure. To address the persistent challenge of newborn death, we are implementing a comprehensive package of Newborn Essential Solutions and Technologies which are as effective as those in high-resource settings but cost less and are setting-appropriate.

As a part of this package, we have successfully implemented a bubble continuous positive airway pressure system in all 4 central and 27 district hospitals in Malawi, including clinical training, education, usage and outcome tracking. Following this model, we are also beginning the process of implementing a robust, low-power syringe pump for delivering fluids and medications, an apnea monitor, and a bilirubin meter for point-of-care diagnosis of jaundice. We are currently refining these and other NEST technologies for commercial manufacture and international regulatory approval. We plan to implement NEST at all hospitals in Malawi, with the goal of preventing 50% of newborn deaths and producing a sustainable roadmap for rapid uptake across the rest of Africa.

R634 Phototherapy to reduce exchange transfusions

Mr. Luciano Moccia, Firetree Asia Foundation, China; Arnolda Gaston,University of Sydney, Australia; Trevisanuto Daniele,Padua University Hospital, Italy

Jaundice is a common problem and if left untreated it can lead to acute bilirubin encephalopathy or death.

In Myanmar, almost half of all neonatal admissions in hospitals are for hyperbilirubinaemia, and all facilities report high rates of Exchange Transfusion (ET). As part of a program of quality improvement we introduced high-power LED phototherapy, with training and follow up, evaluating the effectiveness of the program in reducing ET. There were 118 ETs among inborn and 140 ETs among outborn. The ET rate was unchanged at Hospital A (RR = 1.07; 95 % CI: 0.80–1.43; p = 0.67), and reduced by 69 % at Hospital B (RR = 0.31; 95 % CI: 0.17–0.57; p < 0.0001). For outborn neonates, the pooled estimate indicated that ET rates reduced by 33 % post-intervention (RR MH = 0.67; 95 % CI: 0.52–0.87; p = 0.002); heterogeneity was not a problem. Hospital A had four times as many admissions for jaundice as Hospital B, and did not reduce ET until it received additional machines. The results highlight the importance of providing enough phototherapy to treat all neonates. An improved version of the machine is 12V device, with external battery to provide treatment even in the absence of electricity.

R310 Premature breathing system

Prof. Anjelica Gonzalez, Yale University, United States of America

PremieBreathe addresses the widespread global health problem of neonatal mortality due to respiratory failure.Over one million newborns die each year due to pneumonia, preterm birth and other respiratory related causes, accounting for 40% of newborn deaths. While life-saving breathing support technologies are widely available in high-income countries, these respiratory aids are not affordable or designed for use in low-income countries, where the majority of these deaths occur.

PremieBreathe is a functional infant breathing aid that serves as a humidified high flow nasal cannula, and has become the modern gold standard of non-invasive neonatal respiratory care in high-income countries. PremieBreathe has been designed to adapt to the constraints of low-resource clinical settings and minimizes reliance on hospital infrastructure and disposable components. Laboratory testing of the device has demonstrated clinical outputs on par with commercial HHFNC technology and can be produced at a fraction of the cost. The development of PremieBreathe, its testing and its implementation strategy have been devised in collaboration with partners at Ayder Hospital in Tigray, Ethiopia. There, the successful implementation of PremieBreathe technology could prevent up to 880 deaths a year in the pilot region, and ultimately save thousands of newborn lives around the world.

	Quality and safety of Medical Devices
R641	Non-ionizing radiation for diagnostic and cosmetic purposes

Prof. Adele C. Green, ICNIRP, International Commission on Non-Ionizing Radiation Protection, Germany; Jacques S. Abramowicz, World Federation for Ultrasound in Medicine and Biology (WFUMB), United States of America; Emilie Van Deventer, World Health Organization (WHO), Switzerland

An increasing number of medical devices, ranging from magnetic resonance imaging (MRI) and ultrasound to laser and light-emitting diodes, employ forms of non-ionizing radiation (NIR). The use of such devices involves human exposure to fields that may be electric, magnetic, electromagnetic, optical or ultrasound. The health risks related to NIR medical devices are clearly less than for those employing ionizing radiation (e.g. X-ray, CT), but as noted in a recent statement by ICNIRP (http://www.icnirp.org/cms/upload/publications/ICNIRPDiagnostic_2017.pdf), there remains a lack of data on certain potential long-term risks (e.g. in workers exposed to MRI, and in fetuses exposed to MRI or ultrasound during the first trimester) which deserves further research.

Given the utility of NIR diagnostic devices and the lack of confirmed health risks from their properly-implemented use, there are not currently calls for enhancing existing regulation. However, the growing unregulated use, often by laypersons, of NIR devices for cosmetic purposes (for example, laser removal of tattoos or body-shaping with ultrasound) is of concern and highlights the need for operator training and regulatory review.

A190-2	The single-use reuse problem in low-income settings

Dr. Ryan Lewis, Megadyne a Johnson & Johnson Family of Companies, United States of America

Low-resource settings by definition do not have the luxury of disposing of single use medical devices. In high resource settings often costs of single use devices are covered by 3rd party payers and threat of litigation is high from patient to patient transmission of diseases due to cross contamination. We explore the conflicts and roadblocks to creating the right devices for the right setting as it pertains to low income nations. Taught by a medical device industry executive and expert (MD, MPH).

R215	Equipments for safer anaesthesia for everybody today

Dr. Philippe Mavoungou, WFSA, United Kingdom

135 Member Societies of anaesthesiologists, covering over 150 countries, constitute the World Federation of Societies of Anesthesiologists (WFSA). It is the largest forum of this medical specialty and unites hundreds of thousands of anaesthesiologists behind the goal of ensuring universal access to safe anaesthesia. The WFSA has official liaison with the WHO.

Use of technology to monitor, support and control vital functions is a crucial part of modern anaesthesia care and it has brought tremendous progress in the safety of anaesthesia.

Unfortunately, access to the medical devices needed for safe anaesthesia remains problematic for many LMICs.

The Ad-hoc Anaesthesia Equipment Committee of the WFSA brings together global expertise in anaesthesia equipment and varied operating environments to advance patient safety and access to safe anaesthesia worldwide. It does this by:

1. Identifying component parts for a basic WFSA "Safe Anaesthesia Kit" (the essential equipment necessary for safe anaesthesia).

2. Defining and agreeing global performance standards for anaesthesia equipment.

3. Anticipating technological developments in anaesthesia equipment and determining whether these will be beneficial to LMICs.

4. Establishing a process for the anaesthesia community to engage with equipment developers to ensure that equipment is developed according to the international context (quality, suitability, affordability).

R513 Neonatal resuscitation equipment maintenance to prevent infection

Dr. Manjari Quintanar Solares, Siobhan Brown, PATH, United States of America

Birth asphyxia is a leading cause of neonatal death. Global efforts such as Helping Babies Breathe (HBB) aim to increase access to neonatal resuscitation in any facility where a baby is born. These efforts include training skilled birth attendants and providing them with neonatal resuscitation equipment. In order to provide quality neonatal resuscitation, maintenance and correct use of the equipment is key. Health workers need training to properly reprocess reusable neonatal resuscitation equipment to make it safe for use with the next patient, and in this way decrease incidence of hospital-acquired infections. To address this need, PATH led a consensus process with global experts to develop Reprocessing Guidelines for Basic Neonatal Resuscitation Equipment in Resource-Limited Settings, which support implementation of HBB. The guidelines contain an overview of reprocessing materials and equipment, space planning and workflow, detailed step-by-step disinfection instructions, training and supervision considerations, and further considerations for health facility administrators and ministry of health officials. Job aids and training materials were also developed. The guidelines provide several disinfection method options and may be adapted to the reality of each health facility. We will share lessons learned from a capacity-building workshop conducted in Uganda on these guidelines.

A116 Is ultrasound safe for my baby?

Prof. Jacques Abramowicz, WFUMB and University of Chicago, United States of America

Ultrasound is one of the most common diagnostic procedures, particularly in obstetrics. The consensus among users and patients is that ultrasound in completely safe. Ultrasound is a form of energy, with positive and negative pressure, causing effects in any insonated tissue: direct effect of the pressure and indirect effect, due to transformation of the acoustic energy into heat. Bioeffects have been demonstrated in cells and animals but harmful effects have been shown in humans. Epidemiological studies, however are about ultrasound machines from before 1992. At that time, the US Food and Drug Administration (FDA) allowed output for fetal use to be increased by a factor of 8, on the condition that two indices were displayed in real-time: the thermal index (TI), an indication of the possible temperature rise in degrees Celsius, for assessment of the risk of thermal effect and the mechanical index (MI) for the risk of non-thermal effect. Some modalities (e.g. pulsed Doppler) will result in high TI (5 or more), if precautions are not taken. Heat is known to be teratogenic, thus clinician's compliance is vital. A major problem is that only 25% of users worldwide know about these indices or safety. Education is of utmost importance.

Radiation for diagnostic and treatment

R695 Innovations in multimodality imaging devices

Prof. Habib Zaidi, Geneva University Hospital, Switzerland

Early diagnosis and therapy increasingly operate at the cellular, molecular or even at the genetic level. As diagnostic techniques transition from the systems to the molecular level, the role of

multimodality molecular imaging becomes increasingly important. Positron emission tomography (PET), x-ray CT and MRI are powerful techniques for in vivo imaging. The inability of PET to provide anatomical information is a major limitation of standalone PET systems. Combining PET and CT proved to be clinically relevant and successfully reduced this limitation by providing the anatomical information required for localization of metabolic abnormalities. However, this technology still lacks the excellent soft-tissue contrast provided by MRI. Standalone MRI systems reveal structure and function, but cannot provide insight into the physiology and/or the pathology at the molecular level. The combination of PET and MRI, enabling truly simultaneous acquisition, bridges the gap between molecular and systems diagnosis. MRI and PET offer richly complementary functionality and sensitivity; fusion into a combined system offering simultaneous acquisition will capitalize the strengths of each, providing a hybrid technology that is greatly superior to the sum of its parts. Future opportunities and the challenges facing the adoption of multimodality imaging technologies and their role in biomedical research will also be addressed.

R317 Diagnostic imaging: vital role in management of non- communicable diseases

Dr. Miriam Mikhail, RAD-AID International, diagnostic radiologist, consultant, Switzerland; Nikita Consul, Columbia University chapter of RAD-AID International, United States of America; Elise Desperito, Melissa Culp, RAD-AID International, United States of America

Granted the known trend of increasing global morbidity and mortality attributable to non-communicable diseases (NCDs), the WHO has elected to prioritize a global

action plan for prevention and control of NCDs. Diagnostic and interventional imaging are vital, appropriate technologies within evidence-based, often algorithmic primary care guidelines for management of: cardiovascular diseases, cancer, chronic respiratory diseases, and diabetes complications. According to WHO data, these 4 disease categories account for 82% of NCDs deaths, almost 3/4 of which occur in low and middle income countries. Therefore, diagnostic and interventional imaging technologies should be considered key within universal health coverage, and under WHO NCDs target 9: "80% availability of the affordable basic technologies..." towards preparation for the Third UN High-level Meeting on NCDs (2018). Optimal NCDs management cannot be achieved in the absence of national strategies for needs assessment, procurement, appropriate use, and maintenance of diagnostic and interventional imaging technologies; as part of a multistakeholder, integrative strategy to NCDs management, essential to complement the goals of WHA resolutions, including those on surgery and palliative care. Moreover, the socioeconomic benefit of addressing the current deficit of medical imaging stands to save or prolong millions of lives and bolster the economies of lower income nations.

A91 Improving universal health coverage : Kenya PPP example

Ms. Gisela Abbam, Farid Fezoua, GE Healthcare Africa, Ministry of Health, Kenya

GE Healthcare partnered with the Kenya Ministry of Health to modernise 98 hospitals across 47 counties to improve access for healthcare as part of the aim of universal health coverage. The process entailed an analysis of the demographics and services required for these hospitals. The partnership also included the development This of a healthcare skills and training institute in Kenya with the aim to train over 10,000 healthcare professionals over the next 3 years.

The session will focus on the Kenya PPP model and discuss the learning from the process of achieving an integrated healthcare system for all the 98 hospitals and the initial impact and outcomes through innovative and affordable medical technologies.

Based on 70 modernized hospitals delivering services to patients in 42 of the 47 counties we see very positive early results.

Emphasizing the Ministry's focus in digital transformation to bring better quality healthcare, an increase in examination volume post implementation from about 1,500 monthly digital exams to 29,000 monthly digital exams across the first 44 hospitals.

Improved workflow efficiency has shown a 14% reduction in average scan time from analogue to digital.

https://www.standardmedia.co.ke/health/article/2000205945/ge-opens-up-sh1-3-billion-training-institute-in-kenya

R453 Status of radiological equipment used in Nepal

Dr. Kanchan P. Adhikari, National Academy of Medical Sciences, Bir Hospital, Nepal

Nepal, one of the least developed countries with population of 26.6 million people is the biggest populated country among countries without a regulatory body. Nepal has a long history of medical radiology since1923. Newer modalities are being introduced in major hospitals and the latest radiological equipment are being imported. This quantitative increment may have a positive impact on the health service system of the country; but the lack of control is a serious problem. Nepal, still do not have legislative body or any radiation act to set standards for radiation safety. Official records of the exact number of the radiological facilities in operation are also lacking.

The aim of this study was to find out present status of radiation emanating equipment being used in Nepal. Questionnaire was designed to make to an inventory of availability of equipment, personnel radiation dose monitoring, commissioning and quality control tests.

Commissioning and quality control program have not practiced in most of the hospitals, but few has maintenance contract with vendor. 65% of workers have never been monitored for radiation exposure. There is an urgent need to establish regulatory authority to regulate the use of radiation.

A110 Ensuring Radiological Security in the Context of Cancer Treatment

M Ms. Kristina Hatcher, U.S. Department of Energy, United States

Radiotherapy is one of the three main pillars of cancer treatment, along with chemotherapy and surgery. According to the International Atomic Energy Agency, the benefits of radiotherapy include: "survival and improved quality of life, but also…immense palliative value, reducing pain and suffering, particularly in settings of limited access to pain medications." Radiotherapy is needed to treat approximately 50-60% of all cancer patients; however, the percentage of patients receiving radiotherapy is highly dependent on the availability of equipment, of which there is a global dearth.

The goal of this workshop is to provide developing countries with a holistic view of the characteristics of two radiotherapy technologies to make an informed decision regarding the most appropriate solution for patients. Aspects such as pricing, human resources, security, infrastructure, clinical capabilities, source replacement, safety and patients' quality of life are examined and compared by clinicians and radiation safety experts in an interactive workshop. Attendees will learn about the broad spectrum of evaluation criteria for selecting and successfully implementing a radiotherapy solution for their health institution or country.

IAEA´s perspective on radiotherapy

Mr. Rajiv Prasad, IAEA, Austria

Radiotherapy is one of the major treatment modalities for cancer, benefiting approximately 50-60% new cancer patients. The process of radiotherapy is complex involving multiple steps and multiple technologies. Setting- up a radiotherapy services in a country requires a systematic approach. It involves the assessment of national needs and countrywide distribution of radiotherapy facility, staffing requirements, selecting the right technology(e.g. Cobalt vs Linear Accelerator) and meeting quality and safety requirements. The decision making process regarding the technology is complex and requires consideration of various factors e.g. patient and technical factors associated with each technology, local circumstances (e.g. consistency of electric supply),cost considerations and safety and security issues etc. Radiotherapy services should be developed within the framework of national cancer control programme.

Innovation for in vitro diagnostics

A173 A new point-of-care diagnostic test for sickle cell disease

Mutsumi Metzler, Patricia Coffey, Mercy Mvundura, Jeanette Lim, PATH, United States of America

Sickle cell disease (SCD) is an inherited hemoglobin disorder that results in mild to severe chronic anemia. In Africa, the majority of children with the most severe form of the disease die before the age of five years. The current laboratory-based diagnostic tests for SCD and SCD traits are complex and costly. An inexpensive, easy-to-use, point-of-care (POC) diagnostic test is needed to enable medical professionals in low- and middle-income countries to start managing SCD early, thereby giving newborns the chance to survive beyond age five. PATH evaluated the usability of a prototype POC diagnostic test for SCD in Uganda, and conducted a cost study to estimate the cost per child screened and diagnosed for SCD (under the current pilot screening program in the country) and the model price thresholds for a POC diagnostic test. Our usability study showed that a POC diagnostic test has the potential for use in primary health care in low-resource settings. The cost study identified that the upper price threshold for a POC diagnostic test for SCD should be between US$4.20 and $5.50, depending on use cases and product profiles, in order for the cost to be comparable to the current method used in Uganda.

R701 Key considerations in implementing point-of-care in Kenya

Ms. Nancy Bowen, Ministry of Health, Kanya; Wafula, Rose, Nascop, Kenya

Background: While Kenya has a robust HIV laboratory network, POCT has been identified as helpful in complementing conventional laboratory practice and bringing services closer to patients in urgent need. In this regard, the NPHLS through partner and stakeholder involvement provides The Key Considerations in Implementing Point of Care in Kenya guidelines. This document is intended for use by various stakeholders including national and county health policy makers and program managers, development partners, investors, implementing partners, logistics and procurement personnel, laboratory and health care service providers.

Methods: Development of key thematic areas in POC programming and a road map necessary for implementation. In addition, mandatory requirements that need to be enforced as a part of a quality management system in compliance with ISO 22870 particular for quality and competency were also developed.

Results: Successful development of a comprehensive national Point of Care business plan in Kenya that now allows for POC implementation

Conclusion: The newly developed national Point of Care Business plan is a promising government initiative that will better treatment outcomes to PLWHAs with the overall goal in using innovative technology to attain the KASF 90-90-90 targets.

R305 Integrated human diagnostics and vector control towards OneHealth

Dr. Konstantinos Mitsakakis, Oliver Strohmeier, Nils Paust, Roland Zengerle, Sebastian Hin, University of Freiburg, Germany; Benjamin Lopez-Jimena, Manfred Weidmann, University of Stirling, United Kingdom; Seamus Stack, Mast Group Limited, United Kingdom; Mohammed Bakheit, MAST Diagnostica GmbH, Reinfeld; Vanessa Klein, Hahn-Schickard; Sieghard Frischmann, MAST Diagnostica GmbH, Germany; Cheikh Fall, Amadou Sall, Institut Pasteur de Dakar, Senegal; Khalid Enan, Central Laboratory, Khartoum, Sudan; Liz Gillies, Mast Group Limited, Liverpool, United Kingdom; Sven Goethel, Viorel Rusu, MagnaMedics Diagnostics BV, Geleen, The Netherlands

Acute fever is one of the most common symptoms among patients globally. The fact that several different febrile diseases exhibit the same clinical symptom increases the risk of misdiagnosis (especially in resource-limited settings) and subsequently misuse of antimicrobials, increase of death rates and resistances. The diagnosis becomes even more complicated in case of co-infections or epidemics overlapping with endemic diseases.

To address these challenges we propose the integrated management of febrile syndrome through genetic-based pathogen identification on a multi-target platform (LabDisk), which was successfully

demonstrated in Senegal and Sudan. The disc-shaped microfluidic cartridge requires 200µL blood/serum for analysis. It performs in situ extraction and amplification of both DNA and RNA of pathogens thanks to its universal components (nucleic acid extraction, lyophilized LAMP isothermal amplification reagents, air-dried sequence-specific primers). Accelerated pre-storage tests indicated reagent stability and no need for cold chain in transport. The platform can detect up to 12 pathogens simultaneously and the time from sample addition to result (including in situ sample preparation) was 90-120min (depending on the assay). The detected pathogens were: malaria, dengue (various serotypes), chikungunya, Salmonella Typhi/Paratyphi, and Streptococcus pneumoniae. Manufacturability and connectivity issues are also presented, to enable affordability, and applicability in surveillance settings.

Prequalification for in vitro diagnostics

Ms. Deirdre Healy, WHO, Switzerland

The lack of regulatory oversight remains a challenge in many countries. To fill this gap, the WHO Prequalification of In Vitro Diagnostics (PQDx) undertakes an assessment of IVDs through a standardized procedure assessing their safety, quality and performance. The

prequalification process includes:

- Review of a product dossier;
- Performance evaluation; and
- Manufacturing site(s) inspection.

PQDx also conducts post-market surveillance and review of changes to prequalified products and/or the manufacturer's quality management system. The outcomes of the prequalification process are used by WHO Member States, UN agencies and international procurement agencies to guide their procurement decisions. Attendees will be guided through a detailed description of the different components of the process.

Affordability, Appropriateness, Acceptability, Availability, Accessibility of Medical Devices

R140 Medical device ownership models and maintenance contracting approaches

Ms. Lisa Smith, Michael Ruffo, PATH, United States of America

Maintenance and after-sales service is a consistent challenge across many developing countries. Traditional warranties have not been as effective at maintaining device functionality in these settings due to limited terms and conditions of warranties, non-transparent sharing of warranty information to the end-users (e.g., health care workers), complex supply chains, and poor accountability of suppliers. Without the capability to ensure effective device operation, both suppliers and end users face the risk of failed implementation. The result of this is wasted financial resources and negative experiences with life-saving equipment, which may adversely affect future procurement decisions.

To understand challenges and successes in the current market, PATH conducted an assessment of existing maintenance approaches for medical devices in select low- and middle-income countries. We evaluated maintenance approaches that are most appropriate for different categories of durable medical devices, ownership models for device procurement and maintenance, contracting terms with distributors (and/or manufacturers), and opportunities for leveraging analogous maintenance approaches from other device industries. This assessment concludes with key considerations and recommended approaches for improving medical device functionality through after-sales service models that are appropriate in developing countries. It also outlines remaining questions and future areas of work to best tailor implementation by country.

R463 Appropriate digital X-ray system with eHealth services

Mr. Romain Sahli, Ecole Polytechnique Fédérale de Lausanne, Switzerland

All too often in developing countries, patients die of trivial problems, which due to a lack of access to diagnosis, take dramatic proportions. Road accidents, tuberculosis and complications from

childhood pneumonia are the most recurrent examples of pathologies causing complications that could have been prevented with functional and efficient x-ray imaging services.

The goal of the GlobalDiagnostiX project is to develop a robust and low-cost digital x-ray system specifically adapted to the context and climatic environments of low and middle-income countries. This means:

- Rugged design to work effectively and durably under the most challenging conditions (tropical climates, electrical instabilities, shocks, etc.)

- Integrated uninterruptible power supply featuring energy stabilization and power reserve for several hours of autonomy in case of power cut and can be powered by renewable sources of energy such as solar panels

- Comprehensive workstation implementing a user-friendly adapted interface with tutorials

- Deployment of eHealth services such as telemedicine and remote maintenance

- Total cost of ownership has to be reduced tenfold (including initial purchase, maintenance and repair costs over ten years) compared to existing solutions available on the market

This ambitious project involves over 40 researchers and experts in Switzerland and in Africa. A functional prototype has been realized in 2015 and demonstrated the feasibility. Ongoing research continues to improve the cost of the technology and its durability in the context, as well as concerning the user interface and the development of eHealth services.

A spin-off company, PRISTEM SA, was incorporated in December 2015 for the industrialization and the deployment stages of the project, raising strong interest from investors.

A99-2 Skill development for growth in emerging markets

Ms. Gisela Abbam, DITTA, Belgium; Marut Setia, Head of Education and Professional Services

While companies including GE toil hard to solve the access, affordability and quality conundrum, one often ignored challenge is availability of skilled manpower to use technology and deliver superior patient outcomes. The burden of creating skills often falls on governments who seldom find themselves ill-equipped to keep up with the pace of technology change and changing manpower requirements.

Identifying this growing challenge in 2014, GE Healthcare collaborated with Government of India to create programs that train high school graduates over 1-2 years and make them employable for healthcare jobs. The program has since been scaled to 20 cities in the country through various collaborations with a projection of more than 2,000 graduates in 2017. The program solves the twin challenge of unemployable youth and lack of qualified technicians in healthcare delivery space. GE Healthcare also runs more than 60 programs for up skilling the current workforce through hands on and online training for physicians, technicians, nurses and administrators.

GE Healthcare is now in the process of expanding these programs (new skill development & upskilling) to other countries in South Asia, Africa and ASEAN at a disruptive cost points to enable delivery of superior healthcare services across the region.

List of medical devices, nomenclature & pricing (Round-table)

National lists of medical devices by country, global nomenclature for medical devices and medical devices pricing

Mr. Alexandre Lemgruber, WHO AMRO, United States of America; Adham Ismail Abdel Moneim, WHO EMRO, Egypt; Adriana Velazquez, WHO, Switzerland; Murillo Conto, PAHO, United States of America

Appendix 4

Poster

Third WHO Global Forum on Medical Devices - Preliminary Poster Programme	
A. Assistive Products	
R333	Hands free body dryer (dry by yourself)
	Dr. Olga Patricia Barragan Vesga, Horacio Galeano Zabala, Inventionspro, Colombia
R177	Manual wheelchairs are great! But…
	Dr. Dafne Zuleima Morgado Ramirez, Catherine Holloway, University College London, United Kingdom
R281	Floss pick fastener
	Dr. Horacio Galeano Zabala, Olga Patricia Barragan Vesga, Inventionspro, Colombia
A88	Arm sled
	Dr. Horacio Galeano Zabala, Olga Patricia Barragan Vesga, Inventionspro, Colombia
R553	Towards better and more equal continence care
	Ms. Eszter Kacskovics, SCA Hygiene Products, Dr Gyula Markovics, SCA Hygiene Products
R296	Motion analysis for supervision of medication intake
	Prof. Maria Elena Algorri, Technische Hochschule Köln, Germany
B. Health Information Systems: Medical Device Issues	
R43	Mobile phone microscope imaging for eHealth applications at low resource setting; image processing for automatic CBC
	Mr. Mulugeta Mideksa Amene, Independent, Ethiopia
R288	Open-source low-cost wearable physical activity tracker
	Dr. Jelena Dragas, ETH Zurich, Switzerland; Walter Karlen, ETH Zürich, Switzerland
R100	Field based validation of integrated clinical severity assessments of children 2-59 months of age by community health workers using the mHealth Medsinc platform
	Prof. Barry Finette, University of Vermont College of Medicine; THINKMD, Inc. Megan Mclaughlin, Susan Zimmerman, Thinkmd; Shah, Rashed, Save The Children-Us; Mark Yound, Unicef; John Canning, Physicians Computing Company; Barry Heath, University of Vermont College of Medicine, United States of America; Rahman, Kazi Asadur, Ituki Chakma, Hosneara Khondker, Save The Children-International, Bangladesh; Salvator Nibitanga, Denis Muhoza, Awa Seck, Valarie Zombre, Ilboudo, Adama, Issiaka Garango, Unicef Burkina Faso; Michelle Grunauer, Enrique Teran, Marisol Bahamonde Universidad San Francisco de Quito, Ecuador; Edy Quizhpe, Ministry Of Health, Ecuador
R167	Patients families co-producing and checking medical records
	Dr. Richard Fitton, Tameside and Glossop Clinical Commissioning Group Manchester, United Kingdom; Sarwar Shah
A150	Following the evolution of chronic diseases
	Mr. Rene Ivan Gonzalez Fernandez; Margarita Mulet, Juan Dayron Lopez, Alejandro Lopez, Olivia Canto, Icid Digital Medical Technology, Cuba
R479	Mobile control of risk factors of NCDS

	Prof. Bao Jiali, Zhejiang University, China; Zhu Chaoyang, Bao Jiaming, Zheng Xiuxiu
A11-1	Telerradiology network in Amazonas rainforest
	Mr. Leonardo Melo, Diagnext.com, Brazil; Alessandro Melo, Universidade Federal Fluminense, Brazil
	C. Human Factors Engineering
A230-2	Involving users as co-designers of medical devices
	Dr. Patricia Coffey, Maggie Kilbourne-Brook, PATH, United States of America
R559	Task-shifting contraceptive implant removal device
	Dr. Ibrahim Mohedas, Carrie Bell, Kevin Jiang, Kathleen Sienko, University of Michigan, United States of America; Zerihun Abebe, Delayehu Bekele, St. Paul's Hospital Millennium Medical College, Ethiopia
A185-2	Engaging stakeholders during Fuzzy front-end design
	Dr. Ibrahim Mohedas, Shanna Daly, Kathleen Sienko, University of Michigan, United States of America
	D. Heathcare Technology Management/Clinical Engineering
R542	Impact of clinical engineering in primary healthcare
	Ms. Priscila Avelar, Renato Garcia, IEB-UFSC/WHO Collaborating Centre Brazil; Carlos Alberto Silva, SMS/PMF, Brazil
R341	Maintenance of medical devices North-West India
	Dr. Vatsal Gupta, Semira Manaseki-Holland, Karin Diaconu, University of Birmingham, United Kingdom
R273	Working group - medical device donations developing countries
	Mr. Anders Lygdman, Sahlgrenska International Care AB, Sweden; Members of network
R660	Methodology for performance assessment of a biomedical engineering department (R255)
	Ms. Maria Eugenia Moreno Carbajal, Starmedica Hospital, Mexico
R420	Medical device service procedures mobile application
	Mr. Jean Ngoie, NHS Tayside, United Kingdom; Kelsea Tomaino, University of Waterloo, Canada
R372	Evaluation of medical devices in Benin
	Mr. Charles Pascal Soroheye, DIEM, Benin; Adjaratou Seidou Maliki, Marc Myszkowski
R188	Case study in spanish medical equipment companies
	Prof. Yariza Chaveco Salabarria, Dr. C Juan Carlos Rubio Romero, University of Málaga, Spain; Dr. C Rosa Mayelín Guerra Bretaña, University of Havana, Cuba
R348	Assessment of technologies for organs preservation
	Mr. Corrado Gemma, Carlo Martinoli, Ilaria Vallone, Paolo Lago, Fondazione IRCCS Policlinico San Matteo, Italy;
A8-2	Codebook for planning, procurement, testing and commissioning
	Mr. Claudio Meirovich, Meirovich Consulting, Spain

A130	Managing Successful Medical device Warranty Period Maintenance
	Ms. Demeru Yeshitla Desta, ; Tegbar Yigzaw Sendeke, Sharon Kibwana, Mihereteab Teshome Tebeje, Jhpiego-Ethiopia, Ethiopia.
	E. Assessment (HTA) of medical devices
R349	The Internet as a tool for an Early awareness and alert (EAA) system in the field of diabetes
	Ms. Vânia Marlene Ferreira De Sousa, Miguel Antunes, INFARMED - National Authority of Medicines and Health Products, I.P., Portugal
A87	Defining criteria for local versus national HTA
	Dr. Katriene Bjørnebek Frønsdal, Arentz-Hansen H, Lauvrak V, Ormstad S, Fure B
R191	Ultrasound adjunct in breast cancer screening
	Mr. Flávio Mauricio Garcia Pezzolla, Priscila Avelar, Renato Garcia, IEB-UFSC, Brazil
R141	Technology decision-making process: MRI purchase in Portugal
	Ms. Maria Maia, Faculty of Sciences and Technology, Portugal
R521	Priority-setting for medical devices and equipment
	Ms. Mutsumi Metzler, Mr. Todd Dickens, PATH, United States of America
R623	Prioritisation of medical devices and diagnostics in India
	Dr. Yogita Kumar, Gupta Madhur, World Health Organisation, Ameel Mohammed, National Health Systems Resource Centre, India
	F. Human Resources for Medical Devices
R136	Overcome the shortage of radiotherapy staff in LMICs
	Dr. Stefan Berz, Michael Sandhu, Access to Care Foundation; Patrick Kupelian, Varian Medical Systems, United States of America; José-Manuel Valentim, Varian Medical Systems; Switzerland; Jan, LäraNära Degerfält, AB, Sweden
R560	Design requirements for task-shifting medical devices
	Ms. Marianna Coulentianos, Amir Sabet Sarvestani, Kathleen Sienko, Richard Gonzalez, University of Michigan, United States of America
A175-2	Prototyping best practices by Ghanaian novice designers
	Mr. Michael Deininger; Kathleen Sienko, Shanna Daly, Jennifer Lee, University of Michigan, United States of America; Elsie Effah Kaufmann, University of Ghana, Ghana
A215	Intern programs of biomedical engineering education
	Prof. Kangping Lin; Tsai, Chenglun, Chung-Yuan Christian University, Chinese Taipei
A109	Educational partnership for human resources and medical devices: Danang, Vietnam
	Dr. Miriam Mikhail, Rad-Aid International, Diagnostic Radiologist Based In Geneva, Switzerland; Lindsey Minshew, Candice Bolan, Hector Robles, J Mark Mckinney, Mayo Clinic, Florida, United States of America; Phuong Thi Loan Nguyen, Danang General Hospital, Danang, Vietnam
A185-1	Usability assessment of a task-shifting medical device

	Dr. Ibrahim Mohedas; Gashaw Andargie, Mula Adefris, Biruk Mengstu,Takele Tadesse, University Of Gondar, Ethiopia; Jose Davila, Ajay Kolli, Kathleen Sienko, Kevin Jiang, Weiner, Annabel, University Of Michigan, United States Of America
R661	Rwanda biomedical technican training program
	Mr. Costica Uwitonze, Rwanda Association of Medical Engineering, Rwanda
R744	Integrated model of universities to promote the clinical engineering
	Prof. Beatriz Janeth Galeano Upegui , Universidad Pontificia Bolivariana, Colombia; Javier García, Juan Guillermo Barreneche, U de A; Nelson Escobar, UPB; Javier Camacho, EIA-CES; Sara Álvarez, ITM; Colombia
	G. Innovation Process/R&D of Medical Devices
A175-1	Influence of prototype type on stakeholder engagement
	Mr. Michael Deininger; Shanna Daly, Jennifer Lee, Kathleen Sienko, University of Michigan, United States of America; Elsie Effah Kaufmann, Samuel Obed, University of Ghana, Ghana
R522	Healthcare management in Brazil: investments in R&D of medical devices
	Mr. Carlos Eduardo De Andrade Lima Da Rocha, Oswaldo Cruz Foundation, Brazil; Fabio Kurt Schneider, Federal University of Technology, Brazil
	H. Medical Devices for Emergencies and Disasters
R263	Developing 21st century PPE against infectious diseases
	Mr. Matthieu Gani, EPFL - Cooperation and Development Center; Manuel Schibler, Geneva University Hospital; Mathieu Soupart, Médecins Sans Frontières; Beat Stoll, University of Geneva; Switzerland
R478	An improved PPE suit for disease outbreaks
	Ms. Margaret Glancey, Patience Osei, Soumyadipta Acharya, Youseph Yazdi, Johns Hopkins University, United States of America
A167	Novel transport isolator for highly contagious diseases
	Dr. Knut Erik Hovda; Broch Brandsaeter, Espen Rostrup Nakstad, Fridtjof Hayerdahl, The Norwegian CBRNE Centre of Medicine, Department of Acute Medicine, Oslo University Hospital
R334	Rapidly deployable clinical solutions
	Ms. Sarah Michel, Sharmila Anandasabapathy, David Hilmers, Baylor College of Medicine, United States of America
R191	A Breath of Hope
	Dr. Oladayo Olakulehin, LigandCorp, Canada
R600	Multiple victims triage using Fuzzy
	Dr. Leandro Zerbinatti, Silveira S.Vieira, Wesley O. Trindade, Ivan G. Duarte, Marcio O. Peres, Rodrigo O. Pastorelli, Uninove-Universidade Nove de Julho, Brazil
R807	Survey on medical devices appropriate for low and middle income countries
	Ms. Barbara Comte, Mélanie Amrouche, Robin Walz and Maurice Page, Humatem, France
R808	Cooperation between biomedical training programs, a challenge for biomedical area
	Ms. Mélanie Amrouche, Barbara Comte, Robin Walz, Humatem, France
	I. Innovative Technologies for Screening and Diagnosis
R456	Laboratory evaluation of EID point-of-care in Kenya
	Ms. Nancy Bowen, Leonard Kingwara, NPHLS, MOH; Dorcus Abuya, NHRL; Rose Wafula,

	NASCOP; Kenya
R199	Current research initiatives
	Dr. Gábor Lovas, Agnes Beczik, Chempolis Ltd.; Mihaly Szacsky, Public Benefit Organization for Natural and Sport Science at the Technical University, Hungary
R98	Evaluation of care, maintenance and user practices of medical laboratory equipment in Malawi
	Mr. Victor Makwinja, University of Capetown, South Africa; Solomon Kachitsa, William Chimwala, Wakisa Kipandula, Tony Nyirenda, University of Malawi, Malawi
A139	Assessment & selection: lead garments in diagnostic imaging
	Dr. Miriam Mikhail, Rad-Aid International; Adam Lustig, Bryan Ashley, Kyle Jones, Ari Isaacson, Robert Dixon, The University of North Carolina at Chapel Hill, United States of America
R311	Design of collimator systems for interventional procedure
	Prof. Seungwoo Park, Korea Institute of Radiological & Medical Sciences, Korea
	J. Innovative Technologies for Treatment
R564	User-friendly delivery platforms for MgSO4 therapy - Evaluation
	Dr. Patricia Coffey, Mutsumi Metzler, Elizabeth Abu-Haydar, Nancy Muller, Dr. David McAdams, Mike Eisenstein, PATH, United States
R497	Affordable alternative orthopedic drills in emerging markets
	Dr. Elise Huisman, Lawrence Buchan, Michael Cancilla, Florin Gheorghe, Arbutus Medical, Canada
A165	Safe medication management in LMICs
	Prof. Beth Kolko; Bradley Younggren, University of Washington/Shift Labs, United States of America
R251	A new handheld cordless thermal coagulator
	Prof. Walter Prendiville, Sankaranarayanan Rengaswamy, Basu Partha, IARC, France; Parham Groesbeck African Centre of Excellence for Women's Cancer Control Zambia; Wallace Dean, Pickett Tim, Riddle Mike, Liger Medical; Juan Felix, University S California, United States of America
R159	A pneumonia prevention system
	Mr. Dr. Peter Young; Maryanne Mariyaselam, Queen Elizabeth Hospital, United Kingdom
R289	Medical device for Feldenkrais therapy
	Mr. Ruben Valenzuela, UNAM, Mexico; Rosa Itzel Flores Luna, Angelo Sandoval Villegas, Diana Hernández Matehuala, José Alberto Lira Montanez
A97	Growing rods system for early onset scoliosis
	Prof. Jaw-Lin Wang; Po-Liang Lai, Chang Gung University; Jaw-Lin Wang, National Taiwan University, Taiwan
R226	Design and fabrication of needle crusher
	Prof. Akinwale Coker, Chibueze Achi, Charles Akintunde, Taiwo Hammed, Mynepalli Sridhar, University of Ibadan, Nigeria
A249	Testing normal pressure hydrocephalus disease
	Mr. Walef Robert Ivo Carvalho; Amanda Kelly da Silva, Ana Flávia de Almeida, Fernando Campos Gomes Pinto, Thiago Moreira de Carvalho Vieira
A185-3	Contraceptive implant removal device target product profile

	Dr. Ibrahim Mohedas; Zerihun Abebe, Delayehu Bekele, St. Paul's Hospital Millennium Medical College, Ethiopia; Tina Al-Khersan, Amy Kamdem, Caitlin Choi, Kathleen Sienko, University of Michigan, United States of America
R608	Affordable clubfoot brace for LMIC clubfoot treatment
	Mr. Saketh Kalathur, MiracleFeet, India; Shriya Soora, MiracleFeet, United States of America
R153	PVC free blood bag
	Ms. Alice Ravizza, Italy; Hans Gulliksson, Lena Stigh
A172	Safer medication administration for labor/delivery
	Prof. Beth Kolko; Bradley Younggren, University of Washington/Shift Labs, United States of America
	K. Innovative In Vitro Diagnostics
R455	Evaluation of a FVE DBS protocol, Kenya
	Ms. Dorcus Abuya, Edward Onkendi, National HIV Reference Lab, Kenya
R330	Low-cost inkjet-printed paper diagnostics
	Dr. Blanca Leticia Fernandez Carballo; Albert Comellas-Del-Castillo, Borros Salvador, Institut Químic de Sarrià Grup d'Enginyeria de Materials (GEMAT), Universitat Ramón Llull, Spain
A164	Low-cost point-of-care rt-qPCR system for RNAvirus detection
	Dr. Blanca Leticia Fernandez Carballo; Christine Mcbeth, Ian Mcguiness, Maxim Kalashnikov, Christoph Baum, Fraunhofer Institute for Production Technology IPT, Germany; Salvador Borros, Grup d'Enginyeria de Materials (GEMAT), Institut Químic de Sarrià, Universitat Ramón Llull, Spain; Andre Sharon, Alexis F Sauer-Budge, Fraunhofer USA Center for Manufacturing Innovation, USA, & Biomedical Engineering Department, Boston University, United States of America
R515	Novel bedside diagnostics for methanol poisoning
	Dr. Knut Erik Hovda, Gaut Gadeholt, Dag Jacobsen, Oslo University Hospital, Oslo, Norway
A153	New urine dipstick for improved preeclampsia screening
	Dr. Brandon Leader, Emily Gerth-Guyette, Nicole Advani, Kelly Randels, PATH, United States of America
R652	Implementing leprosy diagnostic and monitoring solution in Pakistan
	Prof. Phillip Olla, Audacia Bioscience, Canada
A75	A system for heart disease screening and prognosis
	Mr. Rene Ivan Gonzalez Fernandez, Jorge Aguilera-Perez, Gisela Montes De Oca, Marisabel Lopez-Fernandez, Pedro Luis Gonzalez, ICID Digital Medical Technology, Cuba
R508	An innovative fetal heart rate monitor
	Ms. Sakina Girnary, Ida Neuman, Kate Halvorsen, Karoline Linde, Jennifer Gilbertson, Laerdal Global Health, Norway
R657	Enabling and scaling early detection of breast cancer in lmics
	Mr. Mihir Shah, UE LifeSciences; Ophira Ginsburg, Laura and Isaac Perlmutter Cancer Centre at Nyu Langone Medical Center; Ari Brooks, Pennsylvania Hospital, United States of America
R218	Ultra-low-cost endoscopy for gastroesophageal cancer screening in low-income countries
	Prof. Pietro Valdastri, Joseph Norton, Simone Calo', University of Leeds, United Kingdom; Beatriz Plaza, Andrew Durkin, MiracleFeet; Federico Campisano, Douglas R. Morgan, Keith L. Obstein, Vanderbilt University, United States of America

R572	An innovative education model for cervical cancer screening training
	Ms. Maria Young, Julia Kramer, Visualize, United States of America;
R267	Rapid diagnostics of mosquito transmitted diseases
	Dr. Robert Burger, BluSense Diagnostics, Denmark
R305	Differential diagnosis of fever in West/East Africa
	Dr. Konstantinos Mitsakakis, Oliver Strohmeier, Nils Paust, Roland Zengerle, Sebastian Hin, University of Freiburg, Germany; Benjamin Lopez-Jimena, Manfred Weidmann, University of Stirling, United Kingdom; Seamus Stack, Mast Group Limited, United Kingdom; Mohammed Bakheit, MAST Diagnostica GmbH, Reinfeld; Vanessa Klein, Hahn-Schickard; Sieghard Frischmann, MAST Diagnostica GmbH, Germany; Cheikh Fall, Amadou Sall, Institut Pasteur de Dakar, Senegal; Khalid Enan, Central Laboratory, Khartoum, Sudan; Liz Gillies, Mast Group Limited, Liverpool, United Kingdom; Sven Goethel, Viorel Rusu, MagnaMedics Diagnostics BV, Geleen, The Netherlands
	L. Innovation for Mother & Child Care
A148	Saving mothers at birth
	Ms. Beryl Ngabirano Arinda; Denis Mukiibi, Martin Kiwanuka, Phiona Akurut, Robert Ssekitoleko, Makerere University, Uganda
R331	Unsupervised electronic stethoscope for childhood pneumonia diagnostic
	Dr. Mohamed-Rida Benissa, University of Geneva, Switzerland; J. Solà, F.Hugon,P.Starkov, F.Braun, S.Manzano, C.Verjus, A.Gervaix
A38	Field testing a neonatal phototherapy device: a novel approach
	Dr. Donna Brezinski, Gary E. Gilbert, Alyssa Pfister
R292	Objective feedback improves resuscitation training and practice
	Dr. Kevin Cedrone; Kristian Olson, Massachusetts General Hospital, United States of America; Santorino Data, Mbarara University of Science and Technology, Uganda
A230-3	A feeding cup for preterm infants
	Dr. Patricia Coffey; Christy Mckinney, Michael Cunningham, Robin Glass, Seattle Children's; Patricia Coffey, Steve Brooke, PATH, United States of America; Karoline Myklebust Linde, Cansu Akarsu, Laerdal Global Health; Norway
R442	Test for management of preeclampsia
	Ms. Wendy Davis, GestVision, United States of America; Irina Buhimschi, Research Institute at Nationwide Children's Hospital; Catalin Buhimschi, The Ohio State College of Medicine; Kara Rood, The Ohio State College of Medicine, United States of America
R112	A multiband reflectance photometric device for reveal gestational age at birth
	Prof. Rodney Guimaraes, Zilma Reis, Universidade Federal de Minas Gerais (UFMG), Brazil
R228	Innovation in umbilical cord severance
	Dr. William Kethman, William Strobel, Novate Medical Technologies, LLC, United States of America
R505	New improved newborn resuscitator
	Mr. Frode Liland, Karoline M. Linde, Jennifer L. Gilbertson, Laerdal Global Health, Norway
A168	Acceptability of conventional and upright neonatal resuscitators
	Dr. Manjari Quintanar Solares; Gene Saxon, Patricia Coffey, PATH; Indira Narayanan, Georgetown University Medical Center; Stephen Wall, Save the Children, United States of America; Rinku Srivastava, State Innovations in Family Planning Services Project Agency; Syed Ali, Aligarh Muslim University, India
R102	Prematurity detection by light

	Prof. Zilma Reis, Rodney Nascimento Guimarães, Gabriela Luíza Nogueira Vitral, Maria Albertina Santiago Rego, Ingrid Michelle Fonseca, Universidade Federal de Minas Gerais, Brazil
R765	Hub-and-spoke models for point-of-care early infant diagnosis
	Mr. Jean-François Lemaire, Rebecca Bailey, Esther Turunga, Jennifer Cohn, Elizabeth Glaser Pediatric AIDS Foundation Switzerland; Flavia Bianchi, Emma Sacks, Elizabeth Glaser Pediatric AIDS Foundation, United States of America
R573	A bundle approach to care for small babies
	Ms. Karoline Linde, Sakina Girnary, Jennifer Gilbertson, Frode Liland, Laerdal Global Health, Norway
A107-1	Hypothermia alert device: saving newborn lives
	Mr. Ratul Narain; Gini Morgan, Bempu Heath, India
A107-2	Preventing apneas of prematurity
	Mr. Ratul Narain; Gini Morgan, Bempu Heath, India
A 107-3	Remote monitoring for critical infants
	Mr. Ratul Narain; Gini Morgan, Bempu Heath, India
A210	Warmer for resuscitation with intact placental circulation
	Dr. Thanigainathan Sivam; Mangalabharathi Sundaram, Institute of Child Health & Hospital for Children, Valiyaveetil Sashikumar, Phoenix Medical System, India
R293	Preventing a never event
	Dr. Peter Young; Maryanne Mariyaselam, Queen Elizabeth Hospital, United Kingdom; Sinéad Renouf, Venner Medical Internationl, United Kingdom
R613	Device to save postpartum-hemorrhaging women in advanced shock
	Ms. Moytrayee Guha, Massachusetts General Hospital, United States of America; Thomas Burke, Sandra Danso-Bamfo, Alyssa Cappetta, Charles Masaki, Moytrayee Guha, Melody Eckardt, Brett Nelson, Massachusetts General Hospital, United States of America; Monica Oguttu, , Kisumu Medical and Education Trust, Kisumu, Kenya; S.A.S. Kargbo, Ministry of Health & Sanitation, Sierra Leone; Niang Mansour, Centre de Formation et de Recherche, Santé de la Reproduction, Senegal; Vincent Tarimo, Muhimbili National Hospital, Tanzania
R557	Warming solution for neonatal surgeries in Nigeria
	Dr. Taiwo Akeem Lawal, Akinwale Coker, University of Ibadan, Nigeria; Robert Murphy, Matthew Glucksberg, David Gatchell, Northwestern University, United States of America
R262	Description of automated epartogram with decision support
	Dr. Marc Mitchell, D-tree International; Douglas Williams, United States of America; Gill, Roopan, University of British Columbia, Canada; Thomas Routen, Things Prime, Switzerland
R472	Validity of a device for jaundice screening
	Dr. Anne Cc Lee, Brigham and Women's Hospital, Harvard Medical School, United States of America; Lian Folger, Salahuddin Ahmed, Lauren Schaeffer, Nazmun Bably , Mahmood Rahman, Rachel Whelan, Pratik Panchal, Arun Roy, Sayed Rahman, Nazma Begum, Abdullah Baqui
R558	Microarray patch for treatment of neonatal sepsis
	Dr. Mary Carmel Kearney, Emma Mcalister, Patricia Gonzalez Vazquez, Maelíosa Mccrudden, Ryan Donnelly, Queen's University Belfast, United Kingdom
	M. Quality and Safety of Medical Devices
R234	Medical devices in legal metrology framework

	Ms. Lejla Gurbeta, Medical Device Inspection Laboratory Verlab; Almir Badnjević, Verlab Ltd., International Burch university, University of Sarajevo, University of Bihac; Lejla Gurbeta, Verlab Ltd, International Burch University, Bosnia and Herzegovina
R504	Global quality and safety alliance in imaging
	Ms. Monika Hierath, Guy Frija, Don Frush, International Society of Radiology (ISR), United States
A41	Good practices for wearing gloves in hospitals
	Dr. Bochra Bejaoui, Zohra Jemmali, Asma Guettiti, National Agency for Sanitary and Environmental Control of Products, Tunisia
A53	Good practices of using a Foley probe
	Ms. Bochra Bejaoui, Zied Snoussi, Zohra Jemmali, National Agency for Sanitary and Environmental Control of Products, Tunisia
	O. Regulation of Medical Devices
A68	Recommendations for proper use of disinfectants
	Dr. Bochra Bejaoui, Zohra Jemmali, Olfa Drissi, National Agency for Sanitary and Environmental Control of Products, Tunisia
R649	Knowledge about materiovigilance in Cluj-Napoca, Romania
	Dr. Simona Maria Mirel, "Iuliu Haţieganu" University of Medicine and Pharmacy Cluj-Napoca, Romania

A. Assistive Products

R333 Hands free body dryer (dry by yourself)

Dr. Olga Patricia Barragan Vesga, Horacio Galeano Zabala, Inventionspro, Colombia

ABSTRACT

HANDS FREE BODY DRYER (DRY BY YOURSELF)

PROBLEM OR CHALLENGE:

Target group:

People living with handicap, elderly and obese people with motor deficiency that prevents them from using a towel and reach areas such as: armpits, back; skin folds (obesity), feet (diabetics), among others.

Background:

Currently these people are in need of a carer to help them dry their body with a towel, exposing themselves to risks of dermatitis or skin mycoses. This practice extends the third part dependency and lack of autonomy.

METHOD:

Description:

This device is a body dryer that does not require the motor manual skills that are necessary to use a towel. Even dries inaccesible areas achieving an optimal drying level, it is easy to use, accurate for people with motor and coordination deficiencies and without help from third parties.

CONCLUSIONS:

It is useful to improve self care (body care) of people living with disabilities, obese and elderly people; allows body drying through ventilation hands free, improving their autonomy and quality of life.

Note: Fan is not part of the invention. Recommended fan: temperature and flow adjustable.

R177 Manual wheelchairs are great! But…

Dr. Dafne Zuleima Morgado Ramirez, Catherine Holloway, University College London, United Kingdom

Long term manual wheelchair (MW) self-propulsion causes prevalent problems such as shoulder pain due to subacromial impingement (42-66% incidence), wrist pain due to carpal tunnel syndrome (49-73% incidence), and general upper limbs muscular pain. The current approach to prevent such injuries is: appropriate and timely provision of wheelchair, and skills training. For long term MW users that already have injuries and pain, the current treatment approach is: physiotherapy, pain killers, surgery or switching to an electric wheelchair. Power assist devices use motors that drive the wheelchair back wheels to help the users self-propel with demonstrated reduction of effort, pain and injuries. We interviewed nine MW users regarding their needs and expectations on adding assistance for propelling their wheelchairs. We also reviewed the power assist devices available. We have found that although MW users understood the benefits of using powered propelling assistant devices, the technology is not widely used due to lack of awareness and unaffordability. A high quality, affordable, open source, fully mechanical and lightweight assist device is needed. While waiting for researchers to create such high quality affordable device, we recommend MW users to use tricycles or lever drive propulsion, when possible, instead of the standard inefficient handrim propulsion.

R281 Floss pick fastener

Dr. Horacio Galeano Zabala, Olga Patricia Barragan Vesga, Inventionspro, Colombia

PROBLEM OR CHALLENGE:

Target group:

People living with handicap or elderly people with motor or coordination deficiency, particularly those

who can not do pincer grasp between index finger and thumb.

Background:

Currently, these people are in need of a carer to help them develop oral care with dental floss; or without its use, exposing themselves to risks of periodontal complications and caries. This practice extends the third part dependency and lack of autonomy.

METHOD:

Description:

This device is a holder for floss picks that allows the self use of dental floss without help from third parties, including people with motor and coordination deficiencies from different origens. The conformation of the set of pieces allows an appropriate subjection to carry out the interdental cleaning in spite of the insufficient grip in the people with motor deficiencies. Due to its shape, lenght and other characteristics allows fasten it and it is easy to use.

CONCLUSIONS:

It is useful to improve self care (oral hygiene) of people living with handicap and elderly people, improving their preventive oral health and quality of life autonomously.

Note: Floss picks are not part of the invention, they are complementary products

A88 Arm sled

Dr. Horacio Galeano Zabala, Olga Patricia Barragan Vesga, Inventionspro, Colombia

ABSTRACT

ARM SLED

PROBLEM OR CHALLENGE:

Target group:

People living with handicap: Upper mobility disorders: Spinal injuries (Quadriplegia, quadriparesis), arm

limitations; neurologic, progressive and degenerative disorders, etc., and elderly people. They are prevented to use by self pencils, pens, paintbrushes, PC keyboards, tablets, smartphones, among others.

Background:

Currently these people are in need of a carer to help them make desktop handmade activities which extends the third part dependency and lack of autonomy.

METHOD:

Description:

This device is a desktop support for arm activities when they are disabled, with difficulties to raise or sustain high, or to be fastly tired, etc. It does not require the neural or muscular ability that is regularly necessary to lift up, move and sustain the arm on or over the table. It is very useful to use desktop tools, accurate for people with mobility disorders and without help from third parties, which makes desktop work easier.

CONCLUSIONS:

Facilitate the sliding of the upper member both anteroposteriorly and rotatably on the table. It is useful to improve productive and entertainment desktop activities of people living with handicap

like upper mobility disorders and elderly people, improving their autonomy and quality of life.

R553 Towards better and more equal continence care

Ms. Eszter Kacskovics, SCA Hygiene Products; Dr Gyula Markovics, SCA Hygiene Products

Introduction: Incontinence is a heavily stigmatizing set of diseases affecting almost 400 million people worldwide, with growing prevalence in ageing population. Despite its high prevalence, tough psychosocial and economic implications, it is still a taboo. Cure rates are low, absorbent products are included in the APL, but there is little guidance on how good symptomatic continence care should look like. This results in low awareness, lack of prevention; late and sub-optimal care; unequal access to and non-appropriate use of devices.

Findings and recommendation: Patient profiling is under-developed, and product classifications in medical device databases hardly make any differentiation between the available product types. On the other hand, proper product selections based on defined patient needs are proven to have significant impact on the dignity, well-being, and social integration of patients and careers.

To ensure the availability and accessibility of appropriate absorbent products, the following needs to be in place:

- revised and aligned medical device code databases for absorbent products
- defined patient profiles considering disease specifics and patient's dependency level
- clear links between these profiles and recommended product types combined in a care guideline.

Workshop: How to ensure these issues are addressed and acted upon in national policies?

R296 Motion analysis for supervision of medication intake

Prof. Maria Elena Algorri, Technische Hochschule Köln, Germany

Studies show that 35 to 50% of all prescription medication in Germany are not taken correctly or at all. We use motion capture and analysis to build a system that can help supervise if a patient takes his/her medications orally. Our system analyses the motion in a 3D scene and detects events where a user holds a glass (of a particular color) and takes it to his/her mouth (as if to take the medications orally) by fusing color, contour and depth information extracted from an optical camera and a 3D depth sensor. The system is able to spatially track arbitrary objects that have been color segmented from the video stream

and to analyze the motion of the user.

To recognize a drinking action we fuse the information about the pose of the user with the 3D position of the segmented glass. We present the methodology used for color calibration, color segmentation, 3D motion tracking and information fusion and show that the system performs robustly for different user poses as well as under different ambient conditions. The system is easily expandable to recognize other actions of the patient and his interaction with different objects.

B. Health Information Systems: Medical Device Issues

R43 Mobile phone microscope imaging for eHealth applications at low resource setting; image processing for automatic CBC

Mr. Mulugeta Mideksa Amene, Independent, Ethiopia

A new mobile phone microscope imaging device will be developed for use in malaria parasite and TB bacteria detection. The new device will work in both white light and fluorescence settings. The work promotes early detection and protection of malaria and TB epidemics. Uses the "JossyBME.com" web site which services as Atlas or as the laboratory image library to compare the tool is cost effective and can be used easily by health extension workers (HEW) and promotes telemedicine applications such as tel-laboratory, tel-pathology, tel-radiography and other e-health systems there-by supporting the national e-health strategy. An image processing scheme will also be developed for automated Red Blood Cell (RBC) count on images acquired through the new coupled system. In this regard, a rigorous mathematical algorithm will be developed.

R228 Open-source low-cost wearable physical activity tracker

Dr. Jelena Dragas, ETH Zurich, Switzerland; Walter Karlen, ETH Zürich, Switzerland

The WHO Global Burden of Disease study identified physical inactivity as one of the most important risk

factors affecting global health in recent years. Physical activity and good sleep reduce occurrences of cardiac [Yusuf et al, Lancet,2004], bone and joint diseases [Warburton et al,CanMedAssoc,2006], and are linked to occurrences of diabetes [Lee et al, SleepMedRev,2016] and Alzheimer's [Spira et al, JAMANeurol,2013]. Devices used for tracking physical activity in clinical settings are too expensive for ubiquitous and long-term use, while low-cost consumer devices fail to replicate the performance of their clinical counterparts. Furthermore, commercially available devices lack transparency in data processing, and hence, reliability.

We have developed a low-cost physical activity tracking platform, consisting of a wearable device based on a 3-axis accelerometer, and a mobile app. The wearable device can be wirelessly configured with validated algorithms, each optimized for a particular type of physical activity and sensor placement. The device features an exchangeable battery, offering up to 6 months of standalone operation. Device hardware and algorithms are open-sourced to offer maximal transparency; this allows configuring the device with customized, user-specific algorithms, enabling novel research and citizen-science applications, as well as monitoring chronic conditions linked to physical inactivity in low-resource settings.

R100 Field based validation of integrated clinical severity assessments of children 2-59 months of age by community health workers using the mHealth Medsinc platform

Prof. Barry Finette, University of Vermont College of Medicine; THINKMD, Inc. Megan Mclaughlin, Susan Zimmerman, Thinkmd; Shah, Rashed, Save The Children-Us; Mark Yound, Unicef; John Canning, Physicians Computing Company; Barry Heath, University of Vermont College of Medicine, United States of America; Rahman, Kazi Asadur, Ituki Chakma, Hosneara Khondker, Save The Children-International, Bangladesh; Salvator Nibitanga, Denis Muhoza, Awa Seck, Valarie Zombre, Ilboudo, Adama, Issiaka Garango, Unicef Burkina Faso; Michelle Grunauer, Enrique Teran, Marisol Bahamonde Universidad San Francisco de Quito, Ecuador; Edy Quizhpe, Ministry Of Health, Ecuador

Problem: The WHO and UNICEF estimates that ~3 million children less than 5 years living in low and middle income (LMIC) die from preventable diseases, mainly due to the global shortage healthcare professionals and limited healthcare infrastructure.
Innovation: MEDSINC is a mHealth clinical assessment, triage and treatment software platform, which enables users to determine how sick a child is for: respiratory distress, dehydration, sepsis-SIRS, acute malnutrition, malaria, meningitis, anemia, urinary tract infection, skin infection, measles, ear infection and dysentery.

Method: We have performed MEDSINC validation and usability testing with community health workers (CHWs) in Burkina Faso, Ecuador and Bangladesh following 2 hours of training. Over 900 independent CHWs generated assessments of children 2-59 months were acquired with the MEDSINC platform and correlated with that of local physician's.

Results: Clinical correlations by CHWs using MEDSINC and local physician examining the same child revealed 55%- over 90% clinical assessment correlations. Analysis of usability and feasibility of all relevant stakeholders revealed very positive responses to ease of use and potential public health impact.

Conclusion: The MEDSINC platform could significantly improve LMIC CHW programs to identify the health status of children and facilitate early triage and therapeutic intervention(s) for children 2-59 months of age.

R167 Patients families co-producing and checking medical records

Dr. Richard Fitton, TamesTameside and Glossop Clinical Commissioning Group Manchester, United

Kingdom; Sarwar Shah

The Rights of Persons with Disabilities to access and share their Electronic Health records, the United Nations convention on the Rights of Persons with disabilities, the European Union general Data Protection and coding as a means of representing patients' selection and marking of sensitive data not to be shared.

This paper presents the case for a global patient centred ethical governance of health data processing and suggests standards of data processing that a United Nation body might in the future have some responsibility for overseeing, balancing the roles of industry, the State and the individual in the processing of personal health data. I hope to attract UN interest in personal health data governance lest we develop a global system of inequality of access to health data as has happened over millennia with petrol, gold, pottery, bronze, iron, coffee, tea, weapons, drugs , spices, etc.

A150 Following the evolution of chronic diseases

Mr. Rene Ivan Gonzalez Fernandez; Margarita Mulet, Juan Dayron Lopez, Alejandro Lopez, Olivia Canto, Icid Digital Medical Technology, Cuba

A system was designed to study the evolution of three chronic diseases: cardiac arrhythmia, arterial hypertension and Diabetes Mellitus. Medical devices to capture an ECG channel, to measure blood pressure and to measure blood glucose are assigned to each patient depending on their needs. Previously, the patient is enrolled in the system to register his general data, his sickness and his medical treatment.

Signals and parameters captured by the medical devices are sent by a Bluetooth channel to a terminal that processes this information and uploads the results to a website. All the signals and values are stored in a database and doctors can review all the data of their patients; trend graphs are displayed for each parameter associated to the studied diseases. In this way, at every moment doctors can know the effectiveness of the treatment of each patient and can modify the treatment if it is necessary. With a phone call, it is enough to tell the patient the change to make in the medicine indications. This way of working creates a more robust link between the patient and the doctor and a more expeditious way to adjust medical treatment to the evolution of the patient.

R479 Mobile control of risk factors of ncds

Prof. Bao Jiali, Zhejiang University, China; Zhu Chaoyang, Bao Jiaming, Zheng Xiuxiu

Most of the people over aged 35 who have 720 million in China do not controlled their lifestyle, as a result is sustained increase a morbidity rate of noncommunicable diseases (NCDs) to reach 15.74%. The one of difficulty to control the risk factors of NCDs is to restrict the communication between people and general practitioners in any time and any region, so that the person doesn't control him/her lifestyle according to the instructions of the general practitioner in time.

The person can easily test his/her physiological parameters, for example, blood pressure, glucose, heart rate and BMI ect. By using electronic medical devices at home and send these data to general practitioner at Community Health Service Centers. Then general practitioner might design a PID control strategy of the risk factors of NCDs according to him/her Human Mathematical Model, currently data and change rate of these physiological parameters. The person might receive a control information of a risk factors of NCDs from general practitioner by smart phone at anytime and anywhere. He/she is prompted to implement the control design of the risk factors as soon as possible.

A11-1 Telerradiology network in Amazonas rainforest

Mr. Leonardo Melo, Diagnext.com, Brazil; Alessandro Melo, Universidade Federal Fluminense, Brazil

Telemedicine was developed to cross borders, bringing medical knowledge, actions and practices to wherever it might be needed. However, the global's reality context doesn't help - infrastructure capable of transmitting the amount of data needed for telemedicine doesn't exist exactly where they are most needed.

After years of engineering and medical studies, a set of protocols, practices, technologies and patents have been developed that are capable of perfecting the infrastructure that supports teleradiology and brings it to a new level - being able to overcome technological barriers and transmit big data volume.

This newest technology was made available to the Amazonas's State, and implemented in 51 forest's hospitals, overcoming all dificults and knowns barriers. It transmits more than 100,000 x-ray and mammography tests per year, 20 times faster than the conventional technology. Finally, all this made the evaluation of a medical examination of up to 6 months to little more than a minute using a slow and unstable satelites communications system.

The major specialty of this technology in this context is in the detection of breast cancer, which has been able to increase patient care, periodic examinations and drastically reduce the incidence of the maladies of the disease to controllable levels.

C. Human Factors Engineering

A230-2 Involving users as co-designers of medical devices

Dr. Patricia Coffey, Maggie Kilbourne-Brook, PATH, United States of America

Over 50% of medical equipment in developing countries is not functioning, used correctly, or maintained. Some equipment is unnecessary or inappropriate for its intended purpose. To address this, PATH develops and introduces appropriate, safe, effective, and affordable medical devices that meet the needs of users in low-resource settings. Our approach puts users at the center of our product development work. First, with country and global partners, we assess health needs and identify gaps. We landscape health technologies available on the market and under development and evaluate them using international standards. When no appropriate technology exists, we develop, adapt, and refine technologies through an iterative user-centered process to ensure the technology meets the needs of users and key stakeholders who influence product access and uptake. As part of the process, we prototype health technologies, assess proof-of-concept, and validate their design, usability, and acceptability with users and within existing health systems. PATH employed a user-centered process to develop, test, and refine two female barrier methods: SILCS diaphragm and Woman's Condom. This user-centered design strategy builds acceptability into products at each step of the process and results in products more likely to meet the needs of the intended user population group.

R559 Task-shifting contraceptive implant removal device

Dr. Ibrahim Mohedas, Carrie Bell, Kevin Jiang, Kathleen Sienko, University of Michigan, United States of America; Zerihun Abebe, Delayehu Bekele, St. Paul's Hospital Millennium Medical College, Ethiopia

Ethiopia has a lack of trained healthcare providers (2.5 physicians/100,000 people) limiting access to effective long-term contraception including subcutaneous contraceptive implants. In Ethiopia, over 35,000 Health Extension Workers (HEWs) service over 50% of the population. In enabling HEWs to administer implants, over 16 million women will gain access to implants in Ethiopia. This access will prevent unintended pregnancies, abortions, miscarriages, and maternal and infant deaths. Our interdisciplinary team consisting of U.S. and Ethiopian healthcare providers and engineers co-designed an assistive task-shifting device for accurate implant administration. The device acts like a template, eliminating unsafe administration common with the current free-hand administration method, allowing for the task to be shifted to HEWs. Use of the assistive device increased depth accuracy by 41% in simulator and cadaver tests. In usability testing, 131 Ethiopian healthcare providers, including 53 HEWs, successfully used the device to insert implants into an arm simulator and minimally trained healthcare providers demonstrated a statistically significant increase in confidence (p=.001) administering implants using the assistive device. Future work includes a pre-clinical trial to assess the device's fit for a diverse population and a clinical trial to assess safety and efficacy.

A185-2 Engaging stakeholders during Fuzzy front-end design

Dr. Ibrahim Mohedas, Shanna Daly, Kathleen Sienko, University of Michigan, United States of America

Designing medical devices is a complex process that requires designers to understand a broad range of stakeholders, each with their own perspectives and opinions on the most appropriate design requirements. Human-centered design processes represent a range of methodologies that allow designers to better understand stakeholder perspectives and, therefore, develop more usable and appropriate products. Stakeholder interviewing is a key method used during the human-centered design process to better understand their perspectives and beliefs; however, educational resources detailing best practices are limited and design interviewing skills are primarily learned through extensive experience. In this study, we performed a systematic literature review and identified thirteen distinct best practices for increasing the quality of design interviews conducted with stakeholders. An empirical study was used to understand the effects that these best practices have on the quality of stakeholder interviews conducted. We found that higher quality stakeholder interviews (as defined by the rate of best practices used) elicited more relevant information during front-end design phases. We believe that these best practices could form a multi-functional framework to guide the development of stakeholder design interview protocols and allow medical device designers to better understand stakeholders during the fuzzy front-end of design.

D. Healthcare Technology Management/Clinical Engineering

R542 Impact of clinical engineering in primary healthcare

Ms. Priscila Avelar, Renato Garcia, IEB-UFSC/WHO Collaborating Centre Brazil; Carlos Alberto Silva, SMS/PMF, Brazil

In primary care, the increase in technological complexity and change in the epidemiological profile has created needs for the application of specialized services in Clinical Engineering. A Technology Management model was presented at the 2013 Forum implemented at the Municipal Health Secretariat of Florianópolis, Brazil. This paper presents the impacts generated by this model in the management domains. In the processes analyzed, adequate infrastructure prevails for the proper functioning of the equipment, lack of training in the use of technologies, purchase/procurement of equipment that does not meet the health demand, and logistical difficulties in attending and controlling the units distributed regionally. The primary care network studied, is composed of 62 units in 05 regional. Actions taken in dental services have generated important improvements and social impact. Activities were carried out training of human resources, dental equipment, adaptation of compressor infrastructure and disinvestment of equipment with obsolete technologies. Clinical Engineering can be an agent of transformation in primary care providing quality, safety and reliability in the technological process in health. In addition to these activities, new tools are being applied with HTA, HFE and Metrology concepts, further enhancing the impact of Clinical Engineering, allowing the development of a ubiquitous health platform.

R341 Maintenance of medical devices North-West India

Dr. Vatsal Gupta, Semira Manaseki-Holland, Karin Diaconu, University of Birmingham, United Kingdom

Objectives:

Maintenance of medical-devices is of importance in utility, cost-efficiency and quality provision. Existing literature reported device maintenance is neglected and understudied in low and middle-income countries. This warrants exploration as these countries have experienced a rise in device demand. India has a device market set to undergo substantive growth within private and public hospitals. We explored issues regarding maintenance of devices in both healthcare sectors in the North-West province of India.

Methods:

This qualitative study used semi-structured interviews with 31 health-care practitioners, administrators and directors from different institution sizes, in both private and public sector hospitals. Purposive sampling using a snowball approach was used. Interviews were recorded and conducted using a validated topic guide. Thematic framework analysis employing an inductive and grounded approach was used for data analysis.

Findings:

We identified three themes that have a compounding effect in causing delayed maintenance, absence of biomedical engineers, procedural delay in fault reporting and discrepancy in after sales maintenance by companies. Despite awareness of these problems amongst decision makers, there was maintenance neglect, particularly in the public-sector.

Conclusions:

Increased delegation of responsibility within the maintenance process and regulation of company service is recommended. Employment of Biomedical-Engineers is imperative.

R273 Working group - medical device donations developing countries

Mr. Anders Lygdman, Sahlgrenska International Care AB, Sweden; Members of network

Abstract
The European Working Group "Medical Equipment in Low-Income Countries "

The purpose is to introduce to a wider audience an emerging network of European NGOs, foundations, public and private actors who are involved in medical equipment donations/ distribution and/or the promotion of their proper maintenance in countries in the developing world.

The network was formed late 2013 after the first EquipAid conference in Chamonix, France. EquipAid was the first international conference that explored the role of international aid in medical device distribution and maintenance and brought together stakeholders such as international policymaking and funding agencies, government representatives, health facility managers from donor and recipient countries, researchers, staff of NGOs involved in such projects, equipment manufacturers and distributors, among others. EquipAid was complementary to the Second WHO Global Forum on Medical Devices.

The network meets annually to discuss issues of common interest connected to the donation /distribution and more globally to healthcare facilities strengthening projects and proper maintenance of medical equipment such as policy, regulation, and capacity building. The aim of the network is to address issues such as quality and coordination in donations, and to share experience and best practice on building the capacity of Biomedical Engineering in Developing Countries.

R660 Methodology for performance assessment of a biomedical engineering department

Ms. Maria Eugenia Moreno Carbajal, Starmedica Hospital, Mexico

A biomedical engineering department is necessary at any hospital unit. Nowadays, the challenge lies in the lack of standardization and homogenization of processes, scope and responsibilities that a biomedical engineering department must have. For this reason, this methodology was developed in a private high specialized hospital with the aim to serve as a tool for any healthcare unit. This tool allows a continuous performance assessment of biomedical engineering departments.

This tool assesses three important components within the healthcare unit: the performance of medical devices, the level of implementation of certain controls and indicators to evaluate medical devices functionality, and the physical state of medical devices.

The evaluation of these three components permits a clear and quantitative measurement of the level of performance that a biomedical department has. According to this tool, it is possible to establish action plans in order to guarantee improvement of the biomedical engineering department, processes standardization and ensurement of functionality and availabiltiy of medical devices within the healthcare unit.

R420 Medical device service procedures mobile application

Mr. Jean Ngoie, NHS Tayside, United Kingdom; Kelsea Tomaino, University of Waterloo, Canada

Globally, medical device used in healthcare setting is designed by the same manufacturers.

However, the delivery of service varies from one institution to another. To guarantee consistency and effectiveness in the delivery of Clinical Engineering services across all hospital sites of the organization, a combination of the WHO guidelines, Clinical Engineering Standards of Practice for Canada (CESOP), ISO 13485 and manufacturers service procedures were used to produce a set of general standards operating procedures (SOP's), as well as specific device procedures and checklists that allows clinical engineering to perform its duties in the same way.

A mobile application was then created so that these procedures and checklists can be easily accessible anywhere at any time. The app has the ability to interface with the department computerized maintenance management system (CMMS). Therefore, when a Technologist completes a checklist using the app, it can be submitted via email and assigned to the work order. It is also used as an audit tool to monitor

The application will be shared with colleagues in the developing countries. It will allow them to better manage their own departments, perform diagnosis and basic services while following comprehensive procedures that have been designed and validated by peers.

R372 Evaluation of medical devices in Benin

Mr. Charles Pascal Soroheye, DIEM, Benin; Adjaratou Seidou Maliki, Marc Myszkowski

Introduction: The management of biomedical equipment is a real problem and a complex challenge for the health sector in Benin. In order to fulfill its mission, Health Ministry carried out an inventory of biomedical equipment in the departments of Atacora / Donga and Mono / Couffo.

Objective: Ensure better management of biomedical equipment

Achievements: Biomedical technicians and engineers have identified 15,000 biomedical equipment, medical furniture and refrigeration equipment in 277 health facilities. .

Results: 29% are biomedical equipment; 8% of total equipment are cold chain related and 63% medical furniture. 8% of total equipment are in good condition but not used with an estimated cost of 300,000 euros; 66.7% of unused equipment is in the store; 1307 equipments are broken down and can be repaired, of which 22% constitutes the cold chain. 38% of the equipment inoperative is biomedical equipment. As a result of this inventory, a maintenance strategy has been developed and implemented with community participation. The implementation of the strategy made it possible to reduce the number of equipment inoperative by 40%.

Conclusion: This inventory provides the basis for a Multiannual Equipment Strategy

Prospects: - Scale up the inventory - development of the multiannual equipment Strategy

R188 Case study in Spanish medical equipment companies

PhD Yariza Chaveco Salabarria, Dr. C Juan Carlos Rubio Romero, University of Málaga, Spain; Dr. C Rosa Mayelín Guerra Bretaña, University of Havana, Cuba

The work presented is part of a research currently under way. The objective is to identify the existence and impact of entry barriers to the European medical devices market. It is part of an exploratory case study with Spanish companies in the sector. Preliminary results show a consensus about the absence of tariff barriers. On the other hand, there are discrepancies with respect to non-tariffs, highlighting the influence of technical barriers.

R348 Assessment of technologies for organs preservation

Mr. Corrado Gemma, Carlo Martinoli, Ilaria Vallone, Paolo Lago, Fondazione IRCCS Policlinico San Matteo, Italy

INTRODUCTION
WHO has dealt with human organ transplantation for 30 years, starting from WHO Guiding Principles on Human Organ Transplantation in 1991 with resolution WHA44.25.

In 2014 Global Observatory on Donation and Transplantation registered around 120,000 organs transplanted annually. The majority of organ transplantations are realized in high-resource countries but also low-resource countries are carrying out these procedures.

In 2010 resolution WHA63.22 promoted the development of systems for the donation of organs highlighting the level of safety, efficacy and quality organs must have for transplantation.

METHODOLOGY
The analysis focused on Machine Perfusion (MP) systems for organs by Donors after Cardiac Death (DCD). MP systems allow organ perfusion ex situ: after organ retrieval and back-table surgery, each graft is connected to the MP. Systems differ in two main characteristics: portability and temperature of perfusate solution. Portable MP systems keep the organ perfused from retrieval site to transplantation one. For the second feature, there are some MP systems working in hypotermic conditions to reduce cellular metabolism and others working in normothermia to simulate physiologic conditions.

CONCLUSIONS
Portable MP systems result the most appropriate to increase number of available grafts and to make possible organs retrieval also in not highly specialized centres.

A8-2 Codebook for planning, procurement, testing and commissioning

Mr. Claudio Meirovich, Meirovich Consulting, Spain

Codebook was developed as a planning tool to allow biomedical engineers to interact in a better way with architects, electrical and civil engineers in a hospital project.

The application allows the planner (biomedical engineer) to develop a hospital equipment plan including all the details for every single piece of FF+E and link them to the Autocad design drawings (or Revit model) to detect any errors in the distribution or proposed installation. It allows several ways of reporting and monitoring the project. Once the equipment is procured it also allows monitoring and recording the installation, testing and commissioning process.

Data is kept in a repository that may be shared avoiding duplication while keeping its consistency and allowing it to be exported to different formats.

A new tablet based tool for T&C was introduced in the summer of 2016 and it was tested by Meirovich Consulting during the final stage of equipment of the Owen King-EU Hospital (St Lucia).

The T&C process was completed documenting several snags during the process and reporting all activities in a very short time (3 months) with very limited human resources.

Codebook is a powerful tool that should be tested in other equipment projects in LMICs.

A130 Managing Successful Medical device Warranty Period Maintenance

Mr. Demeru Yeshitla Desta, ; Tegbar Yigzaw Sendeke, Sharon Kibwana, Mihereteab Teshome Tebeje, Jhpiego-Ethiopia, Ethiopia

Background: Jhpiego-Ethiopia, under the USAID funded HRH Project procured 14 anesthesia machines from Gradian Health System, which were then donated to public hospitals in Ethiopia to deliver anesthesia services as well as for teaching purpose at anesthesia training schools. Objective: The objective of this abstract is to share the program learning experience in management of medical devices warranty period maintenance. Description of interventions: Through collaboration of Jhpiego, the supplier and the health facilities, a total of 55 biomedical engineers/technicians and anesthesia preceptors were trained. Maintenance visits for each machine was conducted twice a year and 2 batches of spare parts were supplied by the Gradian Health System for maintenance purpose. Results and lessons learned: The effective collaboration ensured continuous functionality of

all the 14 anesthesia machines. The average running time of the machines was 501 hrs. 501 patients got surgical service. A total of 1,003 anesthesia students received hands on training. Although providing periodic maintenance support incurred extra cost and effort to Jhpiego, we have demonstrated the warranty period support for medical devices should not be the sole responsibility of the supplier. It is possible to achieve better result through collaboration of all stakeholders.

E. Assessment (HTA) of medical devices

R349 The Internet as a tool for an Early Awareness and Alert (EAA) system in the field of diabetes

Ms. Vânia Marlene Ferreira De Sousa, Miguel Antunes, INFARMED - National Authority of Medicines and Health Products, I.P., Portugal

Early awareness and alert (EAA) systems can be used as part of a national Health Technology Assessment (HTA) system to identify and filter new and emerging technologies which have potentially large implications for a health service, taking into account potential benefits and costs, allowing policy makers to have timely information before its adoption. There are multiple sources of information and tools to consider and an EAA system can be build based on an active identification, passive identification or a combination of both, depending on budget and staff of the agency. This work aims to develop an EAA system at INFARMED, I. - National Authority of Medicines and Health Products, I.P., based on the most used tool for an active identification – a web-search protocol - focused on an area set as a priority by the Portuguese National Health Plan: diabetes. A protocol was created and applied specifically to medical devices with a 5-year time frame, including sources of information, key terms and frequency of use. A prioritization process was also made, considering certain criteria based on national needs, signalising major interesting technologies for HTA purposes.

A87 Defining criteria for local versus national HTA

Dr. Katriene Bjørnebek Frønsdal, Arentz-Hansen H, Lauvrak V, Ormstad S, Fure B

The Norwegian health authorities established a system for introduction of new health technologies in the specialist healthcare in 2013. Mini-HTA is part of this system along with horizon scanning and HTA. Whereas mini-HTAs are performed locally in hospitals for local decision making, early warnings and HTAs are produced by the national HTA-centers to support national decisions. Mini-HTAs is a simplified version of a HTA, and takes several weeks to accomplish. Deciding on whether a mini-HTA is "sufficient" or an assessment at the national level is necessary has large implications on the following decision-making processes and use of resources. Therefore, a set of overall guiding criteria has been set to help this decision, but the use of these is currently being discussed. Among the nearly forty mini-HTAs that have been carried out so far, three have been "redirected" to the national level. We have used these to isolate possible determinants that might influence the decision on whether a medical device or other non-pharmaceutical technology should be evaluated in a mini-HTA at the local level or in a HTA at the national level. These experiences indicate that main determinants are related to economical, organizational and ethical issues.

R191 Ultrasound adjunct in breast cancer screening

Mr. Flávio Mauricio Garcia Pezzolla, Priscila Avelar, Renato Garcia, IEB-UFSC, Brazil

This research presents an evaluation of Ultrasound as an adjunct to mammography diagnosis in women between 30 and 60 years old with high risk of breast cancer in Brazil. The methodology is based on the Methodological Guidelines for Elaboration of Studies for the Evaluation of Medical Equipment developed in Brazil. In this study, a scientific and technical advice was performed addressing the Clinical Domain after the evaluation of the admissibility of the equipment in the country. In this Domain it was necessary to define a specific key question with appropriate inclusion and exclusion criteria for a better research strategy in the scientific literature. The process of finding evidence was through descriptors in the main databases, analyzing Systematic Reviews and Randomized Clinical Trials and using quality checking tools such as the GRADE table. The initial results indicated that combining ultrasound in early stage diagnosis led to more false-positives. However it is not evident the reduction of mortality, interval rate and in advanced stage diagnosis, just a low increase positive diagnosis on dense breasts. Further studies are needed in other areas defined in the guideline due to a lack of high quality evidence.

R141 Technology decision-making process: MRI purchase in Portugal

Ms. Maria Maia, Faculty of Sciences and Technology, Portugal

MRI is a recent medical device, with a promising future and high cost associated to its purchase and maintenance. Since "equipment purchase is an easy way for the health system to waste resources" (WHO 2000,139), the present research aims to contribute to a deeper understanding on the purchase decision-process characterization of MRI, in the Portuguese healthcare system. Moreover, it is important to try to answer the question: "Is the decision-making process based on the described HTA model? If not, does it include social and ethical aspects?" Following a mixed-method approach, and using questionnaires and interviews as strategies of inquiry, preliminary results show that there is a market-driven rationality behind the decision process. Radiology Departments tend to be reactive, meaning that an investment planning is not considered rather triggered by Radiologist/Radiographers requests or as an answer to increase competition.

Also, the HTA core model for assessing technologies is not fully considered, meaning that besides costs, suppliers and technology characteristics, for instance, the social and ethical aspects should not be ignored when evaluating health technologies in an acquisition decision process.

There are no guidelines for assisting decision-makers in their purchase decision.

R521 Priority-setting for medical devices and equipment

Ms. Mutsumi Metzler, Mr. Todd Dickens, PATH, United States of America

Countries frequently must make complex decisions in order to introduce high-impact health technologies. Making effective decisions therefore requires a systematic, evidence-based process. The process should also involve multidisciplinary stakeholders using multidimensional criteria to assess health technologies, not only from economic perspectives but also from ethical and social perspectives. Employing a priority-setting process, or health technology assessment, to support decision making is essential for strategic procurement, supply chain management, and management of medical technologies. Making inappropriate decisions results in the procurement of unusable devices and equipment, and wastes both money and opportunity. Priority-setting for medical devices and equipment presents unique challenges because additional factors must be taken into account. These factors include 1) product life span and utilization rate to make demand projections, 2) alternative acquisition models for procurement of capital equipment, and 3) cost of maintenance and repair to estimate total cost of ownership. PATH will share results and lessons learned from a regional workshop and technical support to Kenya, Tanzania, and Uganda on building the capacity that local health officials need for rational decision-making in the selection and procurement of medical devices and equipment.

R623 Prioritisation of medical devices and diagnostics in India

Dr. Yogita Kumar, Gupta Madhur, WHO, Ameel Mohammed, National Health Systems Resource Centre, India

The global priority medical device project was initiated under the guidance of World Health Organisation to bring attention of the international community on the specific needs, problems, and challenges of the crucial public health area of medical devices. Government of India (GoI) is now focussing on improving access to appropriate medical devices to address its public health goals. Under this project, gaps in availability of medical devices will be identified in context of services under National Health Mission/Universal Health Coverage and burden of diseases (ICD-10) in the country. The availability matrix of mapping medical devices to priority diseases and disabilities based on clinical guidelines and medical device nomenclatures will be used as a basis for the gap analysis. Also, challenges related to accessibility, appropriateness, availability and affordability that hinder full use of these devices as public health tools will be assessed. New innovations will be evaluated for uptake by Sector Innovation Council for Health, Government of India. Areas where new innovations are required will also be identified and promoted. National health policymakers, international organizations, manufacturers and other stakeholders will be brought together for requisite funding, designing innovations and indigenous manufacturing of medical devices.

F. Human Resources for Medical Devices

R136 Overcome the shortage of radiotherapy staff in LMICs

Dr. Stefan Berz, Michael Sandhu, Access to Care Foundation; Patrick Kupelian, Varian Medical Systems, United States of America; José-Manuel Valentim, Varian Medical Systems; Switzerland; Jan, LäraNära Degerfält, AB, Sweden

How to overcome the shortage of radiotherapy staff in low and middle income counties

Cancer presents a significant obstacle to development in low- and middle-income countries (LMICs), where it is the leading cause of death and disability. LMICs carry 80% of the global cancer burden, but have access to only 5% of the resources needed to control cancer. For example, state-of-the-art radiation therapy is not available in many of the world's LMICs as a result of high investment costs, high resource demand, and complex technical and clinical use. To overcome this shortage in radiation therapy the Access to Care Foundation investigates educational solutions which can be used for basic scientific and clinical training of Radiation Therapists, Radiation Oncology Medical Physicists and Radiation Oncologists.

The Foundation's training portfolio includes distant learning courses, on-site workshops, local training curricula and the installation of fully equipped training centers.

In this workshop, the current demands in emerging countries are presented, and the Foundation's training programs are discussed regarding their advantages, disadvantages and needed resources. The session will conclude with an open discussion of the audience's experience and expectations to overcome the immense demand of skilled health care professionals in the world's growing and emerging countries.

R560 Design requirements for task-shifting medical devices

Ms. Marianna Coulentianos, Amir Sabet Sarvestani, Kathleen Sienko, Richard Gonzalez, University of Michigan, United States of America

Task shifting has gained attention as a solution to address the limited health workforce in low-resource settings, but currently, there are no guidelines available for the design of task-shifting medical devices, which could enable lower cadres of health providers to achieve their newly defined tasks. This study investigates the priority product requirements for the design of task-shifting medical devices for use in low-resource settings.

An online survey focused on task-shifting medical devices was used to elicit responses from approximately 100 stakeholders including healthcare providers, biomedical engineers, and public health staff, through open-ended questions, multiple choice questions, and rank order scaling. Themes and categories were developed based on the qualitative responses and rank ordering was used for quantitative responses.

In addition to prioritizing conventional medical device design requirements (e.g., safe, effective), participants identified easy to use as the most important design requirement (100% of respondents). Additionally, participants further defined easy to use as capable of facilitating peer-to-peer training (90%) and able to be maintained locally (80%). These findings can be used to inform the design of task-shifting medical devices for use in low- and middle-income countries

A175-2 Prototyping best practices by Ghanaian novice designers

Mr. Michael Deininger; Kathleen Sienko, Shanna Daly, Jennifer Lee, University of Michigan, United States of America; Elsie Effah Kaufmann, University of Ghana, Ghana

Prototypes are essential tools in the design process but are often underutilized by novice designers. Prior studies have shown that experts use prototypes throughout the design process and for a variety of tasks, but novice designers are often more limited in when and how they use prototypes, as well as what types of prototypes they use, potentially restricting the design outcome. In this study we investigated how Ghanaian novice designers used prototyping best practices during their engineering design coursework. Thirty-three biomedical engineering design students from the University of Ghana participated in semi-structured interviews aimed at exploring their prototype

usage behaviors. We found that novice designers reported the frequent use of prototypes, the use of prototypes to define a design problem, and the use of prototypes to identify, prioritize and isolate functional blocks which is consistent with expert prototyping best practices. Using prototypes to engage with stakeholders occurred only infrequently and quick and simple prototyping, i.e., using readily available local materials, was not mentioned by any of the participants. Pedagogy and design internship opportunities that promote the use of prototypes to engage stakeholders and encourages the construction of low-fidelity prototypes should be explored.

A215 Intern programs of biomedical engineering education

Prof. Kangping Lin; Tsai, Chenglun, Chung-Yuan Christian University, Chinese Taipei

Clinical Engineers (CE) plays an important role in hospitals and medical equipment maintaining system. Having well educational practices are important to train student major in biomedical engineering for realizing how to support the healthcare systems including hospitals, long term care organizations, manufacture industries of medical devices/instrumentations/systems, and sales/services companies of medical devices/instrumentations/system. In past 15 more years, Taiwanese Biomedical Engineering society has accumulated hundreds people hold clinical engineer or medical equipment technician certification, and work as a clinical engineer in hospital and healthcare system. Most of BME students have been trained in biomedical engineering departments with a required program to have internship trainings in related hospitals or institutions out of campus for 320 hours before graduating. Almost all the biomedical engineering departments are certified by IEET (Institute of Engineering Education Taiwan), and met the IEET requirement in which required practice course. The CE practice course provides unique learning contents that can effectively help BME students in practical knowledge. In current status, some students in other engineering departments in university are encouraged to join the practice program with BME department to extend good multidisciplinary students having CE background.

A109 Educational partnership for human resources and medical devices: Danang, Vietnam

Dr. Miriam Mikhail, Rad-Aid International, Diagnostic Radiologist Based In Geneva, Switzerland; Lindsey Minshew, Candice Bolan, Hector Robles, J Mark Mckinney, Mayo Clinic, Florida, United States of America; Phuong Thi Loan Nguyen, Danang General Hospital, Danang, Vietnam

Mayo Clinic Florida (MCF) has been steering annual onsite visits to Danang General Hospital in Danang, Vietnam for over a decade with specific imaging involvement for >3 years. Danang General Hospital has 1,250 inpatient beds, 9 radiologists, and performs >700 radiographs, >400 US, >150 CT and >45 MR exams per day.

During the most recent visit to Danang several accomplishments were made including completing the RAD-AID International Radiology Readiness and PACS assessments, holding a national educational symposium for Vietnam radiologists, conducting daily case conferences, performing and teaching interventional procedures (IR) for trauma embolization, abscess drainage, and nephrostomy tube placement and addressing supply chain needs for IR medical devices.

Several future goals and plans were established including further strengthening relationships between Danang and MCF, further assessing the educational needs of Danang radiology physicians, working to meet these needs, continuing to assess the needs of the physical radiology infrastructure in Danang with a specific focus on obtaining a PACS infrastructure via planned proposals submitted through RAD-AID International, focusing on teaching new minimally invasive IR procedures during the next annual visit, and establishing teleradiology monthly conferences between Danang and MCF for case review and education. Within the realm of diagnostic imaging, this project serves as a model of stepwise, sustainable health systems strengthening in a middle-income country.

A185-1 Usability assessment of a task-shifting medical device

Dr. Ibrahim Mohedas; Gashaw Andargie, Mula Adefris, Biruk Mengstu,Takele Tadesse, University Of Gondar, Ethiopia; Jose Davila, Ajay Kolli, Kathleen Sienko, Kevin Jiang, Weiner, Annabel, University Of Michigan, United States Of America

The lack of trained healthcare providers limits healthcare access in rural areas of low- and middle-income countries. Task-shifting devices, which reduce training barriers, enable minimally-trained healthcare providers (e.g. community health workers (CHWs)) to provide more healthcare services, improving access. The usability of a task-shifting device, which aids in the administration of contraceptive implants, was assessed in this study. The study was conducted in Addis Ababa and Gondar, Ethiopia where 131 healthcare providers (e.g. CHWs, nurses, physicians) participated. Each participant administered contraceptive implants on an arm simulator using the standard free-hand method and using the device. Field notes and video recordings were taken as each participant administered implants. Audio recordings were taken of post-study interviews. The qualitative data were thematically analyzed. Interviews showed that participants responded positively to several device features such as its insertion depth control and patient fear reduction. Thematic analysis revealed unforeseen design changes associated with usability such as visual cues for insertion angle and the challenge of using a blood pressure cuff within the procedure. The study informed design changes and improved understanding of end-users. Additionally, the study reinforced the importance of usability testing in developing task-shifting devices, which leverage a new population of end-users.

R661 Rwanda biomedical technician training program

Mr. Costica Uwitonze, Rwanda Association of Medical Engineering, Rwanda

The aim of this training was to providing the Rwandan health system with sufficient BMETs to maintain and repair the medical equipment in the Rwandan hospitals and to lift the system to a higher level, through implementation of good Healthcare Technology Management□.

R744 Integrated model of universities to promote the clinical engineering

Prof. Beatriz Janeth Galeano Upegui , Universidad Pontificia Bolivariana, Colombia; Javier García, Juan Guillermo Barreneche, U de A; Nelson Escobar, UPB; Javier Camacho, EIA-CES; Sara Álvarez, ITM; Colombia

Six universities in Medellin, Colombia have joined trough inter university agreements to promote the clinical engineering at the regional and national level for more than three years. Universities are: Universidad de Antioquia, Escuela de Ingeniería de Antioquia in agreement with CES, Instituto Tecnológico Metropolitano, Fundacion Universitaria María Cno and Universidad Pontificia Bolivariana. Members participate in different projects related to the management and evaluation of technologies at the service of the health care in the different faces of the cycle of life of technology. They are linked to the network of evaluation of technologies for health in the Cluster of Services of Medicine and dentistry of the Chamber of Commerce of Medellin and Node Antioquia in biomedical Equipment driven by the Direction of Drug and technologies in health of the Ministry of Health and Social Protection of Colombia. This union between the universities aims to also promote innovation, research, academic development and dissemination of the policy associated with the themes of the clinical engineering by creating spaces in which we can strengthen relations University-Company-Health Care Institute-Government, such as the organization of the International Congress of Clinical Engineering in version 2 and 3, the last held in March of this year with support of the ACCE and the IFBME.

G. Innovation Process/R&D of Medical Devices

A175-1 Influence of prototype type on stakeholder engagement

Mr. Michael Deininger; Shanna Daly, Jennifer Lee, Kathleen Sienko, University of Michigan, United States of America; Elsie Effah Kaufmann, Samuel Obed, University of Ghana, Ghana

Receiving input from stakeholders is critical during the early stages of a product design process to frame the initial problem definition and establish user wants and needs. Stakeholder input is also imperative during the concept generation stage to ensure that potential designs are addressing the actual problem and meeting their expectations. The objective of this study was to characterize the quality and quantity of stakeholder feedback for different types of prototypes. During this study, healthcare stakeholders in Ghana including nurses and midwifes, medical students, and medical doctors were presented with a variety of low- and high-fidelity prototypes of an assistive medical device. Semi-structured interviews were conducted and participants were asked several questions to evaluate the concept solution. Stakeholder responses were categorized according to how actionable the feedback was for a designer. We found that the type of prototype influenced the

feedback stakeholders provided, and this paper discusses differences between physical, 3-dimensional models and non-physical models like sketches or virtual CAD models. These findings highlight the importance of preparing appropriate prototype types when seeking feedback from stakeholders and underscore the need for additional research.

R522 Healthcare management in Brazil: investments in R&D of medical devices

Mr. Carlos Eduardo De Andrade Lima Da Rocha, Oswaldo Cruz Foundation, Brazil; Fabio Kurt Schneider, Federal University of Technology, Brazil

Abstract: The Brazilian strategic supplies industry for the public healthcare system largely depends on imported products to satisfy the needs of the Unified Healthcare System (Sistema Único de Saúde (SUS)), resulting in institutional weakness for the SUS. From this perspective, considering healthcare as a fundamental right, the technological development and production of new medical devices into the SUS represents a challenge for Brazilian Federal Government. Brazil now faces the challenge of enhancing economy-wide productivity-driven growth to secure and expand the social achievements of the last decade. Methods: This abstract was prepared based on a qualitative bibliographic study and considering reports by the World Health Organization (WHO), the Organization for Economic Cooperation and Development (OECD) and the World Trade Organization (WTO). Conclusions: Based on the analysis of the theoretical framework presented in this study, the entrepreneurial role of the Brazilian government is essential to the technological development and production of strategic healthcare supplies. It is possible to conclude that the actions of the Brazilian Federal Government were guided by a policy for articulation of efforts and production of synergies between institutions of various areas of scientific knowledge, both in the public and private sectors.

H. Medical Devices for Emergencies and Disasters

R263 Developing 21st century PPE against infectious diseases

Mr. Matthieu Gani, EPFL - Cooperation and Development Center; Manuel Schibler, Geneva University Hospital; Mathieu Soupart, Médecins Sans Frontières; Beat Stoll, University of Geneva; Switzerland

Currently available protection equipment against deadly emerging diseases like the Ebola virus suffer from a series of shortcomings, like a lack of fresh air that reduces working time with patients, complicated procedures to don and doff the equipment that increase the risk of self-contamination, or a limited field of view for the health workers which adds to the difficulty and risk of the tasks, and which limits visual interaction and empathic care with the patients. Based on disposable items, they are expensive and create large amounts of infectious waste.

The goal of the SmartPPE project is to develop a new protective equipment solution, that will offer an appropriate level of biosecurity against existing and emerging threats, and be specifically adapted to the context of vulnerable countries: budget constraints, storage conditions, usage environment, staff training, available disinfection facilities and all the other elements of a comprehensive value chain must be taken into account.

The development of a sustainable business model alongside the necessary technological innovations is also mandatory for the long term and large scale deployment.

Technology challenges include the development of a miniaturized ventilation system, an anti-microbial textile, and an improved design to facilitate donning, doffing and comfortable use.

R478 An improved PPE suit for disease outbreaks

Ms. Margaret Glancey, Patience Osei, Soumyadipta Acharya, Youseph Yazdi, Johns Hopkins University, United States of America

HCW were at 21 to 32 times greater risk for Ebola infection compared to the general population during the 2014 epidemic. To address this problem, our team developed an improved PPE suit for use during infectious disease outbreaks.

Challenges with the current PPE suit were identified through research and stakeholder meetings conducted in US and West African healthcare settings. Manufacturers, clinicians, nurses, and frontline

HCWs were engaged in the process. Needs for an improved suit were prioritized, followed by rapid iterative prototyping. Stakeholder engagement and testing was conducted after each iteration.

The final design included a new coverall and respirator hood. Compared to the standard PPE suit used during the Ebola outbreak, the new suit reduces the number of suit components, the number of contamination points, and the number of steps to doff. Comfort and visibility was improved in the hood by including a large, clear, face-shield, respirator face mask with large integrated inhalation vents, an isolated exhalation path and a double flap shroud - improving view, patient visibility, decreasing fogging and increasing ease of breathing.

A167 Novel transport isolator for highly contagious diseases

Dr. Knut Erik Hovda; Broch Brandsaeter, Espen Rostrup Nakstad, Fridtjof Hayerdahl, The Norwegian CBRNE Centre of Medicine, Department of Acute Medicine, Oslo University Hospital

Highly infectious diseases pose a threat to global health, being it SARS, MERS, Ebola, or other pandemics. Further, the ongoing threat of antibiotic-resistant infections continues to challenge modern health care, and the global problem of multi-resistant tuberculosis is increasing.

Adequate preparedness for biological incidents is a demanding task for health care services. Personnel must be protected, and environmental contamination avoided. Pre-hospital transportation of infectious patients is particularly challenging, and the barrier securing the treating personnel increases the risk for the patient.

We have developed the patient transportation isolator "EpiShuttle", with a unique design that provides access to the patient for intensive care treatment and emergency procedures, including intubation and insertion of central venous catheters etc. It is compatible with most mechanical ventilator circuits, and offers easy communication and patient comfort. It can be safely decontaminated after use. By using a negative-pressure mode, it provides environmental protection from particulate cross-contamination of highly infectious diseases. In positive pressure mode, the isolator protects immune-compromised patients, or protects from hazardous environmental agents through the use of CBRN filters. To be released in 2017, it will be made compatible with transport in ambulances, medium & large-sized helicopters as well as most aircrafts (see www.epiguard.com).

R334 Rapidly deployable clinical solutions

Ms. Sarah Michel, Sharmila Anandasabapathy, David Hilmers, Baylor College of Medicine, United States of America

During the Ebola crisis in W. Africa, Ebola Treatment Units (ETUs) limited the providers' ability to care for patients efficiently, effectively and safely. Tents, already existing hospitals, and new construction were used as ETUs. [Describe issues with all from PPT]. The Smart Pods are an innovation created to replace ETUs as a state of the art clinical management unit for EVD patients. Smart Pods are invaluable in enhancing current efforts to provide a more effective and safer environment for patients and staff.

The Smart Pod is a Modular, Scalable, and Rapidly Deployable Clinical Management Unit that can quickly scale up to a plug and play facility. Units are shipped with all necessary medical supplies inside an ISO certified freight shipping container (pod) and each pod is stocked with a smart IT system featuring mobile apps to facilitate dissemination and training, a QR-code scanning system to track patients and supplies, and a user's manual for the Pod. Another key feature of the pod is the infection control system, designed to reduce transmission of EVD and promote protocol compliance. A HEPA filtration system and contained waste and effluent management system allow for easy cleaning and disinfection. Patients are treated in the same unit and this provides a rapid, cost-effective and scalable solution to the previous Ebola crisis, as well as other epidemics and natural disasters (tsunamis, hurricanes, etc.)where immediate medical facilities are needed and patient/supply tracking is critical. The unit can easily be adapted for areas without infrastructure (including solar-power) and adapted for use in emergency care as well as basic clinical care and procedural care (surgery, obstetrics). Currently we are working on the laboratory and pharmacy modules that will connect with the clinic to create a mobile, off grid solution to detect, diagnose and treat patients with a variety of health care needs in a variety of settings.

R191 A Breathe of Hope

Dr. Oladayo Olakulehin, LigandCorp, Canada

During emergency situations, and for patients requiring life support, health workers in most hospitals in developing countries, often have to squeeze CPR bags to keep their patients alive. The D-Box was designed for settings like this to automate the bag compression, releasing medical staff to attend to other patients. Conventional ventilators are designed for use in an Intensive care Units. ICU admission costs remain exorbitant for the majority of populations of developing countries, even the middle class. The D-Box can be used in the Emergency room, hospital ward or theatre, or recovery room providing a more efficient method for resuscitation and life support, pending availability of intensive care.

The D-Box is an innovative affordable battery operated ventilator designed to automate CPR bags and deliver controlled breaths to patients. The D-Box is easily deployable, affordable and requires little expertise to use. It is powered by a rechargeable battery that facilitates usage in remote rural communities.

R600 Multiple victims triage using Fuzzy

Dr. Leandro Zerbinatti, Silveira S.Vieira, Wesley O. Trindade, Ivan G. Duarte, Marcio O. Peres, Rodrigo O. Pastorelli, Uninove-Universidade Nove de Julho, Brazil

Seasonally occurring disasters involving nature force, equipment / human failure, or weapons of mass destruction, causing victims to a greater number of physicians and public health resources available for service. Thus, the first-aid team needs to decide to take them to the immediate treatment in the best conditions that the resources currently provide.

This study developed a software modeling in Fuzzy Logic, converting the START (Simple Triage and Rapid Treatment) protocol into diffuse rules. When recording the physical conditions (Pulse, Mental State, Bleeding, Breathing), the software ranks between the Black, Red, Yellow, and Green labels, indicating the first aid team the priority in the priority emergency rescue.

It was processed through Fuzzy Logic, several input conditions being possible to identify the behavior of the sorting outputs through color coding. As one of the conditions of entry of the protocol, it acts with a breath higher or lower than 30 movements, if the classification is exactly 30, the output represented is between the priority Yellow and Red simultaneously, it is up to the rescuer to better classify the individual. In this way an improvement point in the START protocol was identified to disambiguate this condition.

R807 Survey on medical devices appropriate for low and middle countries

Ms. Barbara Comte, Mélanie Amrouche, Robin Walz and Maurice Page, HUMATEM, France

According to WHO, in the Sub-Saharan Africa region, a large proportion (up to 70 per cent) of equipment lies idle due to mismanagement of the technology acquisition process, lack of user-training and effective technical support. This is often associated with inadaptability of the medical devices produced by developed countries, in the context of developing countries.
Given this situation, the NGO Humatem seeks sustainable solutions for a real strengthening of health infrastructures in developing countries. It is looking particularly at an innovative concept: medical technologies considered “appropriate for developing countries”.

They can be qualified as “appropriate” if they match certain criteria such as toughness, ease of use, adaptation to the local context, reduced capital and operational cost, availability of local maintenance and training, etc. Certain technologies considered “appropriate” are currently commercialized in these countries.

It appears however, that these technologies remain nevertheless relatively unknown to most users, biomedical workers, health authorities of developing countries, and international development organizations. Humatem has conducted a survey to validate the importance and interest in elaborating an information and awareness support to promote this innovative concept.

The poster will showcase the initial problem statement, the survey methodology, as well as the key results and testimonies obtained.

R808 Cooperation between biomedical training programs, a challenge for biomedical area

Ms. Mélanie Amrouche, Barbara Comte, Robin Walz, HUMATEM, France

The lack of programs in France and francophone Africa. Its purpose is to identify the existing partnerships between biomedical training programs, and to better understand the different factors that lead to or prevent the establishment, success, and growth of such partnerships. A survey has been created and shared with biomedical training programs to gather information from existing partnerships and also incentives and barriers to the creation of new partnerships.

The main result that there are only few partnerships between training programs: among the 22 French and 15 African programs that took part in the survey, only 12 percent are in partnership with another institution locally or internationally. When they are existing, they mostly involve student or instructor exchanges.

The value and potential impact of partnerships appears to be well known. Unfortunately, motivation and enthusiasm are often insufficient for such projects to come to life. This study identified the gaps that need to be filled in order to strengthen the quality of such partnerships.recognition, biomedical professionals are facing today, is a major challenge to the strengthening of healthcare in developing countries. Accordingly, biomedical training programs are still very limited. The NGO Humatem conducted a study on partnerships between biomedical training.

I. Innovation Technologies for Screening and Diagnosis

R456 Laboratory evaluation of EID point-of-care in Kenya

Ms. Nancy Bowen, Leonard Kingwara, NPHLS, MOH; Dorcus Abuya, NHRL; Rose Wafula, NASCOP; Kenya

BACKGROUND: In Kenya, MTCT for HEIs remain above 5% despite PMTCT scale up. The country has a centralized laboratory system for HIV EID and as a result, only 67% of HEIs are accessing EID testing. Furthermore, with additional PCR tests at birth, 6 and 12 months, it is expected that the number of EID tests will escalate to over 250000 tests. POCTs can now be used for HIV EID testing and has potential to decentralize testing and markedly reduce the turnaround time. However, there is very limited in-country evaluation data on POCs. We sought to evaluate the performance characteristics of Alere Q and Cepheid Gene xpert HIV 1 Qual assays.

METHOD: Laboratory comparison of Alere-Q and Gene Xpert to the existing 'gold' standard of care method (Roche CAP-CTM assay) at the National HIV Reference Laboratory, Kenya.

RESULTS: Alere Q and Gene Expert achieved sensitivity of 97.6% and 99.1% respectively while the specificity was 100% and 98.9% respectively.

CONCLUSION: The two EID POCs reported a good laboratory performance making their upcoming implementation a great initiative for Kenya in trying to race towards the UNAIDS 90-90-90 targets.

R199 Current research initiatives

Dr. Gábor Lovas, Agnes Beczik, Chempolis Ltd.; Mihaly Szacsky, Public Benefit Organization for Natural and Sport Science at the Technical University, Hungary

The SOMATOINFRA©® functional imaging technology, that was developed in Hungary allows real-time visualization of functional life processes without using any harmful radiation. The concept of technology was developed in full accordance with the mass screening guidelines of the WHO. The aim was to develop a medical decision support tool both preventative and everyday medical purposes.

There are three major areas onto investigative research efforts were concentrated on.

1) To develop a tool supporting screening and risk assessment investigations in low-income countries, especially for people living in isolation from proper healthcare facilities. A whole body screening method was established looking for signs of altered health status, regardless if it should be related to malnourishment, environmental pollution or other kinds of healthcare challenges.

2) To assess the applicability of the SOMATOINFRA©® system to visualize neurological pain syndromes and other forms of autonomic nervous system imbalances related neurodegenerative processes in the daily clinical practice.

3) As in-hospital infections related to the increasing presence of multi-resistant bacterial strains put great burden to healthcare and medical disease management, there is an ongoing effort to develop a suitable model of the SOMATOINFRA©® system for detecting early signs of both postoperative local and systemic infections.

R98 Evaluation of care, maintenance and user practices of medical laboratory equipment in Malawi

Mr. Victor Makwinja, University of Capetown, South Africa; Solomon Kachitsa, William Chimwala, Wakisa Kipandula, Tony Nyirenda, University of Malawi, Malawi

Background: Laboratory services are essential to supporting and improving health service delivery and are dependent upon the availability of functional equipment. Medical equipment is indispensable for the prevention, diagnosis, treatment, and management of all diseases. Functional equipment requires maintenance, spare parts, reagent supplies and proper use. There has been lack of preventive maintenance, user training and proper care of equipment in hospitals in developing countries.

Methods: A cross sectional study design was used in which 42 questionnaires were administered to professional and certified laboratory personnel at four central hospital laboratories in Malawi who had reported to work on the day of data collection.

Results: More equipment inventories are kept in electronic form. Preventive maintenance is performed. On-job user and care trainings are conducted. External repair services are reliable but expensive. Purchase and operation of equipment are heavily funded by donors.

A139 Assessment & selection: lead garments in diagnostic imaging

Dr. Miriam Mikhail, Rad-Aid International; Adam Lustig, Bryan Ashley, Kyle Jones, Ari Isaacson, Robert Dixon, The University of North Carolina at Chapel Hill, United States of America

Interventional radiology is a subspecialty of diagnostic imaging that focuses on the diagnosis and treatment of many diseases and uses imaging guidance to perform minimally invasive procedures. Protective garments are a necessary medical device used in this field of medicine for the occupational safety of the practitioner and the staff. Based on a survey of manufacturers, a literature search, and a review of testing standards, including those from ASTIM and IEC, the authors suggest an ideal method for protective garment selection which considers scatter radiation quality, types of cases, and garment mass. Important selection criteria for garments include protective matrix, thickness, and design. New research has explored improved methods to evaluate garments. Intelligent selection of a protective garment should balance consideration for protection and orthopedic strain. This exhibit outlines key practical considerations for the selection process. In the strategic planning for universal health coverage, protective garments should be a priority medical device in all diagnostic imaging departments. Imaging is frequently critical for the diagnosis and management of both non-communicable and infectious diseases, priorities of the World Health Organization, ministries of health and the broader health sector collaborating towards health systems strengthening.

R311 Design of collimator systems for interventional procedure

Prof. Seungwoo Park, Korea Institute of Radiological & Medical Sciences, Korea

The critical organ of patient was exposed for a long time during interventional procedure compared with another diagnostic radiography. To reduce dose of patient, it is designed the variable collimator system differently from previous study for patient safety through reduction of unnecessary patient dose in interventional procedure

We designed two modules to develop variable collimator system of interventional procedure. First module is the multileaf collimator possible to change shape of exposure field and the module was attached to the X-ray tube's head of C-arm at the exit slit of the X-ray beam. Second was user interface module. User can designate resign of interest (ROI) as treatment area was exposed for a long time during interventional

procedure and set shielding resign of critical organs.

Previous studies on dose reduction have been carried out using shielding materials and used selective lead collimator has limitation that was invariable shape, provided that the shielding itself does not affect the diagnosis. Our designed system was possible to change shape, freely and reduce the unnecessary dose of patient. The study would be look forward to increase the quality of life for patient undergoing interventional procedure.

J. Innovative Technologies for Treatment

R564 User-friendly delivery platforms for MgSO4 therapy – Evaluation

Dr. Patricia Coffey, Mutsumi Metzler, Elizabeth Abu-Haydar, Nancy Muller, Dr. David McAdams, Mike Eisenstein, PATH, United States of America

WHO recommends MgSO4 as the most effective anticonvulsant for treatment of severe PE/E, yet this intervention is widely underused. PATH identified five user-friendly technology solutions for MgSO4 intravenous treatment: 1) dilution bottle, 2) ready-to-use MgSO4 dose packs, 3) rectally administered gel, 4) dosing/dilution mobile application, and 5) reusable, electricity-free, low-cost infusion [RELI] delivery system. During development, PATH rigorously assessed market viability, acceptability, and health system fit and made a no-go/go decision at each milestone to advance technology solutions that best achieve value for money and health impact. Based on these considerations, we discontinued development of three of five technology solutions. User feedback about the dilution bottle from Ugandan and Ethiopian providers showed it did not significantly reduce steps currently required for dilution. These stakeholders concurred on the convenience of having all necessary items in a single ready-to-use dose pack, but they expressed strong desire for 20% MgSO4 solution, thereby avoiding need for dilution. Animal studies did not show sufficient bioavailability of MgSO4 rectal formulations to warrant product advancement. A low-cost delivery system and dosing/dilution mobile application could make it easier for health care professionals at lower-level facilities to administer MgSO4, thereby increasing proper use of this life-saving product.

R497 Affordable alternative orthopedic drills in emerging markets

Dr. Elise Huisman, Lawrence Buchan, Michael Cancilla, Florin Gheorghe, Arbutus Medical, Canada

The increasing presence of motorcycles on the aging infrastructure in emerging countries has resulted in a drastic increase in trauma orthopedic patients globally. Annually, over 50 million traffic accidents happen (WHO), that require simple surgical treatment for full recovery. Hospital budgets aren't increasing at the same pace, leading to a lack of adequate surgical equipment.

For nearly all surgical fracture treatments, orthopaedic surgeons must drill multiple holes in bone, yet many surgeons in low-resource settings only have a choice between two unsafe options: i) improvise with a nonsterile off-the-shelf hardware drill; or ii) use an inefficient, inaccurate manual hand drill. Even if a surgeon has access to one or two safe surgical drills at their hospital, that surgeon is often faced with delays between cases while waiting for their drill to be sterilized. Since western orthopaedic drills cost as much as $30,000, many hospitals in emerging countries cannot afford new equipment. Donated or refurbished surgical drills do not survive because batteries fail and replacement parts are rarely available.

Arbutus Medical's vision is to provide access to safe surgery globally as 5 billion people lack that access, while starting with access to a safe and affordable alternative to orthopedic drills.

A165 Safe medication management in LMICs

Prof. Beth Kolko; Bradley Younggren, University of Washington/Shift Labs, United States of America

Delivering intravenous medication safely and efficiently is a global challenge. Medication management tools like syringe or large volume infusion pumps require an ecosystem that is difficult to deploy in many LMICs; in addition to purchase price, pumps require regular calibration and maintenance, investment in training, regular AC power, and often proprietary disposables. Furthermore, they aren't optimized for environmental conditions like temperature extremes, humidity, dust, etc.

In this presentation we discuss a new approach to safe, cost-effective IV medication management: a medical device that monitors gravity infusion and increases patient safety while accommodating supply chain and training challenges.

We developed the US FDA-cleared and CE-marked DripAssist Infusion Rate Monitor which allows healthcare workers to leverage existing workflow patterns. DripAssist is a simple monitoring technology that provides 99% accurate medication drop counting and continuous monitoring via an optional alarm, all while running off one AA battery.

R251 A new handheld cordless thermal coagulator

Prof. Walter Prendiville, Sankaranarayanan Rengaswamy, Basu Partha, IARC, France; Parham Groesbeck African Centre of Excellence for Women's Cancer Control Zambia; Wallace Dean, Pickett Tim, Riddle Mike, Liger Medical; Juan Felix, University S California, United States of America

Cryotherapy is widely used to treat cervical pre-cancer in low and middle income countries. Difficulties with the reliable supply of gas and technical problems with equipment combined with the duration of treatment (11minutes) have led to interest in alternative methods of effective treatment. The authors have developed and are evaluating a novel method of Thermal Coagulation (previously known as cold coagulation) which is delivered through a lightweight cordless hand-held battery operated instrument (Liger TC) which is now available. Early in-vitro assessment is encouraging. Several clinical trials are at an early stage. This presentation will present the device and results of benchtesting tissue destruction depths.

R159 A pneumonia prevention system

Mr. Dr. Peter Young; Maryanne Mariyaselam, Queen Elizabeth Hospital, United Kingdom

PneuX™ Pneumonia Prevention System is a tracheal tube and tracheal seal monitor that prevents leakage of contaminated fluid to the lungs by maintaining a safe and effective seal continuously and uniquely allows for saline irrigation to maintain excellent pharyngeal hygiene. Pneumonia is the leading cause of nosocomial mortality in ICU resulting in tens of thousands of avoidable deaths and increasing ICU stay with an excess spend estimated at £60m per year for the NHS. Pharyngeal secretions rapidly become colonized with pathogenic bacteria that continuously drip into the lungs past all standard tube cuffs. Accumulating bacteria invades lung tissue causing pneumonia. It has recently been shown by investigators at Massachusetts General Hospital and Cardiff University that all current cuffed tubes leak bacteria and that the PneuX™ stops this 24/7. An independent NHS RCT showed significant reductions in hospital-acquired-pneumonia using the PneuX™ and health economists reported a saving of £700 per PneuX™ tube used. Listed as a Cleveland Clinic Top 10 innovation, the PneuX™ was selected for the NHS Innovation Accelerator and was awarded a tariff for adoption in the NHS.

The ICU is an incubator of antimicrobial resistance and the PneuX™ has been shown to break the antibiotic/re-infection cycle.

R289 Medical device for Feldenkrais therapy

Mr. Ruben Valenzuela, UNAM, Mexico; Rosa Itzel Flores Luna, Angelo Sandoval Villegas, Diana Hernández Matehuala, José Alberto Lira Montanez

Body awareness therapies (BAT) aims to augment mental awareness, movement harmony, concentration and peacefulness. The Feldenkrais therapy is a BAT based in slow movements in an isolated environment so an individual can increase his sensitivity to a maximum and distinguish finer details. However some may not be able to perceive these, otherwise unnoticeable sensations by themselves, so a medical device for the hand movement was developed. This device is used to help the user to observe through a visual feedback that, there is indeed a slight movement in their finger, improving their sensitivity and thus regaining lost functionality of minor movements.

A97 Growing rods system for early onset scoliosis

Prof. Jaw-Lin Wang; Po-Liang Lai, Chang Gung University; Jaw-Lin Wang, National Taiwan University, Taiwan

Early onset scoliosis (EOS) is defined as a spinal deformity that occurs before 10 years of age. Severe EOS

may be associated with an increased risk of death due to heart and lung disease. EOS can be treated either conservatively or invasively. It is recommended to have surgery with a growing rod system while conservative treatment fails to keep the scoliosis from progressing, or if the Cobb angle is more than 50 degrees. The growing rod system is a non-fusion spinal instrument that aims to correct the spinal deformity without adversely affecting future growth of vertebral body. The growth guidance system utilizes a gliding mechanism to guide the growing direction of the spine; however, Owing to the less restrictive nature of the implantation, these systems may not be able to provide sufficient spinal stability. Given the shortcomings and the disadvantages of the currently available growing rod systems, we developed a naval self-adaptive growing rods system.

R226 Design and fabrication of needle crusher

Prof. Akinwale Coker, Chibueze Achi, Charles Akintunde, Taiwo Hammed, Mynepalli Sridhar, University of Ibadan, Nigeria

A research was conducted on Sharps medical waste with needles selected because of the high level of risk involved in its traditional disposal and the huge volume of it being expended annually both locally and globally.The study was aimed at disinfecting and shredding needles into harmless steel materials for reuse. Several healthcare facilities (HCFs) were visited in southwestern part of Nigeria to assess the current methods of disposing used needles. The study shows that waste managers of most HCFs do not know the final destination of the disposed needles and there is no needle recycling system in Nigeria as at the time of the study in 2016. The waste management system we came up with is made up of four chambers (disinfecting, inlet, crushing and outlet). Tests were carried out on the fabricated system using 300 needles for each round of experiment. The results show that the machine operates at 7,5% retention and 92.5% passing efficiency with average run rate of 3 needles per second. It was proved that the system would safely dispose needle waste and encourage sustainability by reusing safely-disposed needles in other industries without compromising the safety of the end users.

A249 Testing normal pressure hydrocephalus disease

Mr. Walef Robert Ivo Carvalho; Amanda Kelly da Silva, Ana Flávia de Almeida, Fernando Campos Gomes Pinto, Thiago Moreira de Carvalho Vieira

The normal pressure hydrocephalus (NPH) is a disease that affects the elderly between 60 and 80 years and is manifested through the clinical triad characterized by gait disturbance, dementia and urinary incontinence. It is about 5% of the causes of cerebral dementia, behind Alzheimer's disease and is surgically treated. The research focused on the development of a pad with sensors and the patient with NPH walk 3 meters of distance under it. The round trip time is obtained and throughout the procedure is filmed and registered. The data go into database developed software and the screen shows all information about the examination of the patient, such as speed, number of steps and cadence. It is able to generate charts and also the software tells you whether the patient has the need for surgical intervention, through the examination of medical images included in the system. The procedures were all performed manually by the medical team at the Institute of Psychiatry hospital of USP (Sao Paulo University). The carpet and the interpretation software developed have sensors and applied technology. It allows accuracy and optimization of exam time. Some qualitative tests have already been done in USP and the results have been satisfactory.

A185-3 Contraceptive implant removal device target product profile

Dr. Ibrahim Mohedas; Zerihun Abebe, Delayehu Bekele, St. Paul's Hospital Millennium Medical College, Ethiopia; Tina Al-Khersan, Amy Kamdem, Caitlin Choi, Kathleen Sienko, University of Michigan, United States of America

Ethiopia has a lack of trained healthcare providers (2.5 physicians/100,000 people) limiting access to effective long-term contraception including subcutaneous contraceptive implants. Currently, the Ethiopian Ministry of Health is training Health Extension Workers (HEWs) to administer Implanon NXT at health posts, allowing women in more rural areas access to long-term contraception. However, these workers are not trained to remove implants and therefore, women must travel long distances to have

implants removed or replaced. The design and development of an assistive device to aid HEWs in the removal of palpable contraceptive implants is crucial to increasing uptake of contraceptive implants in rural areas of LMICs. We have developed a target product profile for an assistive device to aid HEWs in the removal of contraceptive implants using design ethnography methods in tertiary and secondary healthcare facilities in Ethiopia. Interviews, observations, and simulated implant removals were performed with a variety of healthcare workers with differing levels of experience. The target product profile comprises required key attributes of an assistive removal device including the need for features to stabilize movement of the implant prior to the delivery of anesthesia, facilitate a minimally invasive procedure, and increase the palpability of the implant.

R608 Affordable clubfoot brace for LMIC clubfoot treatment

Mr. Saketh Kalathur, MiracleFeet, India; Shriya Soora, MiracleFeet, United States of America

1 in 750 children worldwide are born with clubfoot, a debilitating condition causing feet to point inward and upward, making it difficult to walk. 1 million people live with clubfoot globally and disabled children are more likely to experience poverty, lack of education, and abuse. Current clubfoot braces are cheap and uncomfortable ($8-60), or comfortable but expensive ($150-$1,000). Research shows that a comfortable and practical brace could increase usage and prevent feet from relapse. Globally, lack of an appropriate brace prevents 200,000 children per year from treatment.

MiracleFeet's brace (MB), developed with Stanford, Clarks Shoes, and Suncast, is easy to use, cost effective ($20), and comfortable. 3,429 MB bars and 5,697 MB shoes have been utilized in 19 LMIC partner clinics. A mobile questionnaire of 152 parents from 5 LMIC countries comparing the MB to a non-MB showed the MB had higher ease of use scores, lower blistering, and increased compliance. All providers surveyed from 7 LMIC expressed positive satisfaction for usage, practicality, and medical appropriateness. In collaboration with IIT-B, an RCT is now in progress comparing compliance between MB and non-MB using integrated brace sensors. The MB revolutionizes feasibility for affordable global scaling to address clubfoot in all LMIC.

R153 PVC free blood bag

Ms. Alice Ravizza, Italy; Hans Gulliksson, Lena Stigh

Blood Bags are currently in PVC, known for posing hazards to health due to phthalates. PVCFREEBLOODBAG is a class IIb Medical device that was developed as part of the EU founded project “PVCFreeBloodBag - Public healthcare and plastics makers demonstrate how to remove barriers to PVC-free blood bags in the spirit of REACH LIFE10 ENV/SE/000037”. It is a set of 3 or 4 bags intended to collect donated blood, preserve it during transportation, process it and store the blood components for further re-infusion. It is 100% PVC-free by design and meets regulatory requirements for red cells storage up to 28 days. The device is not ready for CE marking as some Essential Requirements are not completely met. Challenges include validation of sterilisation and shelf life, prolongation of red cells life and plasma storage.

A172 Safer medication administration for labor/delivery

Prof. Beth Kolko; Bradley Younggren, University of Washington/Shift Labs, United States of America

Postpartum hemorrhage and eclampsia/preeclampsia remain leading causes of maternal death, with disproportionate burden on LMIC women. Active management of third stage of labor is essential; a key component is early administration of oxytocin and magnesium sulfate intravenously, usually via gravity. Without proper medication management tools, gravity infusion carries risks for patient safety. For example, treating patients with too high a dose and/or rapid administration of oxytocin is associated with peripheral vasodilation, hypotension and increased pulmonary artery pressures.

In May 2016, Shift Labs began working with five hospitals in Haiti to examine whether labor and delivery procedures would benefit from gravity infusion monitoring. The goal was to see if a gravity infusion tool would be accepted by clinicians, used regularly, and contribute to accurate dosing of critical medications like oxytocin and magnesium sulfate. Use of DripAssist was tracked for each treated patient, and ongoing interviews with nurses were conducted.

79 patients received gravity infusions with DripAssist, including magnesium sulfate and oxytocin. Nurses reported increased confidence that patients were receiving correct dosages, and DripAssist was integrated into existing practices, eventually being used for a range of infusions. These findings suggest that infusion monitoring technology can improve medication management practices for maternal health.

K. Innovation In Vitro Diagnostics

R267 Rapid diagnostics of mosquito transmitted diseases

Dr. Robert Burger, BluSense Diagnostics, Denmark

BluSense Diagnostics is developing a novel point-of-care platform for the rapid detection of infectious diseases such as dengue and zika from a single drop of blood. BluSense's portable laboratory system (BluBox) is designed for decentralized diagnostics of various biomarkers and delivering results in a few minutes, with minimal user interaction.

The system comprises of a small, portable and low-cost reader (BluBox) and single use disposable cartridges the size of a credit card.

BluSense is currently finalizing development of the reader and the first test for dengue fever, which will be available in 1Q2018.

R455 Evaluation of a FVE DBS protocol, Kenya

Ms. Dorcus Abuya, Edward Onkendi, National HIV Reference Lab, Kenya

Evaluation of ROCHE FVE DBS protocol, Kenya1. Dorcus Abuya 2. Edward Onkendi 3. Nancy BowenRoutine HIV-1 viral load monitoring for patients under anti-retroviral therapy is still a challenge in Kenya due to the high cost of obtaining, processing and transporting plasma samples required for viral load monitoring. DBS can be used for viral load monitoring since this sample type requires minimum resources. EDTA blood samples from 180 HIV-1 patients on HAART were used to prepare DBS and plasma samples for viral load testing using Roche Cobas Taqman assay. In general, HIV-1 RNA measurements in DBS were lower than those obtained in plasma samples. However, detection rates in DBS samples were 100% in plasma samples with $\geq$ 3.0 log10 copies/ml. Plasma samples with $\leq$ 2.3 log10 copies/ml were not detected in DBS. There was high correlation (Pearson's correlation, $r = 0.917$, $P < 0.05$) in HIV-1 RNA measurement between DBS and plasma samples. In addition, there was good concordance between individual plasma and DBS results based on Bland-Altman analysis. Overall, results from this validation suggest that DBS can be used as an alternative sample type for HIV-1 RNA measurements in patients attending remote and peripheral health care facilities.

R330 Low-cost inkjet-printed paper diagnostics

Dr. Blanca Leticia Fernandez Carballo; Albert Comellas-Del-Castillo, Borros Salvador, Institut Químic de Sarrià Grup d'Enginyeria de Materials (GEMAT), Universitat Ramón Llull, Spain

Background: Developing countries lack basic medical devices, and when available, they are very often inappropriate to their conditions and end up malfunction or are broken due to the lack of maintenance know-how and/or in-country spare parts and supplies. Most of these issues could be solved by enabling developing nations to design and manufacture their own medical devices. In this context, we present a diagnostic device that can be easily manufactured in limited resources laboratories: chemical paper dipsticks to detect biomarkers present in biological fluids produced with domestic inkjet printers and simple ink preparation recipes. This fabrication technique for diagnostic strips was tested for the detection of iodine deficiency. Two chemical reactions were selected.

Methods: The procedure for developing and characterizing chemical inks, as well as the printing protocol are described.

Results: Successful experiments for chemical inks preparation, printing in paper and semi-quantitative detection of iodine in the concentrations present in the urine are herein presented. Differences between deficient, adequate, and excessive iodine intake groups could be well discriminated.

Conclusion: This simple and versatile manufacturing process for diagnostic tests would allow hospitals and

laboratories with limited infrastructure to design diagnostics for relevant diseases in a format and quantity adapted to each community needs.

A164 Low-cost point-of-care rt-qPCR system for RNAvirus detection

Dr. Blanca Leticia Fernandez Carballo; Christine Mcbeth, Ian Mcguiness, Maxim Kalashnikov, Christoph Baum, Fraunhofer Institute for Production Technology IPT, Germany; Salvador Borros, GEMAT, Institut Químic de Sarrià, Universitat Ramón Llull, Spain; Andre Sharon, Alexis F Sauer-Budge, Fraunhofer USA Center for Manufacturing Innovation, United States of America, & Biomedical Engineering Department, Boston University, United States of America

Point-of-care (POC) medical devices are promising for diagnosing and managing diseases in limited resources settings because they have the potential to be more rapid, portable, and simple to use than conventional device while maintain the same sensitivity and specificity. We present a novel low-cost POC real-time fluorescence-based continuous flow RT-PCR chip that allow identifying and quantifying RNA-based pathogens within 30 min. The system is designed around a disposable microfluidic chip produced by hot embossing at low cost. The chip works by introducing the pathogen sample along with nucleic acid reagents into a lengthy microfluidic channel that first go through a 50-57 C heated area where reverse transcription takes place. Next, the newly formed cDNA travels cyclically between 95 C and 62 C heated areas. By thermally cycling the sample, the DNA gets amplified and it is detected on chip by real time fluorescence measurements. To demonstrate the functionality of the chip, Ebola viral RNA was selected as a model target. Flow velocity experiments were performed, the limit of detection of the RT-PCR system was determined, and PCR efficiencies were calculated. Our successful results together with the speed, low-cost production, and versatility of our system make it promising for the detection of wide variety of RNA-based viruses.

R515 Novel bedside diagnostics for methanol poisoning

Dr. Knut Erik Hovda, Gaut Gadeholt, Dag Jacobsen, Oslo University Hospital, Oslo, Norway

Background

Every year, thousands of people are poisoned by methanol. Despite effective treatment, the lack of awareness, knowledge and especially diagnostic equipment, leaves thousands of dead, blind or brain damaged. Methanol poisoning most often affects the poorest of the poor – children and adults – predominantly in the low- and middle income countries. By often tearing away the young and healthy members of society, it increases the social burden. We have therefore developed a point-of-care diagnostic tool (MeTOX) for measuring formate, the toxic metabolite of methanol.

Methods

The strips are constructed in a similar manner as a glucose meter, where one drop of blood from the finger detects formate by a color change.

Results

The prototype is now finalized, with testing rendering a high sensitivity and specificity. The result can be read within 2-3 minutes from a disposable strip. Shelf life is > 2 years.

Conclusion

We have developed a simple, bedside tool for diagnosing methanol poisoning and for screening metabolic acidosis of unknown origin: No laboratory equipment is needed. The sensitivity and specificity is high, it is stable, and can be disposed after use. The production of MeTOX Generation 1 is expected to start in 2017 as non-for-profit for the inventors.

A153 New urine dipstick for improved preeclampsia screening

Dr. Brandon Leader, Emily Gerth-Guyette, Nicole Advani, Kelly Randels, PATH, United States of America

Preeclampsia (PE) is a leading cause of maternal death worldwide. Prevention of severe clinical complications, including death, due to PE requires accurate, timely identification of women at high risk and linking them to proper care. Proteinuria remains one of the primary indicators to identify women at high risk for PE. However, current tools for proteinuria determination have significant limitations in accuracy, in the case of the widely-used protein-only dipstick, or their accessibility due to the technical

complexity and expense of laboratory-based reference standards such as the 24-hour urine collection.

PATH and its partners are working to advance a simple Protein-to-Creatine (PrCr) ratiometric urine dipstick test manufactured by LifeAssay Diagnostics (South Africa) that has an estimated cost comparable to common protein-only dipstick products. Unlike protein-only dipsticks, the PrCr test adjusts for urine dilution to account for the level of body hydration and improve test accuracy. Prior laboratory-based evaluations of the PrCr test demonstrated performance of 85% sensitivity and 71% specificity (95%CI) for proteinuria determination versus laboratory-based reference assays. Late stage development activities for the PrCr test are ongoing including upcoming evaluations in South Africa and Ghana beginning in 2017. Early launch of the product is anticipated within the next two years.

R652 Implementing leprosy diagnostic and monitoring solution in Pakistan

Prof. Phillip Olla, Audacia Bioscience, Canada

Leprosy is a 3000-year-old disease caused by Mycobacterium leprae. It causes irreversible damage to the skin and the peripheral nervous system. There are over 200,000 new cases globally, which equates to a new diagnosis individual every 2 minutes, with many more cases going undiagnosed. Despite challenges faced by untrained clinical staff, most current cases are diagnosed in areas that have limited or no laboratory equipment available. Diagnosis is performed by identifying hypopigmented patches of skin with loss of sensation, thickened peripheral nerves, or both. It can also be diagnosed by conducting a skin biopsy in a specialized lab. This approach is inadequate to support early diagnosis, as it relies on symptoms appearing, which are irreversible after treatment.

The availability of easy to use Point of Care (PoC) test medical devices to enable early diagnosis and referral to specialists are not universally available. This presentation will examine the current PoC techniques emerging, and discuss an innovate approach being deployed in Pakistan. The solution uses a PoC rapid test that could be used in the community. The solution is integrated with a smartphone-based mHealth platform, which facilitates reliable, objective test interpretation and supports a real-time telemedicine referral system

A75 A system for heart disease screening and prognosis

Mr. Rene Ivan Gonzalez Fernandez, Jorge Aguilera-Perez, Gisela Montes De Oca, Marisabel Lopez-Fernandez, Pedro Luis Gonzalez, ICID Digital Medical Technology, Cuba

The proposed system is focused on the early detection and follows up of persons suffering cardiac disturbances in the community. The system is composed by a portable device for standard ECG recording, henceforth Recorder, and a desktop application, called Analyzer, to storage and study the signals acquired. The Register acquires and processes the standard ECG automatically, providing monitoring capabilities for emergency situations too. The patient data, the ECG and measurements are stored on the Recorder to be transmitted to the Analyzer later. The received information is stored in a database; the trend of several parameters associated with heart disease is computed for each patient. The studied parameters are: spatial dispersion of QT interval for malignant arrhythmias, the Selvester´s Score for heart attacks, the Sokolow´s index and Cornell's index for ventricular dilatation or hypertrophy. In an emergency situation, the ECG can be transmitted in real time to a Telecardiology system where experts analyze the incoming signal to indicate how to treat the patient. The same standard and the CSE database were used to test the ECG's processing algorithms. This approach seems a useful tool to detect cardiac disturbances in their early stages and reduce their morbility without significant costs.

R508 An innovative fetal heart rate monitor

Ms. Sakina Girnary, Ida Neuman, Kate Halvorsen, Karoline Linde, Jennifer Gilbertson, Laerdal Global Health, Norway

Stillbirths and deaths due to birth asphyxia account for two million perinatal deaths every year, of which 98-99% occur in low-and-middle-income countries. In 2012, Laerdal Global Health partnered with Tanzanian, Norwegian and other international research institutions to form Safer Births, a research and development collaboration including 12 PhDs with the aim to establish new knowledge and develop innovative solutions to better train and equip health-workers to save newborn lives. One of these innovative solutions is Moyo; a low-cost fetal heart rate (FHR) monitoring device. Appropriate intrapartum FHR monitoring has the potential to detect fetuses at risk at an early stage, providing the opportunity to

make correct and timely obstetric interventions. However, in resource-limited settings, there is often neither sufficient staff nor proper equipment to do this. With a 9-¬crystal sensor, Moyo can accurately detect FHR within 5 seconds and can differentiate the maternal HR and the FHR. Moyo comes with a 30-minute histogram display of the FHR, as well as an audio-visual alarm if abnormal FHR is detected, and can also monitor continuously, even while the mother is moving around. Moyo therefore has great potential to effectively reduce the workload of health-workers without interrupting current routines, and detect abnormal FHR earlier.

R657 Enabling and scaling early detection of breast cancer in lmics

Mr. Mihir Shah, UE LifeSciences; Ophira Ginsburg, Laura and Isaac Perlmutter Cancer Centre at Nyu Langone Medical Center; Ari Brooks, Pennsylvania Hospital, United States of America

Background: With the incidence of breast cancer rising worldwide, we are evaluating the iBreastExam (iBE) (UE LifeSciences Inc.), a handheld breast scanning device that can be utilized by community health workers to screen for breast abnormalities. The purpose of this study is to determine the sensitivity of the iBE in a population undergoing diagnostic breast imaging.

Methods: Adult patients presenting to a breast imaging center for a diagnostic workup were eligible. Patients underwent an iBE exam performed by a trained ultrasound technician followed by their indicated imaging. Demographic, imaging, and biopsy data were recorded.

Results: Seventy-eight iBE exams were completed, 77 females and one male with a mean age of 42 (21–79). All patients were evaluated by ultrasound, 52 had diagnostic mammography and 39 had biopsies. Imaging and/or biopsy confirmed a mass (fibroadenoma, cyst, papilloma, myofibroblastoma, fat necrosis, DCIS, or cancer) in 60 patients. Twelve patients had a cancer diagnosed. In total, 342 quadrants were scanned, 77 quadrants had lesions confirmed on imaging, and iBE correctly identified 66 lesions for a sensitivity of 86 % and specificity of 89 %.

Conclusions: This validation study demonstrated excellent sensitivity of iBE for the identification of clinically significant lesions in patients presenting for diagnostic imaging.

R218 Ultra-low-cost endoscopy for gastroesophageal cancer screening in low-income countries

Prof. Pietro Valdastri, Joseph Norton, Simone Calo', University of Leeds, United Kingdom; Beatriz Plaza, Andrew Durkin, MiracleFeet; Federico Campisano, Douglas R. Morgan, Keith L. Obstein, Vanderbilt University, United States of America

Gastroesophageal cancer is a major leading cause of cancer death worldwide and screening programs have had a significant impact on reducing mortality. The majority of cases occur in low- and middle-income countries (LMIC), where endoscopy resources are traditionally limited. In this paper, we introduce a platform designed to enable inexpensive gastric screening to take place in remote areas of LMIC. The system consists of a swallowable endoscopic capsule connected to an external water distribution system by a multi-channel soft tether. Pressurized water is ejected from the capsule to orient the view of the endoscopic camera. After completion of a cancer screening procedure, the outer shell of the capsule and the soft tether can be disposed, while the endoscopic camera is reclaimed without needing further reprocessing. The capsule, measuring 10 mm in diameter and 28 mm in length, is able to visualize the inside of the gastric cavity by combining waterjet actuation and the adjustment of the tether length. Given the compact footprint, the minimal cost of the disposable parts, and the possibility of running on relatively available and inexpensive resources, the proposed platform can potentially widen gastroesophageal cancer screening programs in LMIC.

R572 An innovative education model for cervical cancer screening training

Ms. Maria Young, Julia Kramer, Visualize, United States of America

Every year, 275,000 women die from cervical cancer, and eighty percent of these cases occur in low and lower-middle income countries. Screening for cervical cancer significantly reduces mortality, given that most cervical cancer and pre-cancer cases caught early are treatable. In Ghana, cervical cancer is the leading cause of cancer-related death for women yet less than 5% of women have ever been screened. Visual inspection of the cervix with acetic acid (VIA) is an effective low-cost method to screen for cervical cancer but is not used widely, due to a lack of training and awareness of the method.

The Visualize trainer is a low-cost model built to aid midwives in learning to perform VIA using realistic simulation with an electronic feedback mechanism. The training model allows students to practice VIA at their own pace with exposure to many different VIA outcomes, allowing them to gain confidence in performing VIA before screening patients. The Visualize trainer features a simulated vaginal cavity that allows a student to pass a speculum and examine a pictured cervix, tabs that show cervixes before and after application of acetic acid, and an Arduino microcontroller and LCD screen that guides the student through the training method.

L. Innovation for Mother & Child Care

A148 Saving mothers at birth

Ms. Beryl Ngabirano Arinda; Denis Mukiibi, Martin Kiwanuka, Phiona Akurut, Robert Ssekitoleko, Makerere University, Uganda

According to the World Health Organisation Fact Sheet 2014, in Uganda alone there were 360 maternal deaths per 100,000 live births. Post-Partum Haemorrhage (PPH) accounts for about 10 deaths/hour on a global scale and is a global concern in both high and low resource countries with marked peaks of mortality recorded more in low resource countries like Uganda. In Uganda, the nearest health facilities are several kilometres away and therefore during emergencies, PPH clinical interventions are delayed leading to deaths. This greatly impedes access to emergency health care in cases where PPH occurs.

The Postpartum Haemorrhage Belt (PPH belt) is a first aid device designed to contain PPH. The belt is designed with a removable inflatable rubber bladder; a pressure monitoring gauge; a squeeze bulb and polyurethane coated nylon. The belt is intended to exert pressure on the uterus to stimulate both uterine contraction hence reducing blood loss. The device's key role is to preserve the mother's life during these emergencies, buying enough time for clinical interventions.

By use of locally designed rudimentary functionality tests there was blood loss reduction of up to 60%. Its human centred and simplistic design ensures that its effectiveness and affordability is not compromised.

R331 Unsupervised electronic stethoscope for childhood pneumonia diagnostic

Dr. Mohamed-Rida Benissa, University of Geneva, Switzerland; J. Solà, F.Hugon,P.Starkov, F.Braun, S.Manzano, C.Verjus, A.Gervaix

With 1.1 million deaths, pneumonia is the leading cause of child mortality under five years of age worldwide, particularly in Sub-Saharan Africa and South East Asia regions. WHO developed a case management algorithm for the diagnosis of pneumonia based on respiratory rate, shortness of breath and chest indrawing.

An electronic stethoscope device was tested in an ongoing feasibility study at the pediatric emergency unit of the Geneva University Hospital (Ethics Committee number 15-217). This medical device records lung auscultation in 8 chest positions. Thus, the sound analysis has detected period for inspiration/expiration and then has identified auscultatory signs of pneumonia using the combination of Mel-frequency cepstral coefficients, Deep Neural Networks and Hidden Markov Models techniques.

Preliminary results on 48 patients have shown a better sensitivity than the WHO algorithm. This method significantly differentiates bronchitis from consolidated pneumonia with an Area Under Curve (AUC) of 0.84.

The electronic stethoscope provides a good diagnostic performance. It could become an unsupervised diagnostic tool for pediatric pneumonia in low-resource settings, particularly for health workers in first level facilities.

A38 Field testing a neonatal phototherapy device: a novel approach

Dr. Donna Brezinski, Gary E. Gilbert, Alyssa Pfister

Severe neonatal jaundice is nearly always curable with rapid deployment of high-intensity blue light phototherapy. Failure to treat can result in permanent neurologic injury or death. Low resource areas of

the world are burdened with high morbidity and mortality from jaundice because context appropriate, effective phototherapy equipment is often unavailable, particularly in remote regions far from tertiary centers with phototherapy capability. The Bili- Hut™ by Little Sparrows Technologies is an ultra-lightweight, collapsible, battery operable phototherapy device designed to facilitate distribution and enable use in downstream clinical settings with unreliable line power. We describe results and lessons learned from a "low cost-high yield" field test pilot in which clinical and demographic data was collected on more than 100 severely jaundiced newborns treated with the Bili-Hut™. Critical components for success included optimizing stakeholder engagement and leveraging existing social media communication methods.

R292 Objective feedback improves resuscitation training and practice

Dr. Kevin Cedrone; Kristian Olson, Massachusetts General Hospital, United States of America; Santorino Data, Mbarara University of Science and Technology, Uganda

Intrapartum hypoxic events are a leading cause of newborn deaths. The Neonatal Resuscitation Program (NRP), Helping Babies Breathe (HBB), and WHO Basic Newborn Resuscitation have significantly reduced newborn mortality, but skill-retention is problematic. [1,2,3] Low-dose, high frequency training can improve skills retention. [4,5] This paper describes a trial of the Augmented Infant Resuscitator (AIR), a device designed to improve resuscitation skills training/practice by giving real-time objective feedback of positive pressure ventilation.

Methods: Birth attendants with recent HBB and/or NRP training voluntarily enrolled in this randomized control trial in the United States or Uganda. Participants ventilated training mannequins for a fixed duration of time. Participants were randomized to receive visual feedback (intervention), or not (control), and requested to administer effective ventilation, and verbally assess the mannequin condition. Each session's mannequin was randomized among three conditions: normal, partial obstruction, or face/mask leak.

Results: Practitioners with feedback assessed mannequins correctly more than twice as frequently (control: 24.7%, intervention: 61.3%, p=1.68e-9), and more quickly (control mean: 54.8s, intervention: 41.3s, p=1.23e-4). Those with feedback also achieved effective ventilation more quickly, and maintained it longer.

Conclusion: Results suggest that real-time feedback could help develop skills and confidence to provide more timely and effective ventilation.

A230-3 A feeding cup for preterm infants

Dr. Patricia Coffey; Christy Mckinney, Michael Cunningham, Robin Glass, Seattle Children's; Patricia Coffey, Steve Brooke, PATH, United States of America; Karoline Myklebust Linde, Cansu Akarsu, Laerdal Global Health; Norway

More than 9 million infants with breastfeeding difficulties are born every year in low-resource settings. WHO and UNICEF recommend hand expression of breastmilk and the use of a small cup to feed newborns with breastfeeding difficulties yet no standard infant feeding cup exists. Often, in low-resource settings small medicine cups are used to feed these infants. Small medicine cups can be difficult to use without spilling, cannot be disinfected, and are used with several infants simultaneously. To address this need, PATH, Seattle Children's, University of Washington, and Laerdal Global Health designed The Nifty Feeding Cup—an innovation to optimize feeding in infants with breastfeeding difficulties. The simple, unique shape of the Nifty feeding cup has an extended reservoir off the cup lip that optimizes the efficient delivery of milk and is sized (40ml) for direct hand expression of breast milk. The design enables rapid, optimal intake, minimizes spillages, reduces stress and fatigue of both infant and caregiver, and ensures sufficient nutrition for infant survival and growth. It is silicone, reusable, boilable, and soft. It is accessible in 95 low- and middle-income countries through a collaborative manufacturing and distribution strategy for US$1/cup

R442 Test for management of preeclampsia

Ms. Wendy Davis, GestVision, United States of America; Irina Buhimschi, Research Institute at Nationwide Children's Hospital; Catalin Buhimschi, The Ohio State College of Medicine; Kara Rood, The Ohio State College of Medicine, United States of America

Preeclampsia results in ~63,000 maternal deaths each year, the majority occurring in resource-limited countries where the correct diagnosis is often delayed. The Congo Red Dot (CRD) test is under development as a diagnostic for assessing misfolded (congophilic) proteins in urine found to be

associated with preeclampsia. The CRD test was superior in establishing and ruling out preeclampsia compared to standard of care in a study of 346 consecutive women enrolled prospectively in a tertiary level obstetrical triage unit in the U.S. Tests were read by trained clinical nurses at bedside before a final diagnosis and a management plan was established. With funding from Saving Lives at Birth and in partnership with a start-up company, we have embarked on a transition-to-scale project to: 1) refine the CRD test prototype to a lateral flow chromatography assay (LFA) fulfilling the attributes of ASSURED diagnostics; 2) determine diagnostic cut-offs for urine congophilia in 4 countries (U.S., South Africa, Mexico and Bangladesh) and 3) analyze the local healthcare ecosystems with respect to preeclampsia diagnosis. The Congo Red test is a point-of-care solution with potential to aid healthcare providers in effectively managing pregnant women up and down levels of care thereby reducing preeclampsia-related morbidity and mortality.

R112 A multiband reflectance photometric device for reveal gestational age at birth

Prof. Rodney Guimaraes, Zilma Reis, Universidade Federal de Minas Gerais (UFMG), Brazil

When a baby is born without information about how old he is, his life is at risk. Without the information of gestational age, the newborn viability could be neglected, as well his potential of a healthy life. We report the construction, development and performance test of a non-invasive, handle and low cost novel device able to infer gestational age at birth. The prototype is based on the use of the amount of reflected light by the neonatal skin as a score for their gestational age. The light emitted by the sensor are in the visible range. The diffuse reflected light is representative of the physio-anatomical differences for each skin layer, Since for each wavelength and distance LED-Photodiode we have a different penetration depth in the skin layers. For this, an Unit control was conceptualized and a measurement setup developed. We have demonstrated that there is a moderate correlation between gestational age and diffuse reflection measured by our device on the forearm and foot are in agreement with other works in the literature. A mathematical model for the prediction of gestational age from the diffuse reflexion was then delineated from tests on 120 newborns.

Potentially the skin age meter can achieve the same level of gestational age error, one week, as the gold standard, the ultrasound.

R228 Innovation in umbilical cord severance

Dr. William Kethman, William Strobel, Novate Medical Technologies, LLC, United States of America

Lack of healthcare infrastructure and unsanitary birthing conditions result in over 500,000-950,000 infection-related infant deaths per year. The unhealed umbilical cord is a conduit for infections and interventions to promote clean delivery are effective in averting 20-30% of newborn deaths due to infection. Several aid organizations distribute safe birthing kits which include string or other plastic clamp devices and razor blades to rural communities. These kits meet a defined need and are cost-effective, however, contamination and reuse are thought to be underreported, occurring in an average of 28% of births. These methods also result in uncontrolled blood or amniotic fluid contact by healthcare providers in up to 39.1-50% of deliveries and unprotected razor blades result in provider injury. Novate Medical Technologies is a medical device development company focused on commercializing high quality, cost-effective technologies to address global health needs. Novate's first product, InfaClip, is a non-reusable obstetric device that cuts and clamps the umbilical cord, focused on addressing neonatal mortality due to umbilical cord infections. InfaClip utilizes a novel clamping and cutting mechanism composed only of plastic polymers to ensure cost-effectiveness. These features reduce the likelihood of reuse and allow InfaClip to safely sever the umbilical cord.

R505 New improved newborn resuscitator

Mr. Frode Liland, Karoline M. Linde, Jennifer L. Gilbertson, Laerdal Global Health, Norway

One in 10 newborns need assistance to initiate breathing after birth. Ventilation providers in low-resource settings rely on the traditional horizontally held bag-valve-mask resuscitators. However, inadequate mask sealing around the baby's mouth and nose frequently causes air leakage and results in less air being delivered to the baby's lungs. Evaluation of training and needs of providers in low-resource countries led to the design of a new resuscitator with a novel vertical orientation of the self-inflating bag, and with a thicker and wider face mask, which is more tolerant to the user's technique of holding and pressing the mask. A significant reduction in mask leakage has been observed in several studies.

To be sustainable in low-resource settings, the device is optimized for reuse and safe reprocessing by having fewer components, improved poster-type reprocessing instructions, and has been tested for high-level disinfection by boiling and utilization with locally available chemicals.

One version also includes a novel reusable PEEP valve to aid lung opening of premature newborns. Traditional reusable resuscitators with PEEP are comprised of 19 components for the user to handle in reprocessing. The new resuscitator with PEEP has only 9 components.

A168 Acceptability of conventional and upright neonatal resuscitators

Dr. Manjari Quintanar Solares; Gene Saxon, Patricia Coffey, PATH; Indira Narayanan, Georgetown University Medical Center; Stephen Wall, Save the Children, United States of America; Rinku Srivastava, State Innovations in Family Planning Services Project Agency; Syed Ali, Aligarh Muslim University, India

Birth asphyxia, a leading cause of neonatal death, can be prevented through basic neonatal resuscitation. PATH conducted a user evaluation to compare the performance and acceptability of the Laerdal Upright resuscitator (innovative) and the Laerdal Pediatric Silicone 500-mL resuscitator (conventional) with health workers in Uttar Pradesh, India. Participants were either inexperienced or experienced users. They evaluated both devices in random order on a manikin connected to a test lung which simulated a 3-kg asphyxiated newborn in two consecutive lung settings: fluid-filled lungs (low compliance) and lungs after fluid absorption (normal compliance). Sixty health workers participated in the study. There were no significant differences in the overall performance of the devices and both provided the required minimum tidal volumes. During normal compliance, both resuscitators delivered excessive tidal volumes. The Upright resuscitator was easier to use, had significantly higher acceptability across all ergonomic measures by both types of users, and was identified as the preferred device by the majority of users. These features make it a suitable alternative for all users in the Indian context and possibly in other resource-limited settings.

R102 Prematurity detection by light

Prof. Zilma Reis, Rodney Nascimento Guimarães, Gabriela Luíza Nogueira Vitral, Maria Albertina Santiago Rego, Ingrid Michelle Fonseca, Universidade Federal de Minas Gerais, Brazil

When a baby is born very small, less than 2.5 kg, he can be premature and birth attendants need warns to timely support him and make decisions as refer the baby to the hospital. Without the critical care, the newborn viability could be neglected, as well his potential of a healthy life. The best time to determine gestational age using ultrasound is during the first three months of gestation, a difficult approach to carrying on in low-income settings. We developed a low-cost, safety, and portable optoelectronic device that can immediately estimate if the newborn is premature. The technology is based on the skin reflectance. Our solution delivers a Premie-Test that addresses one answer to support a big global health problem: the quality of care at birth, facing the doubt or unknown on the chronology of gestation. The device is easy to manufacture without high-technological support. The approach is noninvasive, automated and it can be used wherever a birth happens, by health workers and midwives in health centres or at home. Our goal is to provide a device and prepare a guidance to assist decision to face the delivery of care when the baby is born small, improving neonatal survival. Contact: http://skinage.medicina.ufmg.br/index.php/en/.

R765 Hub-and-spoke models for point-of-care early infant diagnosis

Mr. Jean-François Lemaire, Rebecca Bailey, Esther Turunga, Jennifer Cohn, Elizabeth Glaser Pediatric AIDS Foundation Switzerland; Flavia Bianchi, Emma Sacks, Elizabeth Glaser Pediatric AIDS Foundation, United States of America

Abstract submission draft WHO Global Forum on Medical Devices

Title: Integrating point-of-care technologies into national early infant HIV diagnosis networks: development of a hub-and-spoke model to increase access to HIV testing

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Background:
Only half of HIV-exposed infants undergo early infant diagnosis (EID) of which, only half receive results. Without diagnosis and treatment, 68% of children die by five years of age. Point-of-care (POC) EID can improve testing efficiencies, but given low demand for EID per health facility, creative strategies are needed to increase access.

Methods:
EGPAF analyzed 7979 sites across 9 African countries to identify only 231 sites with sufficient EID demand to support placement of a POC instrument. The hub-and-spoke strategy allowed to further increase access to POC EID by identifying an additional 77 testing and 1432 spoke sites.

Results:
Hub-and-spoke models constructed in countries utilize: 1) existing transport networks wherever possible; 2) other courier services to complement; 3) tailored monitoring tools ensuring sample and results tracking; 4) EDTA-whole blood specimens instead of dried blood spots; 5) guidance to ensure timely patient return for results. Preliminary data show samples from spoke sites (n=134), achieve successful turnaround times of <5 days from sample collection to caregiver receipt, with 98.5% of results communicated to caregivers.

Conclusions: Use of hub-and-spoke sites to support POC EID testing is a promising model for increasing access to rapid EID results.

R573 A bundle approach to care for small babies

Ms. Karoline Linde, Sakina Girnary, Jennifer Gilbertson, Frode Liland, Laerdal Global Health, Norway

Low-birth-weight (LBW) contributes to 60-80% of all neonatal deaths. The global prevalence of LBW is about 16%, which amounts to 20 million LBW infants born each year - 97% of them in low-income countries. The Helping Babies Grow kit brings together affordable training and therapy solutions to provide appropriate feeding, infection prevention and skin-to-skin care – the essential elements of care for helping babies survive and thrive. The bundle includes:

Essential Care for Small Babies: Evidence-based, hands-on newborn care learning materials developed by the American Academy of Pediatrics.

Breastfeeding and small babies training videos, developed by Global Health Media.

MamaBreast: A wearable simulator that allows realistic training of breastfeeding and breast milk expression

PreemieNatalie: A preterm simulator with realistic appearance and size that supports training in skin-to-skin positioning, nasogastric tube placement, and breast, cup, and nasogastric tube feeding.

CarePlus: An ergonomic preterm wrap designed to help mothers provide continuous and quality thermal care. Studies shows improved weight gain for LBW babies when using CarePlus instead of the traditional wrap.

Nifty Feeding Cup: A reusable product for feeding breast milk to newborns with breastfeeding difficulties designed in collaboration with PATH, Seattle Children's Hospital and the University of Washington.

A107-1 Hypothermia alert device: saving newborn lives

Mr. Ratul Narain; Gini Morgan, Bempu Heath, India

Newborns are unable to regulate their body temperature often leading to hypothermia, a condition affecting 32-85% of newborns globally. Hypothermia can result in poor growth, poor organ development, and death. The BEMPU Hypothermia Alert Device, or the BEMPU Bracelet, is a simple, innovative device that detects and alerts in the event of hypothermia, facilitating improved thermal care of newborns. The device sits on a newborn's wrist and continuously monitors temperature for the neonatal period. The BEMPU Bracelet has been clinically validated by top neonatal centers across India. JIPMER, Pondicherry conducted a sensitivity/specificity study of the device; results show the bracelet to be 95% specific and 98.57% sensitive. Additionally, the bracelet has been tested in government hospitals across India and shows a promotion of KMC, increase in weight gain, early detection of sepsis in the home, and increased health-seeking behavior in parents. Feasibility pilots are being conducted with state health missions and UNICEF across India to prove community uptake in rural and tribal areas. Initial results from community-based feasibility pilots show the device is largely accepted by doctors, nurses, and parents, a possible reduction in mortality. Evidence of market demand exists from Indian and International governments and private centers.

A107-2 Preventing apneas of prematurity

Mr. Ratul Narain; Gini Morgan, Bempu Heath, India

Almost all preterm infants under 34 weeks experience apneas. Apnea requires continuous monitoring and rapid intervention to prevent any damage. However, in low- and middle-income countries, skilled staff and monitoring equipment are often unavailable, leading to delayed or absent attention to apnea. Using pulse oximetry and an auto-stimulation mechanism, the BEMPU Apneboot is a foot worn device to prevent apneas. The boot "flicks" and vibrates the foot sole of the newborn stimulating the nervous system to restart breathing in the case of an apnea; the device also creates an audio-visual alarm to get caretakers' attention. The boot is battery powered, fits extremely low birth weight babies, and is made specifically for low-resource settings. The device won the USAID's Saving Lives at Birth Challenge in 2016, and is now being piloted in Indian government centers.

A107-3 Remote monitoring for critical infants

Mr. Ratul Narain; Gini Morgan, Bempu Heath, India

Sepsis and pneumonia cause 29% of infant mortality; early intervention saves lives. Critical infants in low- and middle-income countries are often discharged to uneducated homes where parents miss early warning signs. The BEMPU CareCradle is a home-use remote monitoring system for high-risk infants. Daily, a single button push sends measurements of the baby's weight and temperature, as well as a 5-minute video recording to remote SNCU staff to monitor for deterioration, lethargy, breath rate, rashes, weight gain, sepsis, and more. CareCradle enables daily monitoring of infants in low-resource areas and heard-to-reach homes and ensures intervention when necessary. The Indian government has heavily invested in home-visit follow up by community health workers who screen for issues like sepsis and pneumonia, especially for high-risk infants discharged from government facilities. However, this follow up system fails where skilled manpower is lacking, visits are not enforced, or homes are hard to reach. BEMPU Health, with the support of an international global health funder is creating the CareCradle and piloting the device with Indian state governments.

A210 Warmer for resuscitation with intact placental circulation

Dr. Thanigainathan Sivam; Mangalabharathi Sundaram, Institute of Child Health & Hospital for Children, Valiyaveetil Sashikumar, Phoenix Medical System, India

Birth asphyxia, third most important cause (23%) of neonatal mortality. Resuscitation of the baby without clamping the umbilical cord allows continuous supply of oxygen, 30% of the blood volume and stem cells from the placenta to baby. Hence Resuscitation with Intact Placental Circulation (RIPC) is considered a promising intervention to reduce the incidence of asphyxia. RIPC is not possible at present with the conventional warmer due to its unfavorable design. We have developed a affordable warmer which can move near mother's perineum without compromising space for delivery team and facilitate RIPC. This device features a compact overhead radiant warmer with rotatable pillar facilitating approach the baby from three sides for resuscitation. Height adjustable baby receiving cradle making it suitable for normal and caesarian cot. Rotatability and sliding-out movement of the cradle enabling to reach close to the perineum and receive the baby with the available limited cord length. The device accommodates the essential equipments for resuscitation (T-piece resuscitator, oxygen cylinder, air cylinder, blender and

suction apparatus). It also has heated mattress, display screen (HR, Spo2, PIP, PEEP) and APGAR timer in a modular design. Functional and safety aspects of the device were reviewed in 20 uncomplicated deliveries in various settings.

R293 Preventing a never event

Dr. Peter Young; Maryanne Mariyaselam, Queen Elizabeth Hospital, United Kingdom; Sinéad Renouf, Venner Medical Internationl, United Kingdom

The Venner WireSafe™ prevents the Never Event of accidental guidewire retention and improves sharps safety during central venous line insertion. Retained guidewires are ranked the second highest retained object in the NHS and result in morbidity and mortality for patients, increased costs to hospitals and the error also devastates individual doctors. After disaster has struck, well-intentioned training programmes and procedural changes following root cause analyses have an effect but this is unsustained and the reported incidence continues to rise. The Venner WireSafe™ is a procedure pack that contains all the equipment needed to complete the procedure from the point where the guidewire should have been removed (stitch, stitch holder, dressing, scissors etc). The guidewire is required to open the pack so nothing can proceed until it is removed. This is known in Human Factor terms as a forcing function and the concept is commonly used in high-risk industries. After use, the Venner WireSafe™ becomes a convenient sharps box, facilitating sharps safety during clean up after the procedure.

The Venner WireSafe™ has been selected for support by the prestigious NHS Innovation Accelerator programme and won 1st prize at the Association of Anaesthetists (AAGBI) safety meeting in 2017.

R613 Device to save postpartum-hemorrhaging women in advanced shock

Ms. Moytrayee Guha, Massachusetts General Hospital, United States of America; Thomas Burke, Sandra Danso-Bamfo, Alyssa Cappetta, Charles Masaki, Moytrayee Guha, Melody Eckardt, Brett Nelson, Massachusetts General Hospital, United States of America; Monica Oguttu, , Kisumu Medical and Education Trust, Kisumu, Kenya; S.A.S. Kargbo, Ministry of Health & Sanitation, Sierra Leone; Niang Mansour, Centre de Formation et de Recherche, Santé de la Reproduction, Senegal; Vincent Tarimo, Muhimbili National Hospital, Tanzania

Objective: To examine the outcomes of women in advanced shock from uncontrolled postpartum hemorrhage (PPH) due to atonic uterus who underwent placement of uterine balloon tamponade (ESM-UBT) devices.

Methods: Data on all women who received an ESM-UBT device among enrolled healthcare facilities in Kenya, Senegal, Sierra Leone, and Tanzania were collected prospectively. Shock class was assigned based on recorded blood pressures and mental status at the time of UBT placement.

Results: 339 women within 117 facilities had uncontrolled PPH and ESM-UBT devices placed, 306 (90.2%) of whom had uterine atony and recorded vital signs. 166 (54.2%) of the 306 had normal vital signs or were in Class I or Class II shock. In this group, one death was attributed to PPH (survival 99.4%), otherwise, uncontrolled hemorrhage was immediately arrested and there were no cases of shock progression. 111 (36.3%) of 306 were in Class III shock and 29 (9.5%) of 306 in Class IV shock. Survival was 108 (97.3%) of 111 and 25 (86.2%) of 29 in Class III and Class IV shock, respectively.

Conclusion: The ESM-UBT device arrests hemorrhage, prevents shock progression, and saves lives among women with uncontrolled PPH from atonic uterus.

R557 Warming solution for neonatal surgeries in Nigeria

Dr. Taiwo Akeem Lawal, Akinwale Coker, University of Ibadan, Nigeria; Robert Murphy, Matthew Glucksberg, David Gatchell, Northwestern University, United States of America

The outcome of neonatal surgery is intricately linked to the control of environmental temperature pre-, intra- and post-operatively. Anaesthesia, provision of a conducive environment for surgery and administration of intravenous fluids, blood and blood products combine to decrease the core temperature by up to 2.10C during surgery, with studies having documented this temperature drop to be associated with increased perioperative morbidity and mortality.

In resource challenged-settings, such as Nigeria, neonatal surgery is performed by using less appropriate alternatives such as hot water bottles and consumer grade electric blankets, which are associated with occasional morbidities.

The US-based Northwestern University and University of Ibadan, Nigeria collaborated to design and develop a cost-effective, easily adaptable technological solution in the form of a warming device to mitigate the problem of perioperative temperature control in neonates. The 4-layered prototype is maintenance-friendly and has multiple inbuilt safety mechanisms, LCD display and a comfortable surface for the patient. This device has been found effective, efficient and safe for use on neonatal surgical patients. This presentation highlights the process of development, challenges encountered and solutions proffered. The collaboration resulting in this life-saving device has proved to be a meaningful one between developed and developing nations.

R262 Description of automated epartogram with decision support

Dr. Marc Mitchell, D-tree International; Douglas Williams, United States of America; Gill, Roopan, University of British Columbia, Canada; Thomas Routen, Things Prime, Switzerland

The diagnosis and treatment of fetal distress during the second stage of labor can have a dramatic impact on the rates of newborn asphyxia and stillbirth in low income countries. Current technology has been limited to the clinical judgement of the nurse/health worker using a manual fetoscope. Our innovation is to automate the process of data collection using low cost ECG leads and an Android tablet that displays fetal heart rate and associated decelerations/accelerations on an electronic partogram (ePartogram). It provides alerts for signs of fetal distress and context specific instructions to the nurse/health worker to take corrective action and if indicated to refer the mother. This technology by D-tree International and its partner Things Prime builds on our prior work developing decision support software for use with the ePartogram. The device will improve the efficiency of nursing staff on busy labor wards by automating the data collection process and improve health outcomes by providing specific instructions to the nurse/health worker leading to more timely and effective interventions to save the life of the newborn. This technology has received a prestigious Saving Lives at Birth award to develop and test the device.

R472 Validity of a device for jaundice screening

Dr. Anne Cc Lee, Brigham and Women's Hospital, Harvard Medical School, United States of America; Lian Folger, Salahuddin Ahmed, Lauren Schaeffer, Nazmun Bably , Mahmood Rahman, Rachel Whelan, Pratik Panchal, Arun Roy, Sayed Rahman, Nazma Begum, Abdullah Baqui

BACKGROUND: Extreme neonatal hyperbilirubinemia affects 480,000 infants annually and carries increased risk of mortality and long-term neurodevelopmental impairment. Improved jaundice screening may identify babies early who require phototherapy and help reduce this burden.

METHODS: We designed an icterometer, a handheld ruler with six shades of increasing yellow hue corresponding to bilirubin levels. A health worker blanches the skin of the infant's nose and chooses the color closest to the underlying skin hue. 700 newborns were enrolled at Brigham & Women's Hospital (Boston, USA) and Sylhet Osmani Medical Center (Sylhet, Bangladesh). Icterometer readings were independently made then compared to transcutaneous bilirubin (TcB) measurements (Drager JM-105).

RESULTS: Icterometer scores were highly correlated with TcB measurements (r=0.7745). The ruler distinguished different levels of hyperbilirubinemia with good sensitivity/specificity (score of 3: sensitivity/specificity of 92.8%/73.1% to identify TcB>11; score 3.5: 89.7% /84.3% for TcB >13; score 4: 81% /86.9% for TcB>15). Areas under the ROC curve for identifying TcB>11, >13, and >15 were 0.92, 0.92 and 0.93, respectively. Inter-rater reliability was high; 91% of readings fell within 0.5 points (N=46).

CONCLUSIONS: The icterometer has high validity to detect clinically-significant jaundice and is a useful screening tool in settings with limited lab capacity for bilirubin testing.

R558 Microarray patch for treatment of neonatal sepsis

Dr. Mary Carmel Kearney, Emma Mcalister, Patricia Gonzalez Vazquez, Maelíosa Mccrudden, Ryan Donnelly, Queen's University Belfast, United Kingdom

Neonatal infections, including sepsis, are a significant cause of childhood mortality in low-resource settings. Treatment guidelines for neonatal sepsis are often not implemented as many infants affected lack access to facility-based care. An innovative microarray patch technology, currently under development, has the potential to deliver antibiotics through the skin, thereby avoiding challenges associated with parenteral and oral delivery of antibiotics to infants. Upon patch application, micron-sized projections on the patch absorb fluid from the skin and swell. The absorbed fluid dissolves an antibiotic-containing reservoir within the patch to release the drug. A patch that combines amoxicillin and gentamicin could have many advantages, including ease of use, potential for administration by less experienced personnel, reduced dose-calculation errors, increased acceptability by caregivers and families. Additionally, a patch treatment option would ease logistics, to ensure consisitent supply in remote areas in comparison to current out-patient treatments. There would be reduced risk of blood-borne infection transmission through needlestick injuries, as patches are self-disabling in nature following use. An easy-to-use, minimally-invasive and affordable delivery method that combines appropriate doses of amoxicillin and gentamicin has the potential to expand access to lifesaving out-patient antibiotic treatment of neonatal sepsis.

M. Quality and Safety of Medical Devices

R234 Medical devices in legal metrology framework

Ms. Lejla Gurbeta, Medical Device Inspection Laboratory Verlab; Almir Badnjević, Verlab Ltd., International Burch university, University of Sarajevo, University of Bihac; Lejla Gurbeta, Verlab Ltd, International Burch University, Bosnia and Herzegovina

Ensuring medical device (MD) safety is recognized as priority in healthcare by various organisations and National Metrology Institutes (NMIs) such as EURAMET, NIST and Federal Agency on Technical Regulating and Metrology in Russia. Guidelines define inspections consisting of electrical safety testing and device performance inspection. NMIs in the world introduce MD into legal metrology system (LMS) so healthcare institutions are obligated to perform inspections of MDs with calibrated etalons achieving traceability chain. In Bosnia and Herzegovina (BH) ten different types of MDs are introduced into LMS. Periods of inspections, and output error ranges are defined by Rules on metrological and technical requirements basing on IEC 60601, other international standards and manufacturer's recommendations. Inspection of MD in the health care system in BH is performed by impartial laboratory accredited by ISO 17020. Two year study results show that the number of faulty MDs is reduced by a half second year of applying procedures. Inspections are useful tool in ensuring quality healthcare leading to increased accuracy and reliability of MD measurements, causing reduction of costs of transferring patients between institutions and especially important in determining MDs which appear to be functioning well but in fact their performance is out of specification.

R504 Global quality and safety alliance in imaging

Ms. Monika Hierath, Guy Frija, Don Frush, ISR, United States of America

The mission of the International Society of Radiology (ISR) is to facilitate the global endeavors of the member organisations to improve patient care and population health through medical imaging. To this end, the ISR formally established the Quality and Safety Alliance (ISRQSA) in 2016. Current members of ISRQSA are existing continental and regional campaigns, including AFROSAFE (with English and French branches), Canada Safe Imaging, EuroSafe Imaging, Image Gently, Image Wisely, Japan Safe Imaging, and LatinSafe. The ISRQSA is responsible for the ISR's quality and safety agenda, and especially functions as convener of and facilitator for continental, regional and national radiation protection quality and safety.

The overarching objective is to establish a strategic plan for global efforts related to quality and safety, which reflect the input of the campaigns. The specific goals of the ISRQSA will embrace contributions towards justification and optimization, education, equipment performance, regulatory guidance, effective communication, as well as research related to medical imaging radiation protection. To achieve its goals, the ISRQSA will work in collaboration with other relevant organisations in the domain of safety and quality, including the IAEA, WHO, IRPA and ICRP as well as global professional organisations of related disciplines.

A41 Good practices for wearing gloves in hospitals

Dr. Bochra Bejaoui, Zohra Jemmali, Asma Guettiti, National Agency for Sanitary and Environmental Control of Products, Tunisia

Problems: The recommendation of wearing gloves as a protective measure appeared with "universal precautions". However, lacks of knowledge of the indications, the deviations of the use of the gloves are numerous. Their use goes from the indispensable to the useful but its use sometimes goes from oblivion to useless.

Objectives:

- To standardize the use of the medical gloves in medium of care according to the brought up to date recommendations.
- To light the pharmacists in the suitable choice of the medical gloves in the health care institutions

Methodology : To this end, and following various complaints of incidents of material surveillance, received from public and private healthcare establishments, the national agency for sanitary and environmental control of products has proposed to analyze and dissect EN 420 (general for gloves) and EN 455-1, 2,3 and 4 (specific for medical gloves).

Results: Medical gloves are medical devices. They must comply with the requirements of the European Directive 93/42/EC as amended by Directive 2007/40/EC.

Technical sheets have been prepared in the form of a guide. It is a precise description of medical gloves, their regulation, their normative framework as well as their indications.

Conclusion: The inadequate wearing of a glove is a frightening infection vector for the patient and contributes to the lack of safety for the nursing staff. It is important to choose the gloves according to the specific constraints related on the manipulators and handling and to test several brands of gloves at the various work stations.

A53 Good practices of using a Foley probe

Ms. Bochra Bejaoui, Zied Snoussi, Zohra Jemmali, National Agency for Sanitary and Environmental Control of Products, Tunisia

Introduction: The Foley probe is a balloon bladder catheter, used for bladder sampling. We distinguish:

- Sterile Foley probes that are Class IIa of medical devices.
- Long-life, silicone Foley probes that are Class IIb of medical devices.

Problem: The bladder sounding is a medical and nursing procedure consisting in introducing a probe through the urinary meatus and ascending to the bladder following the path of the urethra. Permanent bladder catheters are the key element of this survey and their choice is essential according to the indication.

Methodology : A retrospective assessment of the incidents of material surveillance was carried out and received by the national agency for sanitary and environmental control of the products relating to the Foley probes and which, following surveys and evaluation, revealed misuses.

Results: An analysis of the critical points of a bladder survey was made by our agency and a detailed description of this medical practice was developed. We have:

- detailed indications, contraindications and complications of an indeterminate survey
- noted the critical points and precautions to be taken during this act
- describes the laying technique in both men and women, emphasizing the precautions for use and the risks involved

Discussions and conclusion :

Bladder sampling is an invasive procedure with an infectious risk requiring rigorous asepsis from lying. Precautions for use should be taken into consideration such as:

- The choice of the smallest hopper possible compatible with good drainage to minimize urethral trauma.
- Do not clamp the probe body.

- Deflating with a syringe should be slow.
- Avoid disconnecting the probe from the manifold. They are laid and removed together.

O. Regulation of Medical Devices

A68 Recommendations for proper use of disinfectants

Dr. Bochra Bejaoui, Zohra Jemmali, Olfa Drissi, National Agency for Sanitary and Environmental Control of Products, Tunisia

Problem: Disinfectants intended for the treatment of medical devices and endoscopes are irritants of the ocular, oro-rhino-laryngeal and bronchial mucosa and potentially sensitizing. Indeed disinfectants are often liable to cause poisonings by inhalation or absorption, cutaneous or ocular burns or allergic sensitizations (eczema, asthma ...).

Objective: To sensitize health professionals and in particular hygienists and sterilizers concerning the proper use of disinfectants and the appropriate conditions for their use.

Methodology: As a result of the various complaints of material safety incidents received by the national agency for sanitary and environmental control of products relating to allergic reactions arising from the use of disinfectants intended for the treatment of medical devices and endoscopes; Our agency proposed to analyze these incidents and to draw up a technical sheet on the proper use of disinfectants.

Results: Medical disinfectant products for the treatment of medical devices and endoscopes are classified as medical devices under European Directive 93/42 / EEC. They belong to Class II disinfectants.

A technical sheet has been drawn up, using collective technical prevention measures and individual protection measures.

Conclusion: The collective technical prevention measures consist of the identification of the products and their plugs but also in an appropriate choice and handling, in appropriate storage and in ventilation of the premises.

Individual protection measures are summarized in the wearing of all personal protective equipment (suitable gloves, waterproof apron and protective goggles).

In addition to detecting skin irritations, the intervention of the occupational physician allows the identification of workers who are predisposed to occupational allergies and their withdrawal from exposure.

R649 Knowledge about materiovigilance in Cluj-Napoca, Romania

Dr. Simona Maria Mirel, "Iuliu Haţieganu" University of Medicine and Pharmacy Cluj-Napoca, Romania

The objective of the study was to evaluate the knowledge of the medical device vigilance policy among the health care professionals and the way it is put into practice in the medical service in Cluj-Napoca, Romania. The results were compared with those obtained in 2011, and reported in our previous study (the first study concerning the materiovigilance in Romania). Although our Competent Authorities improved the visibility of reporting system at national level, the results are not much better: less than half of the practices surveyed conveyed only a relative knowledge of the materiovigilance system. Our study confirms once again that the use of medical devices and the regulations of the vigilance system should be integrated into the medical education. It is necessary to organize local structures with a designated representative for each care unit and to encourage the process of giving reports. Due to the increasingly regulated policy towards medical safety, health care professionals should start to report incidents involving medical devices.

Video

B. Health Information Systems: Medical Device Issues	
A211	A health and education m-App
	Dr. Livia Bellina, Ilenia Nucatola, MobileDiagnosis Onlus, Italy
R304	Towards global integration of digital diagnostics devices
	Dr. Lena Kruckenberg, Owen Johnson, Mike Messenger, University of Leeds, United Kingdom; Stephen Box, National Pathology Exchange, United Kingdom
D. Healthcare Technology Management/Clinical Engineering	
R272	Transforming asaesthesia services in Somaliland
	Mr. Robert Neighbour, Diamedica, United Kingdom
I. Innovation of Technologies for Screening and Diagnosis	
A102	Diagnostic Imaging improvement in Malawi
	Dr. Miriam Mikhail, RAD-AID International, Switzerland; Melissa Culp, RAD-AID Internaitonal, United States of America
K. Innovation for In Vitro Diagnostics	
	Disc-shaped point-of-care platform for infectious disease diagnosis
	Dr. Konstantino Mitsakakis, Univeristy of Freiburg & Hahn-Schickard, Germany
L. Innovation for Mother & Child Care	
R326	Journey of premature baby Yohannes in Ethiopia
	Ms. Seung Eun Lee, Kelemua Abera, GE Healthcare, Ethiopia
A79	Affordable bubble CPAP for low-resource settings
	Mr. Robert Neighbour, Diamedica, United Kingdom

B. Health Information Systems: Medical Device Issues

A health and education m-App

Dr. Livia Bellina, Ilenia Nucatola, MobileDiagnosis Onlus, Italy

The human development is spreading around the world, but not in a fair way.
Suburban areas and the poor areas of the industrialized countries are excluded from this global renewal.
This "development gap" is increasing by excluding "de facto" more than 80% of the world population.
In this scenario the use of m-technology among medical students and young doctors helps to improve medical training and profession, however, in rural places, the workforce faces the shortage of a quality education.
Parasitoses hematic intestinal and others affect the most fragile part of the population.
To locally improve the diagnosis and education may change this scenario.
The authors have designed and created an App, thought to help low-skilled users in hard and isolated contexts, able to improve locally education and diagnosis.
The education area is a" portable" interactive "library" that provides the users with the most useful links, therapies, and lessons with didactic tables, didactic images, and movies, together with the news about the tropical medicine.
The diagnosis area supports the local diagnosis by visually comparing the unknown image to a gallery of didactic images stored in the App. (at now limited to helmints eggs)

Towards global integration of digital diagnostics devices

Dr. Lena Kruckenberg, Owen Johnson, Mike Messenger, Univeristy of Leeds, United Kingdom; Stephen Box, National

Pathology Exchange, United Kingdom

Medical diagnostic devices are getting smarter. As digital devices they generate data that can be transmitted to electronic health systems and used to monitor long term conditions, inform screening, surveillance and epidemiology and accelerate medical research through data analytics. The challenge is how to integrate huge numbers of remote devices with diverse e-health systems on a global scale.

In laboratory medicine, the UK has achieved 100% integration of diagnostic results into lifelong primary care e-health records for all 65 million citizens using national systems backed by NLMC coding standards. Our National Pathology Exchange (NPEx), links 65 of the UK's top 100 laboratories together through a central hub for lab to lab transfers and this infrastructure is being extended to link to remote diagnostic devices that could be in hospital wards, clinics, pharmacies, care homes and patients' homes. This new NPEx service is based on very cheap, massively scalable and globally accessible cloud technology and provides a solution for linking large numbers of both diagnostic device suppliers and healthcare providers. Our goal is a global network of vendor-specific and vendor-neutral cloud solutions that link medical diagnostic devices with secure electronic health record systems. Our video will demonstrate the NPEx solution.

D. Healthcare Technology Management/Clinical Engieering

Transforming anaesthesia services in Somaliland

Mr. Robert Neighbour, Diamedica, United Kingdom

Health services in Somaliland were destroyed by decades of conflict from which the country is slowly recovering. In recent years more than 30 anaesthesia technicians have graduated from new training programmes. The Safe Anaesthesia for Somaliland (SANSOM) project aimed to provide graduates with appropriate equipment and continuing support in order to improve anaesthesia services in Somaliland.

In January 2017, SANSOM held Somaliland's first ever continuing medical education (CME) conference for anaesthesia. The 3-day conference focused on Anaesthesia for the Mother and Paediatric Surgical Patient in Somaliland. Workshops included simulations with a sophisticated infant manikin; training in use and maintenance of anaesthesia equipment; and data collection using supplied android tablets.

Kits of appropriate anaesthesia equipment designed to function in remote, low resource locations were supplied. A 2-day road trip was undertaken to deliver, install and provide in-house training on the new equipment at recipient hospitals.

SANSOM demonstrated a cost-effective approach to improving anaesthesia services in impoverished locations and has laid the foundations for further improvements in Somaliland. SANSOM is a partnership of the Edna Adan Hospital, Kijabe Hospital, Kenya, Diamedica (UK) Ltd, DAK Foundation and Safe Anaesthesia Worldwide.

I. Innovative Technologies for Screening nad Diagnosis

Diagnostic Imaging improvement in Malawi

Dr. Miriam Mikhail, RAD-AID International, Switzerland; Melissa Culp, RAD-AID International, United States of America

Here is the link address: https://www.youtube.com/watch?v=jNwcFoRUTwA&authuser=0

The relevant video showcases radiology improvement in Malawi in collaboration with and facilitated by RAD-AID International, a non-state actor "in official relations with the WHO" for whom this initiative constitutes a component of a collaborative workplan towards advancing WHO strategies.

L. Innovation for Mother & Child Care

Jounary of premature baby Yohannes in Ethiopia

Ms. Seung Eun Lee, Kelemua Abera, GE Healthcare, Ethiopia

The video highlights the impact of Ethiopia's Neonatal Intensive Care Unit(NICU) program from a premature baby Yohannes and his mother's perspective.

Neonatal mortality continues to be a critical challenge in developing countries. Ethiopia, is still a long way off from achieving its 2030 Neonatal Mortality Rate (NMR) targets, which are part of the UN's SDG's. It has been established that to reduce NMR, well-equipped healthcare facilities and skilled healthcare workers are vital for identifying and treating neonatal health problems during birth and the first week of life.

In this context, an innovative model was put in place that involved collaboration between, local and non-profit organizations, technology partners, skill development partners, and sustenance Monitoring & Evaluation partners which were managed by GE Healthcare, with the active guidance of the Ethiopian Federal Ministry of Health. The model included setting up advanced technology within the NICUs and training the healthcare staff on how to use the technology, and good clinical practices in new-born care (NICU solution).

Overall, this innovative partnership model had a positive impact on neonatal health outcomes. Such strategic partnerships, which focus on improving neonatal health outcomes, can be replicated and sustainably scaled up.

Affordable bubble CPAP for low-resource settings

Mr. Robbert Neighbour, Diamedica, United Kingdom

Respiratory failure is a leading cause of neonatal mortality in developing countries. Continuous Positive Airway Pressure (CPAP) is an effective and lifesaving treatment for respiratory distress. It involves applying a mixture of air and oxygen continuously to the upper airway to prevent the alveoli from collapsing and may be required for days or weeks. In poor countries this rate of consumption of compressed gases puts an intolerable burden on the gas supplies, is logistically difficult especially in isolated hospitals and prohibitively expensive. As a result it is often unavailable even in lifesaving situations.

The Diamedica Baby CPAP has been designed to make this lifesaving therapy affordable and widely available. It is driven by an oxygen concentrator capable of delivering flows of both oxygen and air at rates of up to 8 litres per minute each. The gas mixture is both warmed and humidified. Running costs are 1% of the equivalent consumption of cylinder gas. FiO2 is calculated from an accompanying chart which dispenses with the need for an oxygen analyser. It is simple to use and maintain in locations with limited technical skills.

The Diamedica Baby CPAP is used in 25 low-income countries and saving lives on a daily basis.

Box 7. Links to the website of collaborating organizations

- ACCE: http://accenet.org
- DITTA: http://globalditta.org/
- GMTA: http://www.globalmedicaltechnologyalliance.org/
- HTAi: http://www.htai.org/
- HUMATEM: http://www.humatem.org/
- IAEA: https://www.iaea.org/
- IFBLS: http://www.ifbls.org/
- IFHE: http://www.ifhe.info/
- IFMBE: http://www.ifmbe.org/
- IOMP: http://www.iomp.org/
- ISR: http://www.isradiology.org/
- ISRRT: https://www.isrrt.org/
- THET: http://www.thet.org/
- UICC: http://www.uicc.org/
- UNFPA: http://www.unfpa.org/
- UNICEF: https://www.unicef.org/
- WASPaLM: http://www.waspalm.org/
- WFSA: http://www.wfsahq.org/

Appendix 5

5.1 Participants evaluation survey results

This appendix contains the participant's feedback received from the online surver. A total of 349 comments were received for the evalutioin and some were selected.

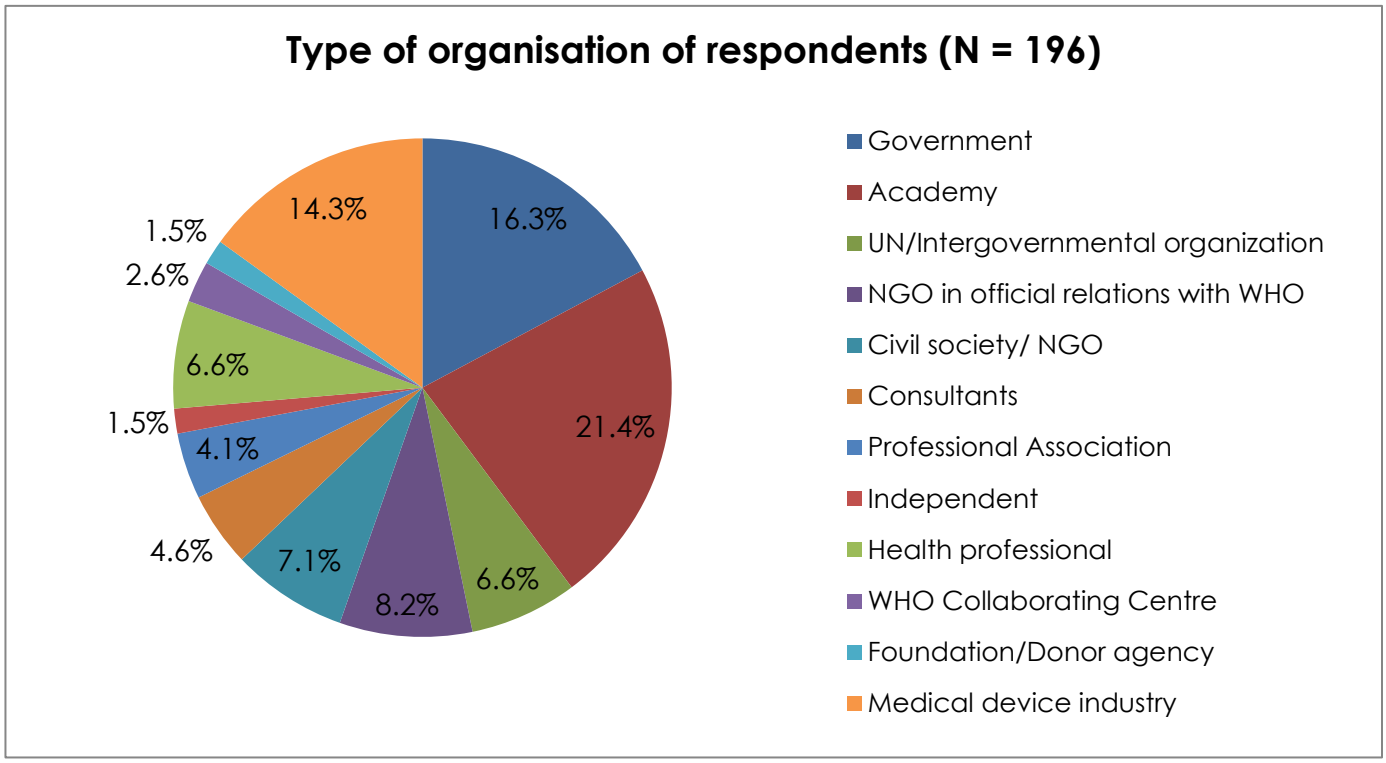

Figure A1. Type of organization of respondents

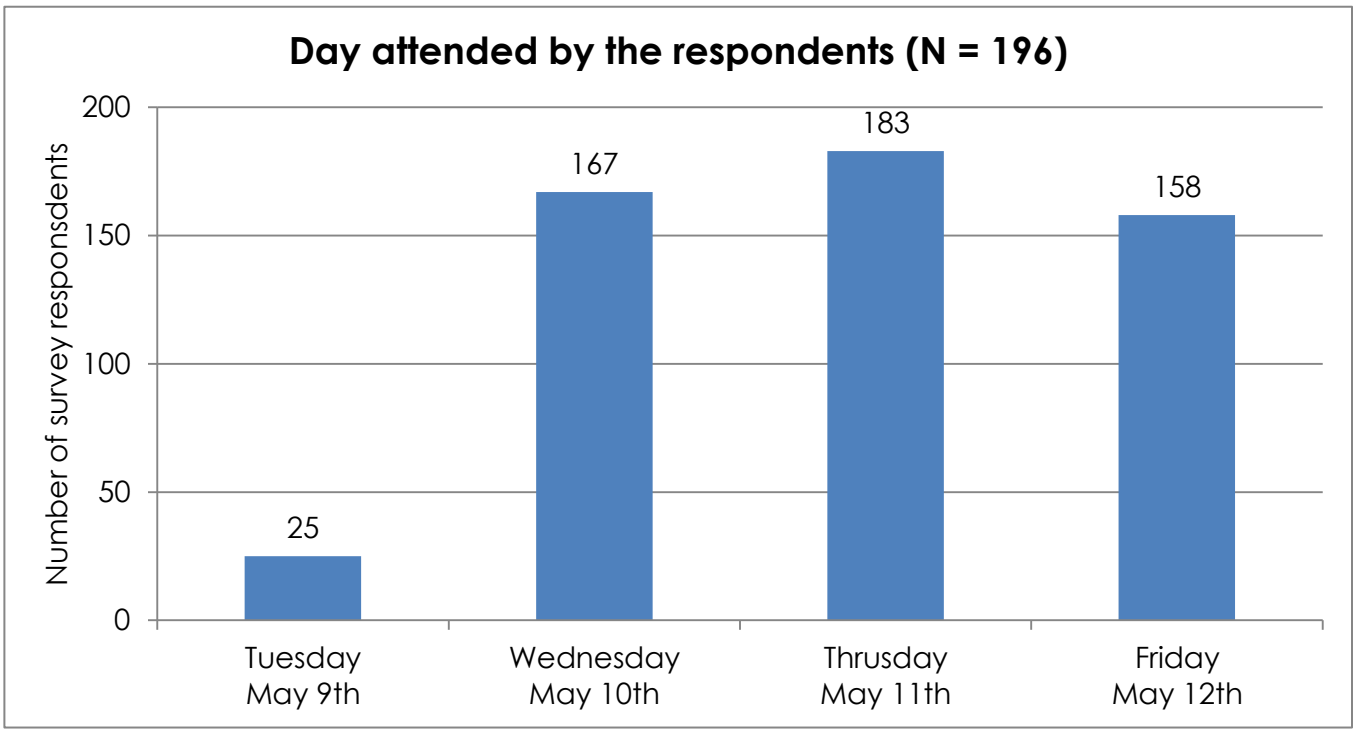

Figure A2. Day attended by the respondents

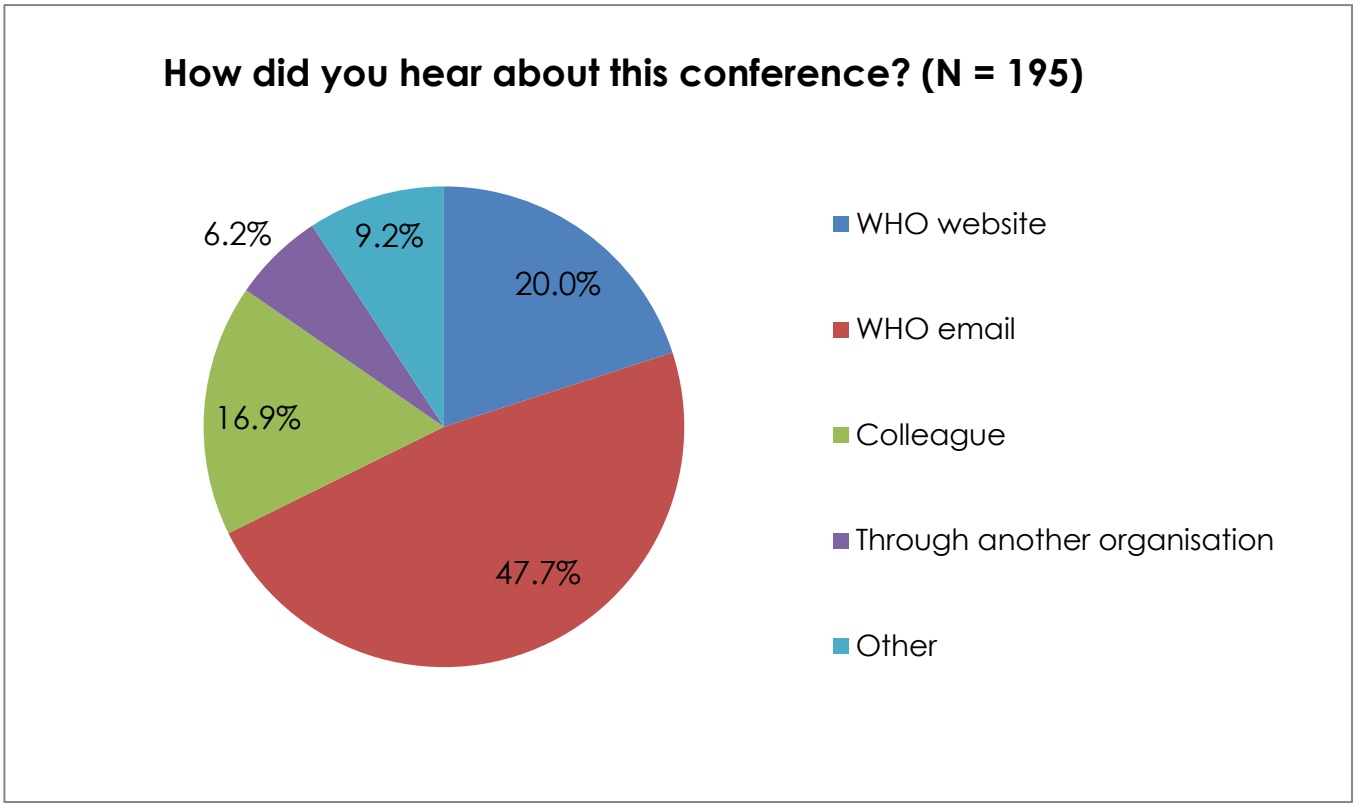

Figure A3. How did you hear about this conference?

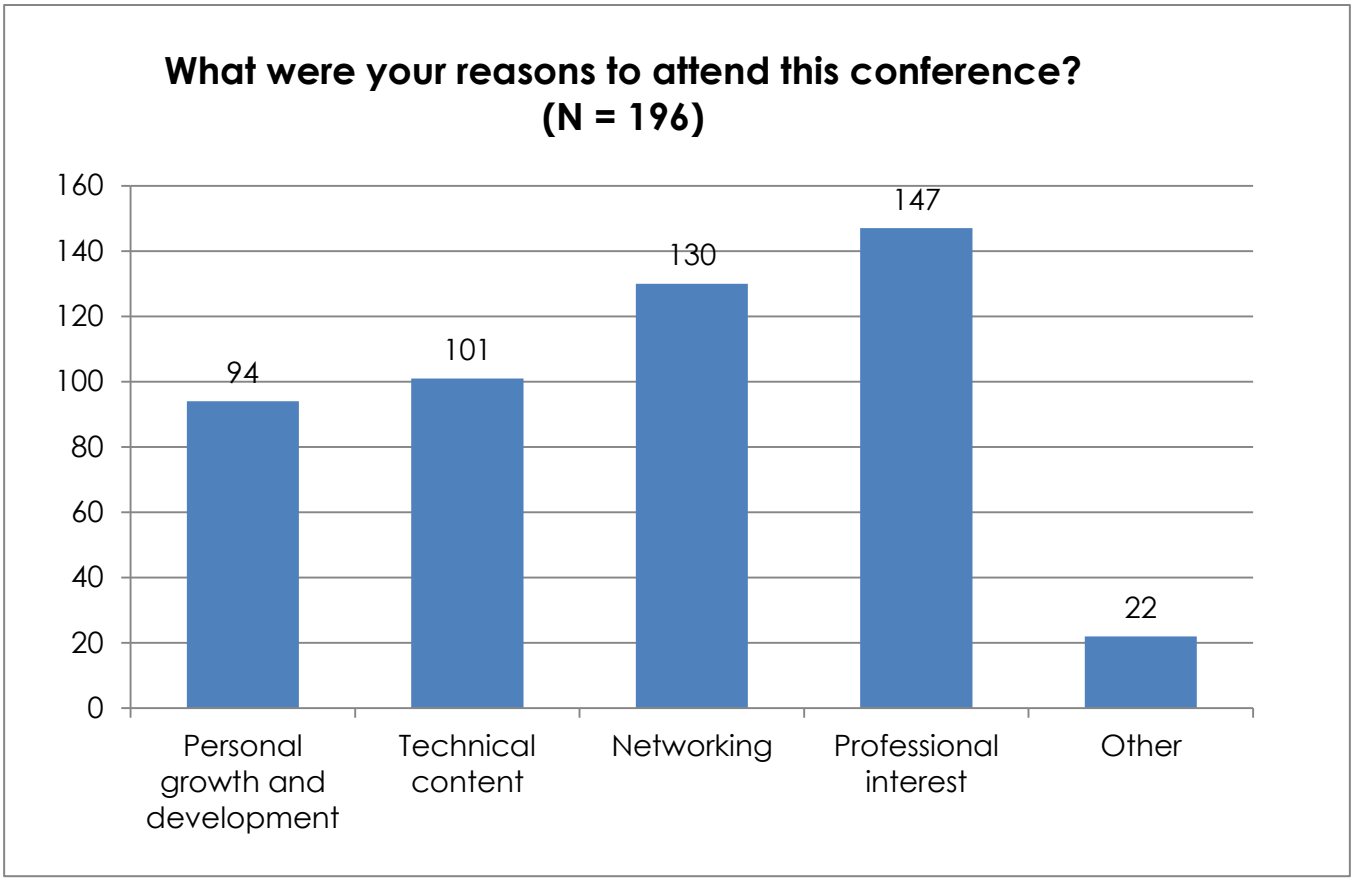

Figure A4. What were your reasons to attend this conference?

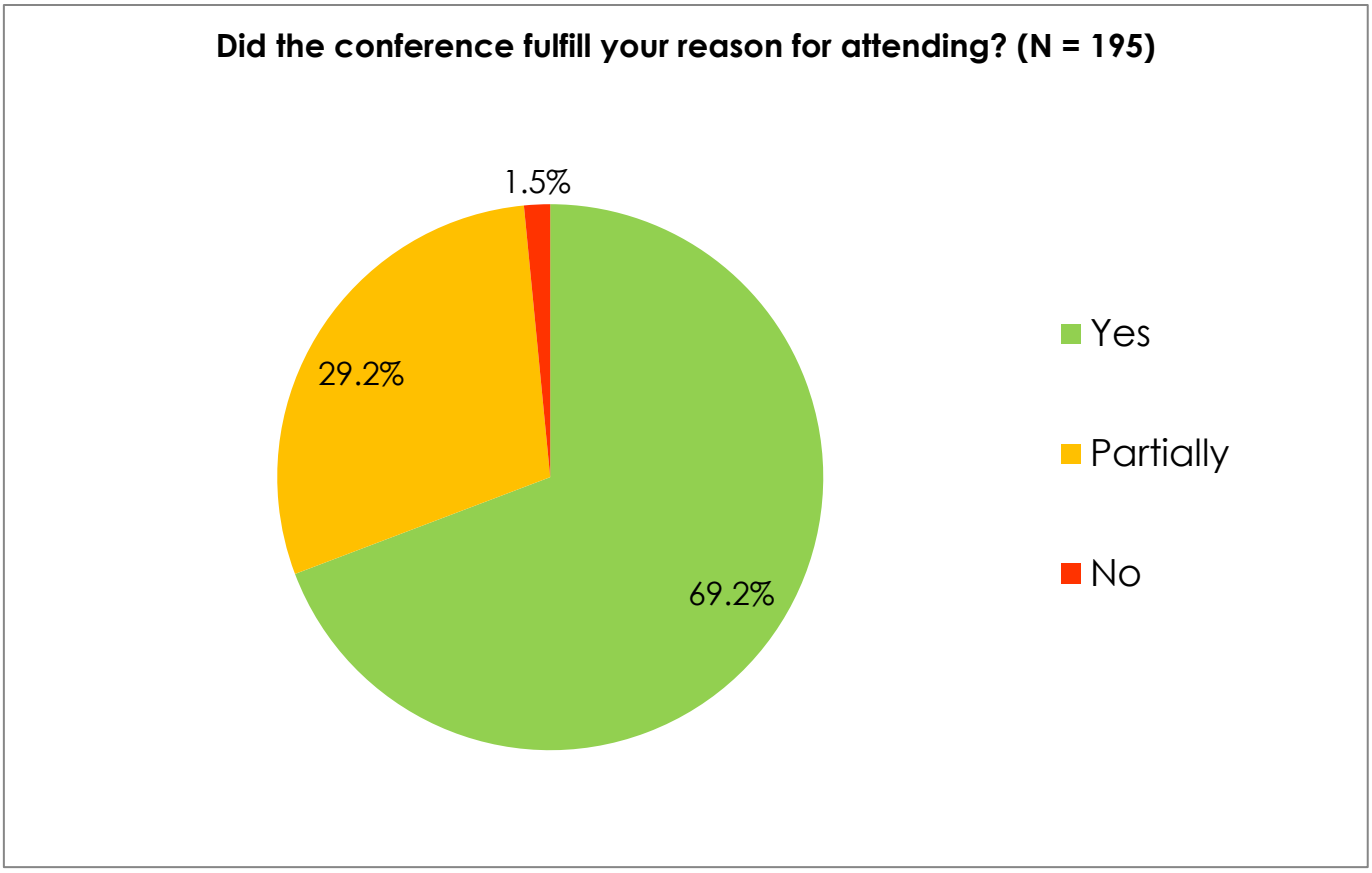

Figure A5. Did the conference fulfill your reason for attending?

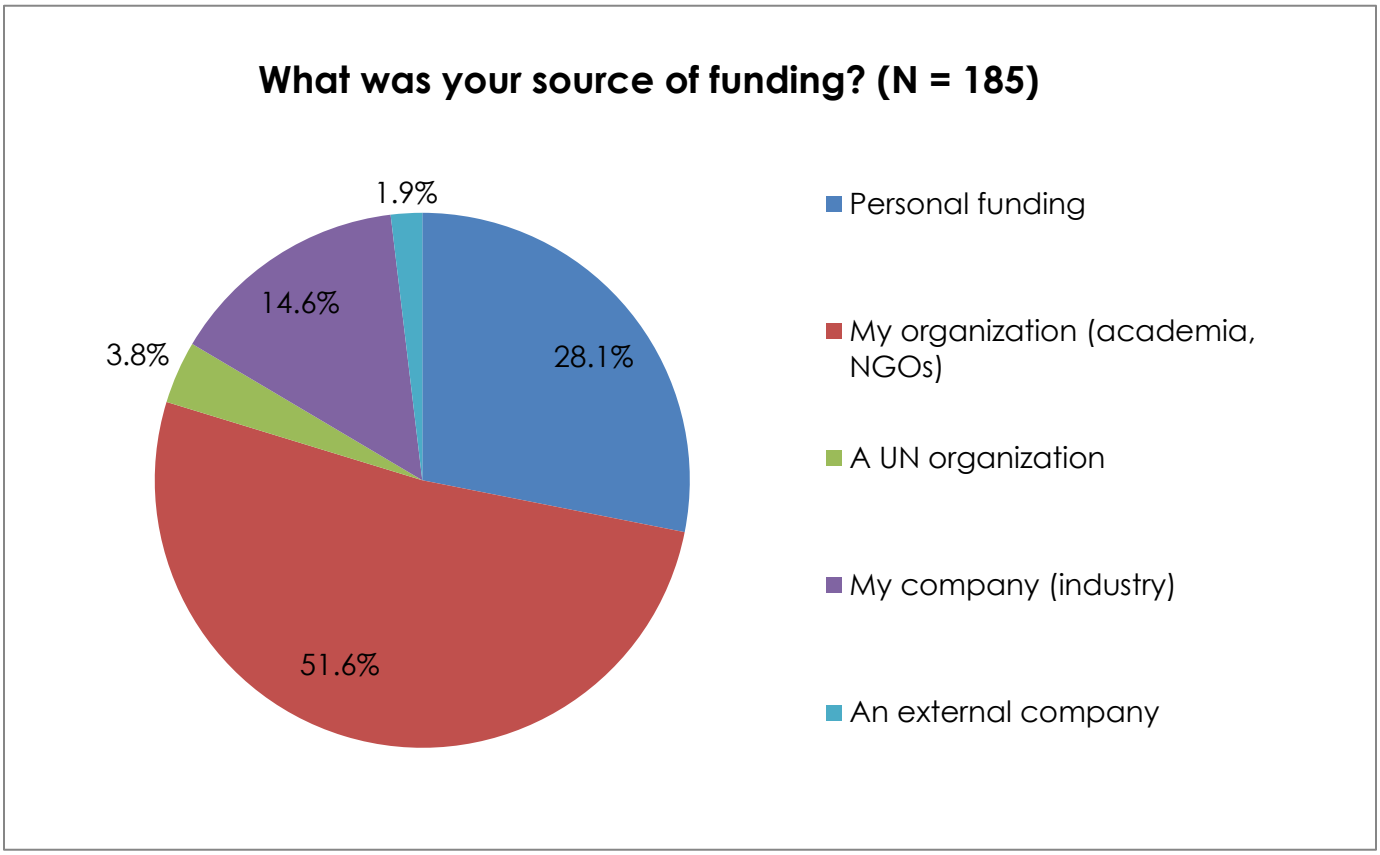

Figure A6. What was your source of funding?

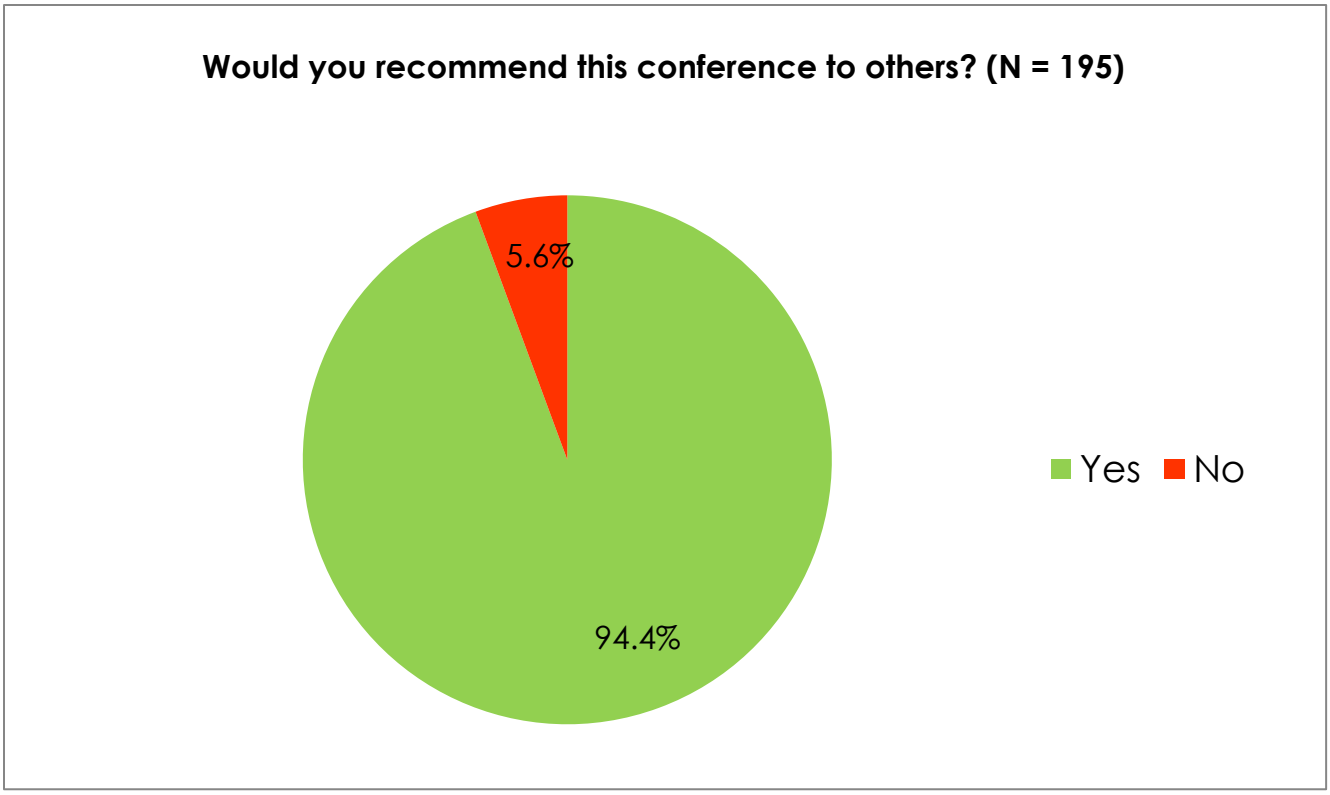

Figure A7. Would you recommend this conference to others?

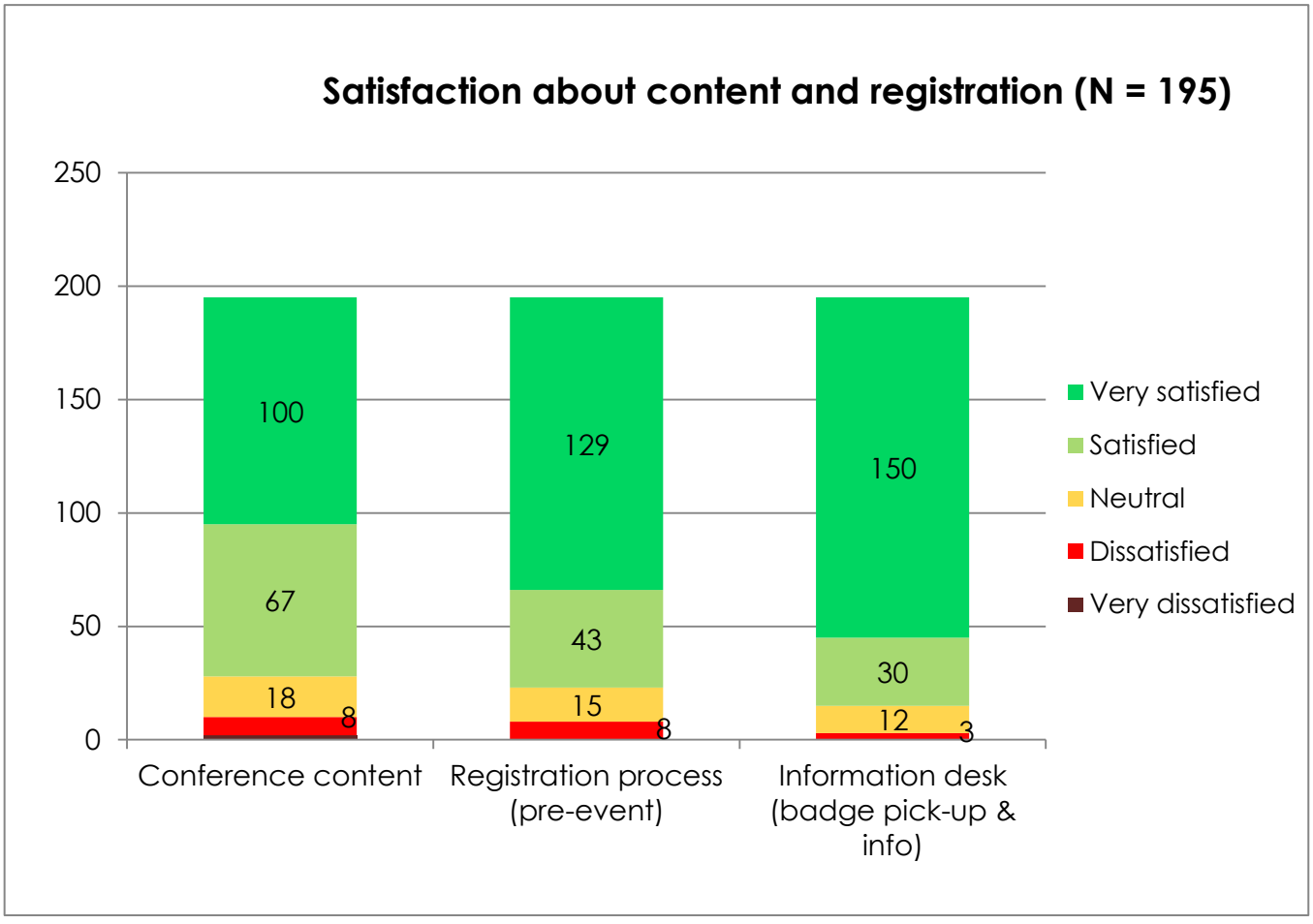

Figure A8. Satisfaction about content and registration

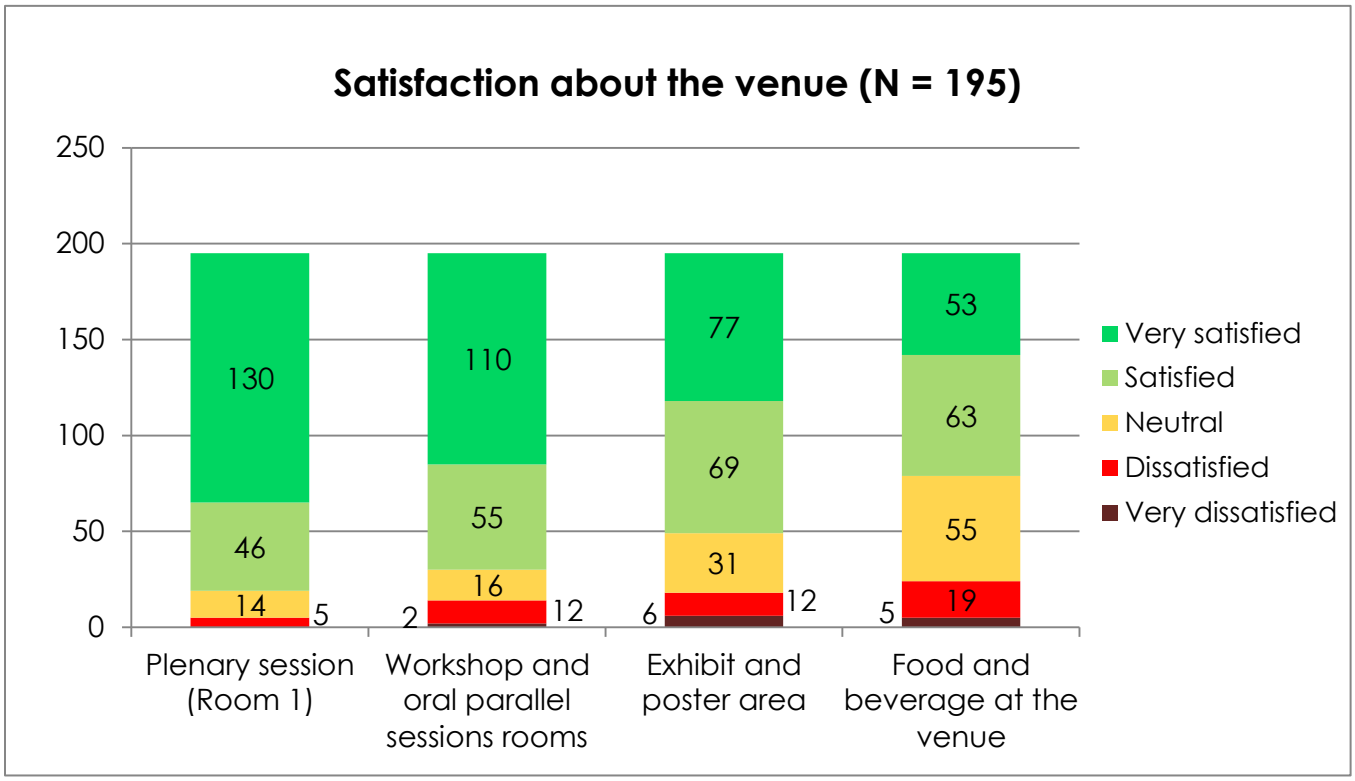

Figure A9. Satisfaction about the venue

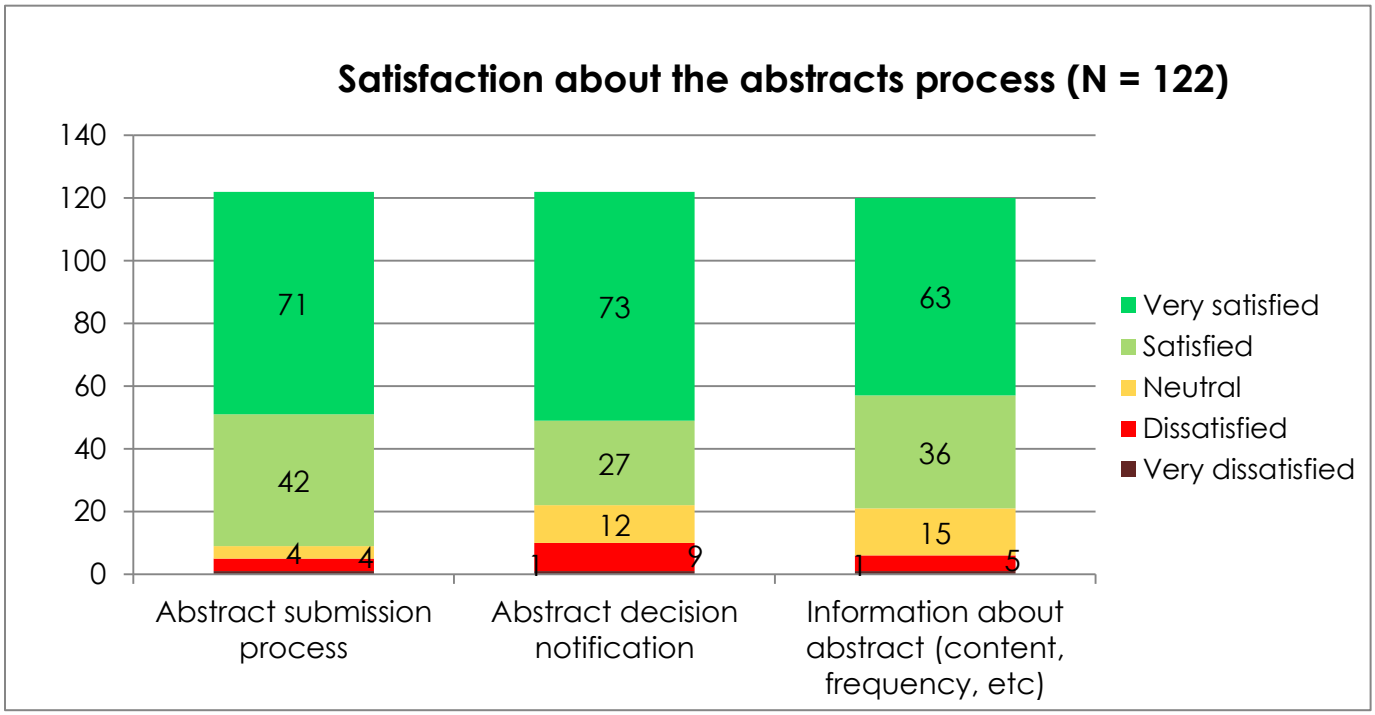

Figure A10. Satisfaction about the abstract process

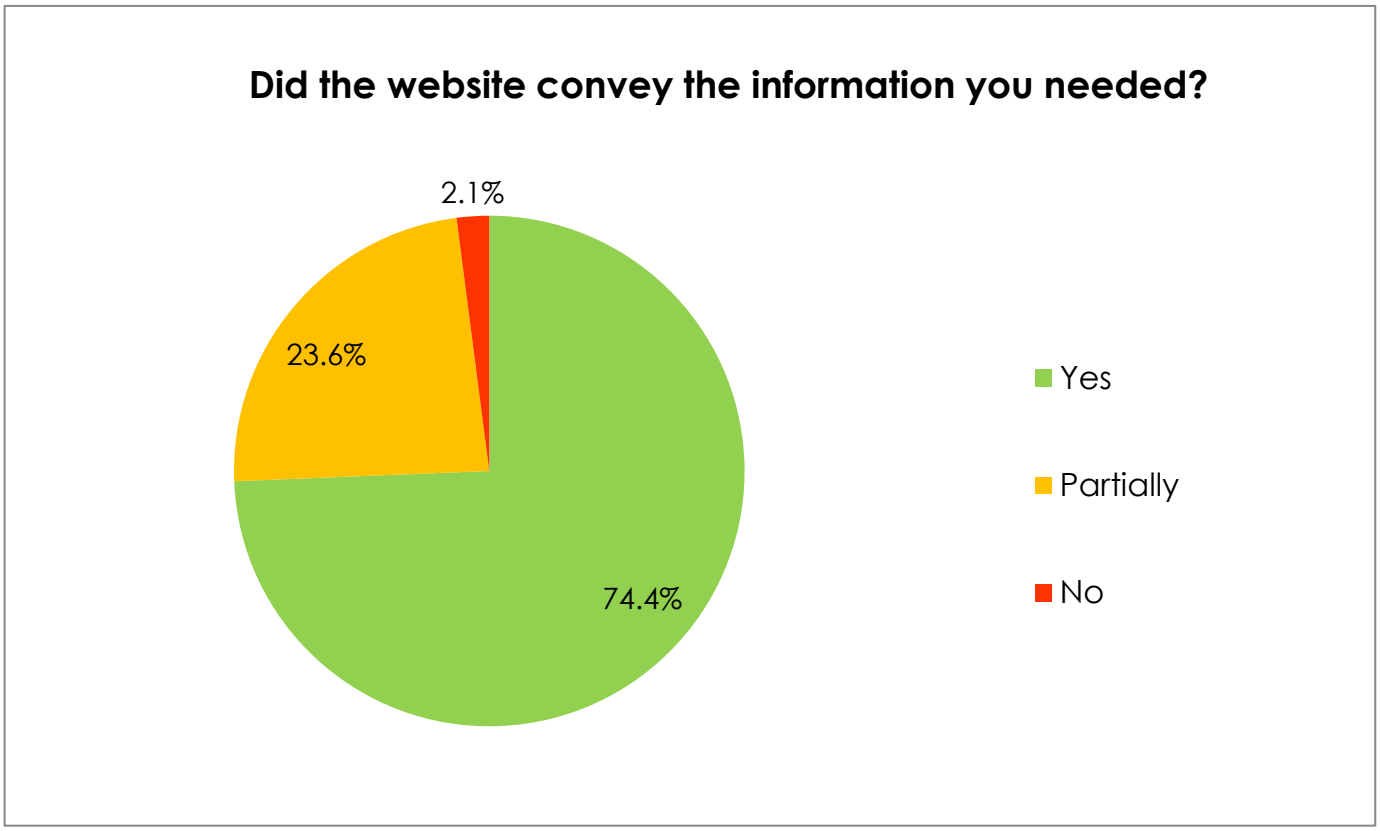

Figure A11. Did the website convey the information you needed?

General Comments

The conference was very well organised! The content was very broad in spectrum and also provided depth in many areas. However, there were no sessions or venues where one could mingle, meet and greet people. (NGO, Canada)

Opportunity to be updated on a rapidly evolving landscape and the most recent Medical Devices/IVDs WHO publications-guidelines-recommendations (Public Private Partnership, Netherlands)

Some good contacts on three continents, confirmation of current beliefs, a clear vision of the potential and obstacles to global universal health coverage (Health professional, United Kingdom)

The first day with workshops was great for meeting people. The second and third days were extremely hard for meeting people and connecting with them. There weren't much discussion going on, especially in the larger conference rooms. (Social Entreprise, Canada)

The conference was dedicated to medical devices, focusing on big medical (hospital) instrumentation. We are providing medical devices for laboratory, so not totally in the scope. (Industry, France)

It would be good to make more round-table and less plenaries, in which the interaction was poor. (NGO, Spain)

Would you recommend this conference to others?

I have recommended the 3rd Global Forum on Medical Devices to my colleagues at academic salon of public health. (Academia, China)

Good organisation and documentation (Independent, United Kingdom)

I would definitely recommend this conference to others (Government, Kenya)

I am trying to persuade others to attend / present next year in India (Health professional, United Kingdom)

The Forum provides professionals working in the medical device a full-package starting from innovation to the product life-cycle. (Independent, South Africa)

The WHO forum on Medical Devices is a very good opportunity for being updated on rapidly evolving and complex topic. (Public Private Partnership, Netherlands)

IT is a good way to network and see also the progress of technological initiatives in different fields (NGO, Switzerland)

Other ministry of health staff especially policy makers and also users (Government, Kenya)

I wish a lot more of our colleagues around the world who work in this area could be present. (NGO, Mozambique)

Absolutely, I believe that everyone who works around healthcare (no matter in development, marketing, innovation, product development, biomedical engineering) must attend at least once this conference. (Academia, Germany)

Did the website convey all the information you needed?

Especially, the website conveyed information on the travel, weather and hotels in Geneva. (Academia, China)

I got all I wanted (Government, Zimbabwe)

And the emails received from the organizers of the event (Government, Kenya)

All information has been put on the Website (Consultant, Mexico)

Could have presented more information on who is attending early on to allow for networking. (Academia, United States of America)

The format of the plenary session and of the workshops was not very clear from reading the planning (e.g. how much time is each talk, is there time for Q&A at the end, is it a round-table, etc.) This type of information was hard to find, so I didn't really know what to expect. (Academia, Switzerland)

We got feedback very late on having to change a few things on the poster - we were lucky that the printers were late... So maybe, next time, review the posters a bit quicker. (Industry, Norway)

The website needs to be updated more often (WHO collaborating center, Switzerland)

It would have been nice to have an app to be able to contact other attendees (Industry, United States of America)

It was difficult to me to know about the decision on my second abstract submission (Government, Benin)

The hotels listed on the Forum's website were, in fact, not aware of this event and the prices listed were much higher in reality (Academia, Switzerland)

5.2 Workshop

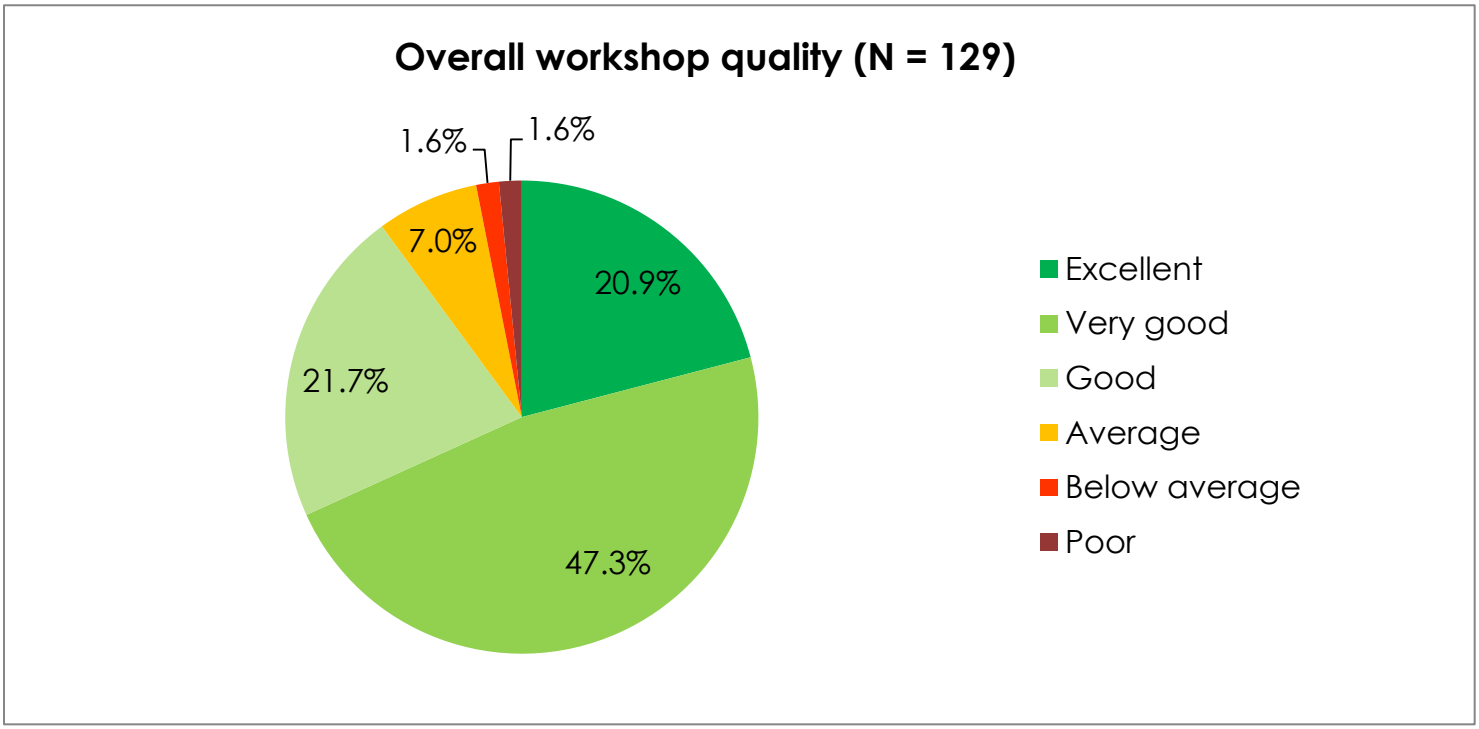

Figure A12. Overall workshop quality

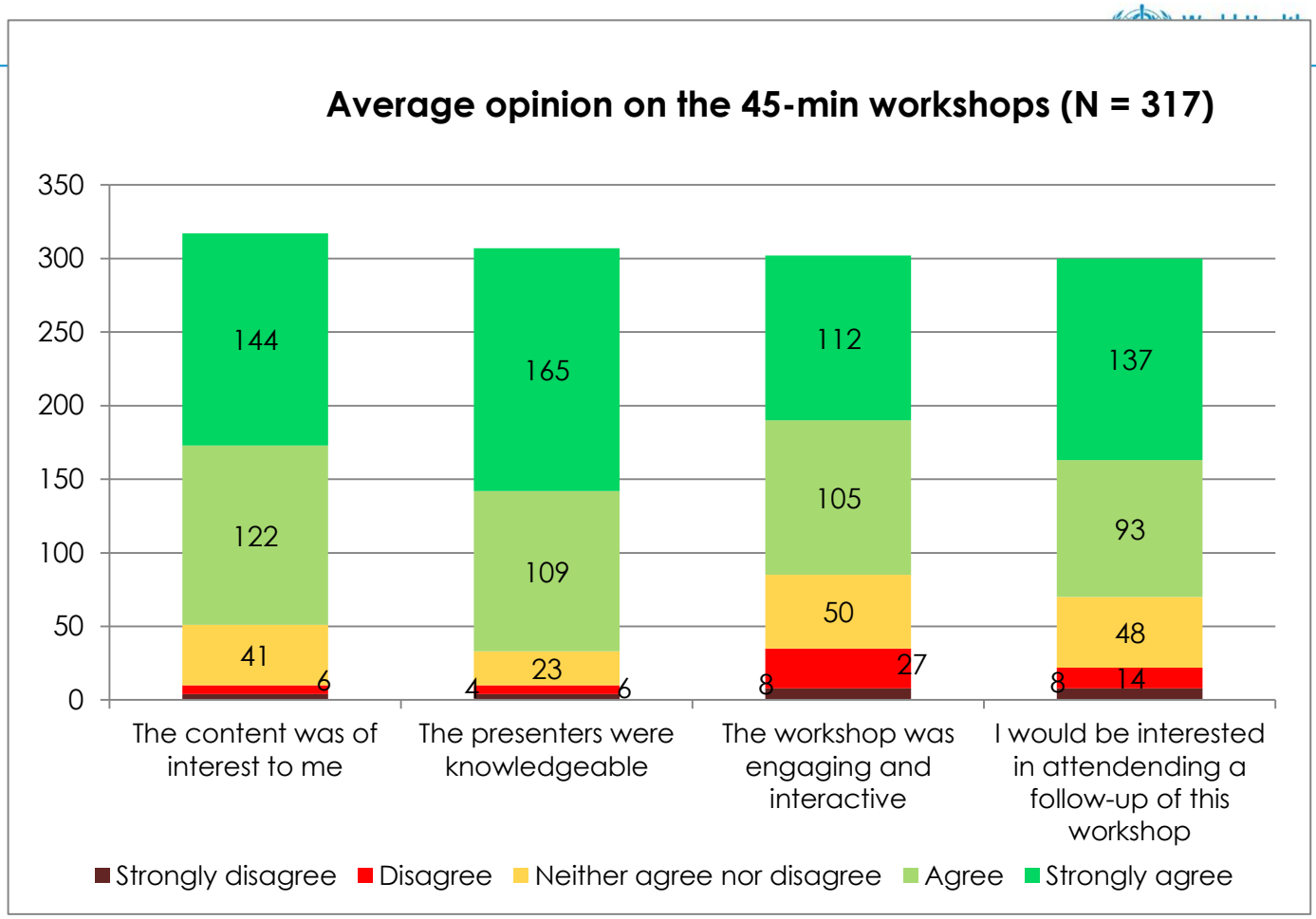

Figure A13. Average opinion on the 45-min workshops

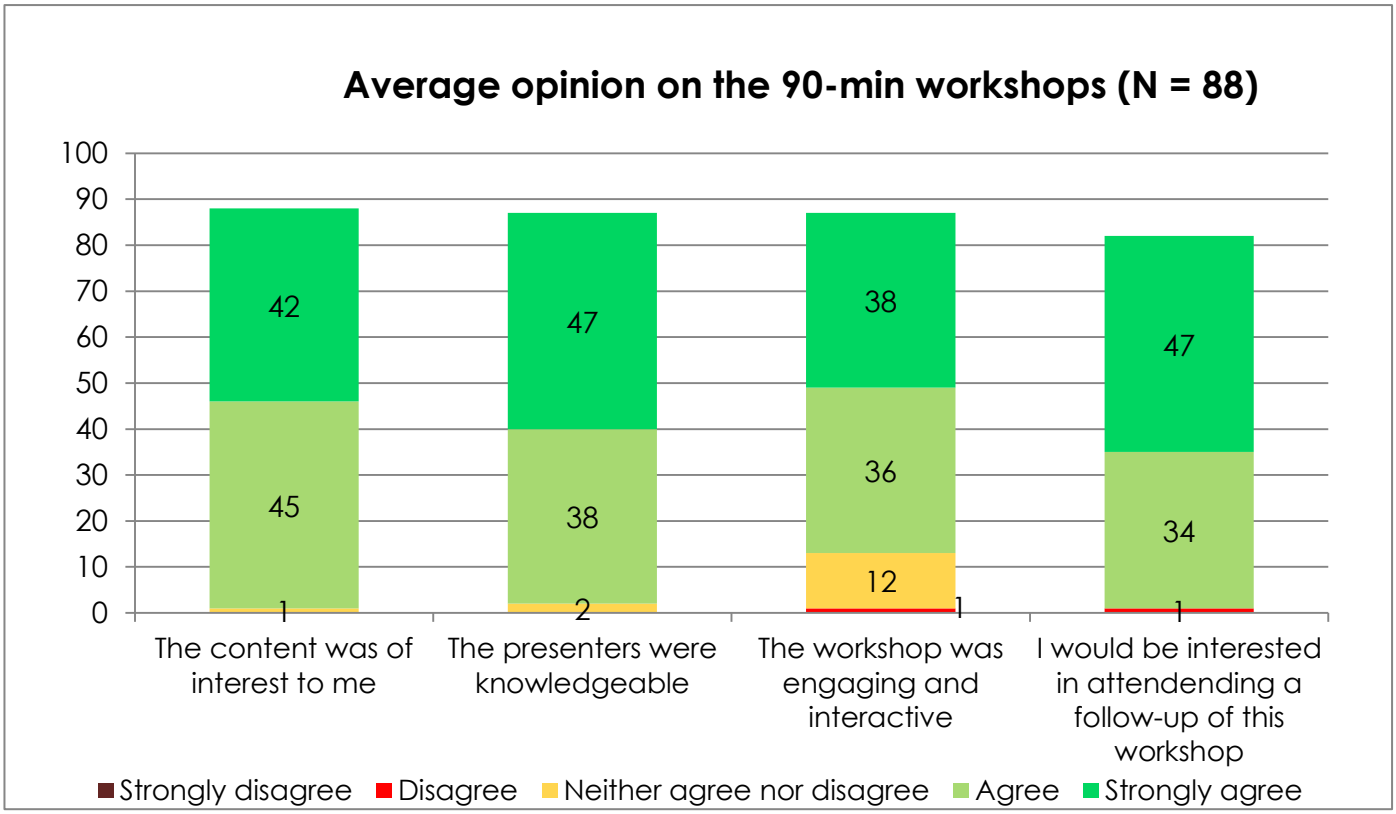

Figure A14. Avergae opinion on the 90-min workshops

Comments on Workshops

Was very interesting for me in order to know what is the situation about of development on different countries. (Government, Cuba)

Lots of interaction with the audience (Academia, Switzerland)

The talks were good, but unfortunately I missed time for discussion. Only 3 questions were answered most of the time, as time was limited. I would have expected more time for interaction and to debate. (Industry, Luxembourg)

Attended although the workshops were in reality designed as presentations and did not enable discussion or interaction, which would have been better. The structure of the rooms in the venue did not allow for a workshop setting. (NGO, United States of America)

Most of the titles of the conference/workshops did not accurately reflect the content or the speakers did not speak to the point (NGO, Switzerland)

I think the workshop time (about 45 min) is too short to really get into deep discussions and have useful outcomes - I would recommend having fewer, longer workshops instead. (Industry, United States of America)

5.3 Plenary Sessions

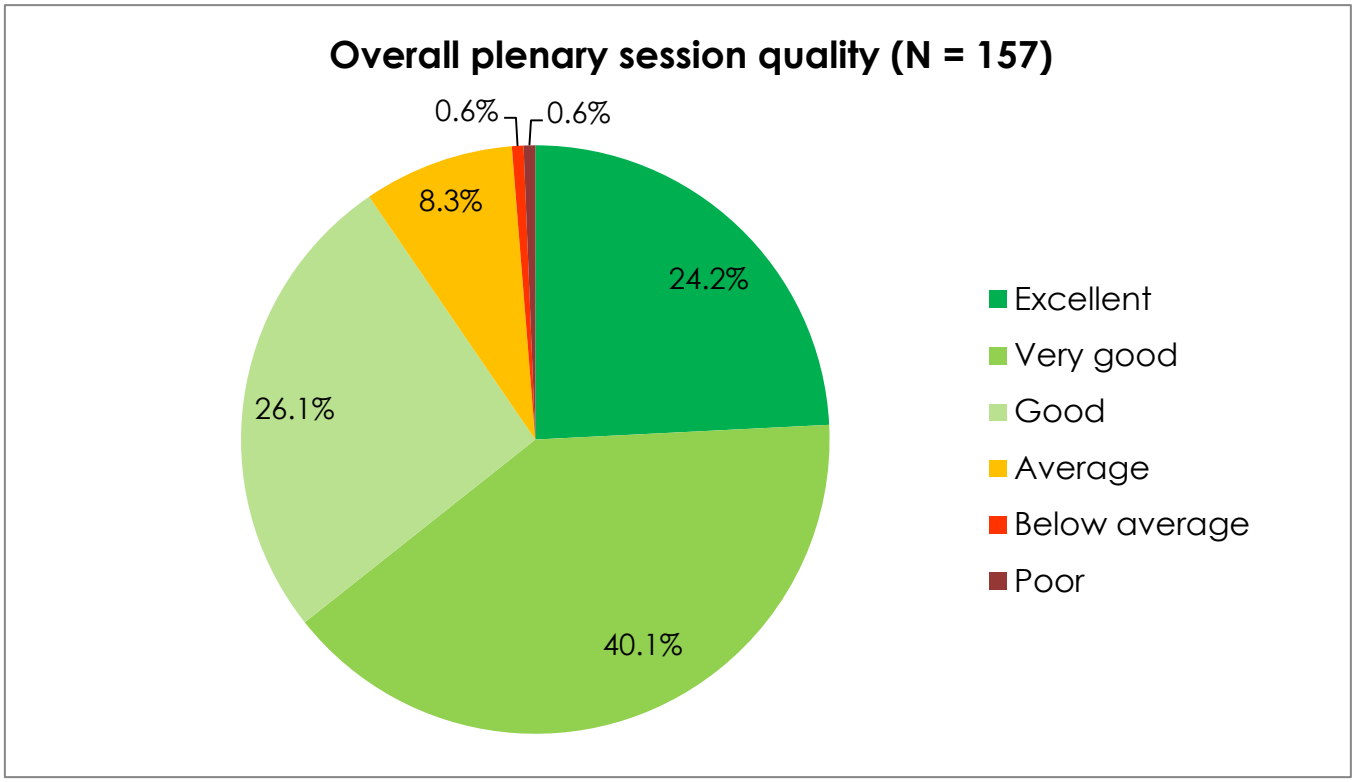

Figure A15. Overall plenary session quality

Comments on the quality of Plenary Sessions

Many useful and fully agreed conclusions (Academia, Spain)

Presenters knew their content so well. (Government, Kenya)

Very good (Industry, Bengladesh)

Some sessions had too many presenters with not enough time each. Perhaps it would have been okay if the presenters had of tailored their slides for the short time but most did not so instead rushed all of their content. (Academia, United Kingdom)

My English level was my problem (Government, Benin)

The presentations were quite brief. Some of them were not too exciting. (Government, Ghana)

Some of the plenary topics felt like odd choices for the full group to attend. Some of the presentations were highly technical and felt irrelevant to the general theme of the conference. (Academia, United States of America)

They would need to have more interaction, practical examples and space for comments and questions (Consultant, Switzerland)

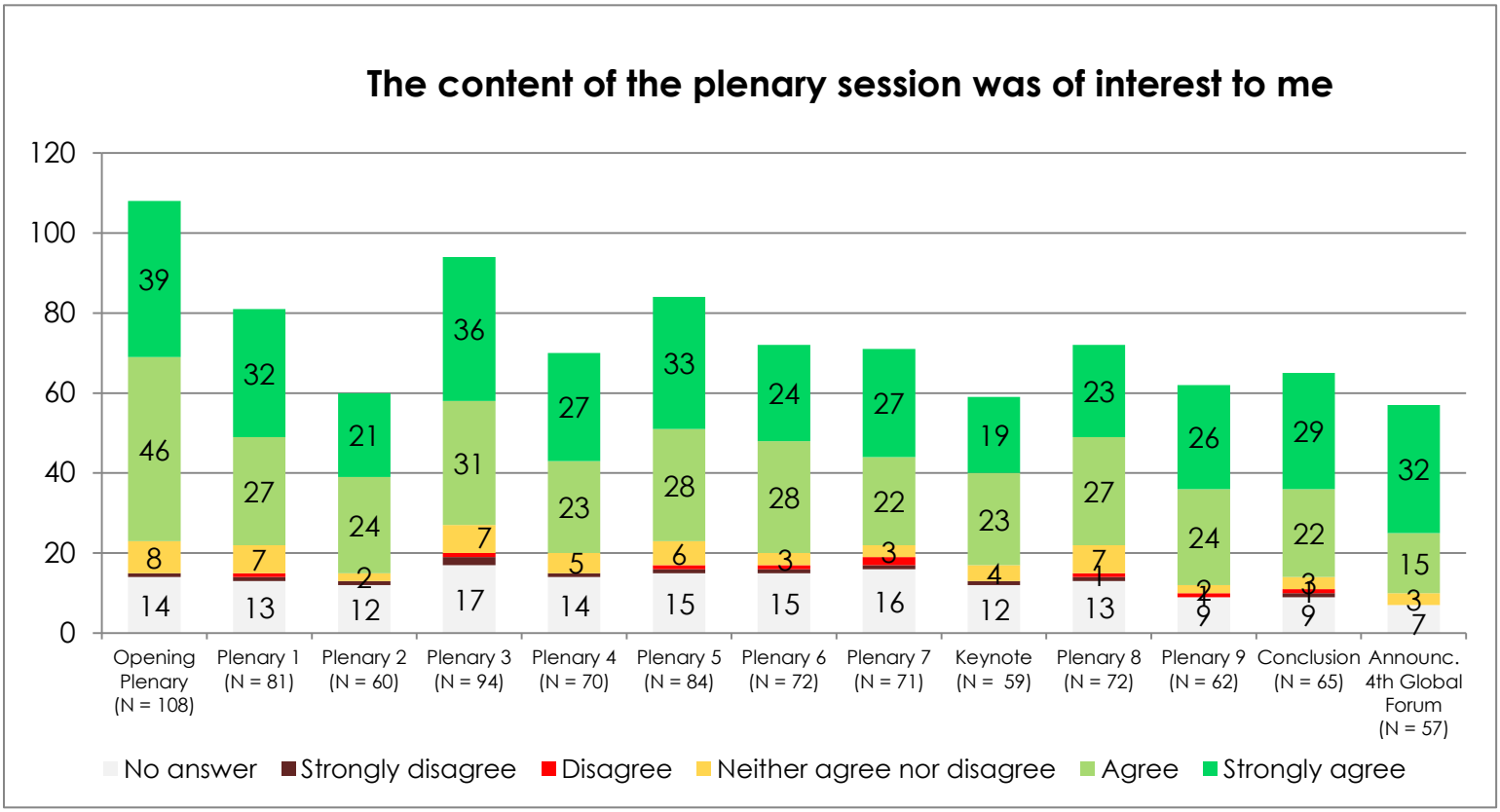

Figure A16. The content of the plenary session was of intereset of me

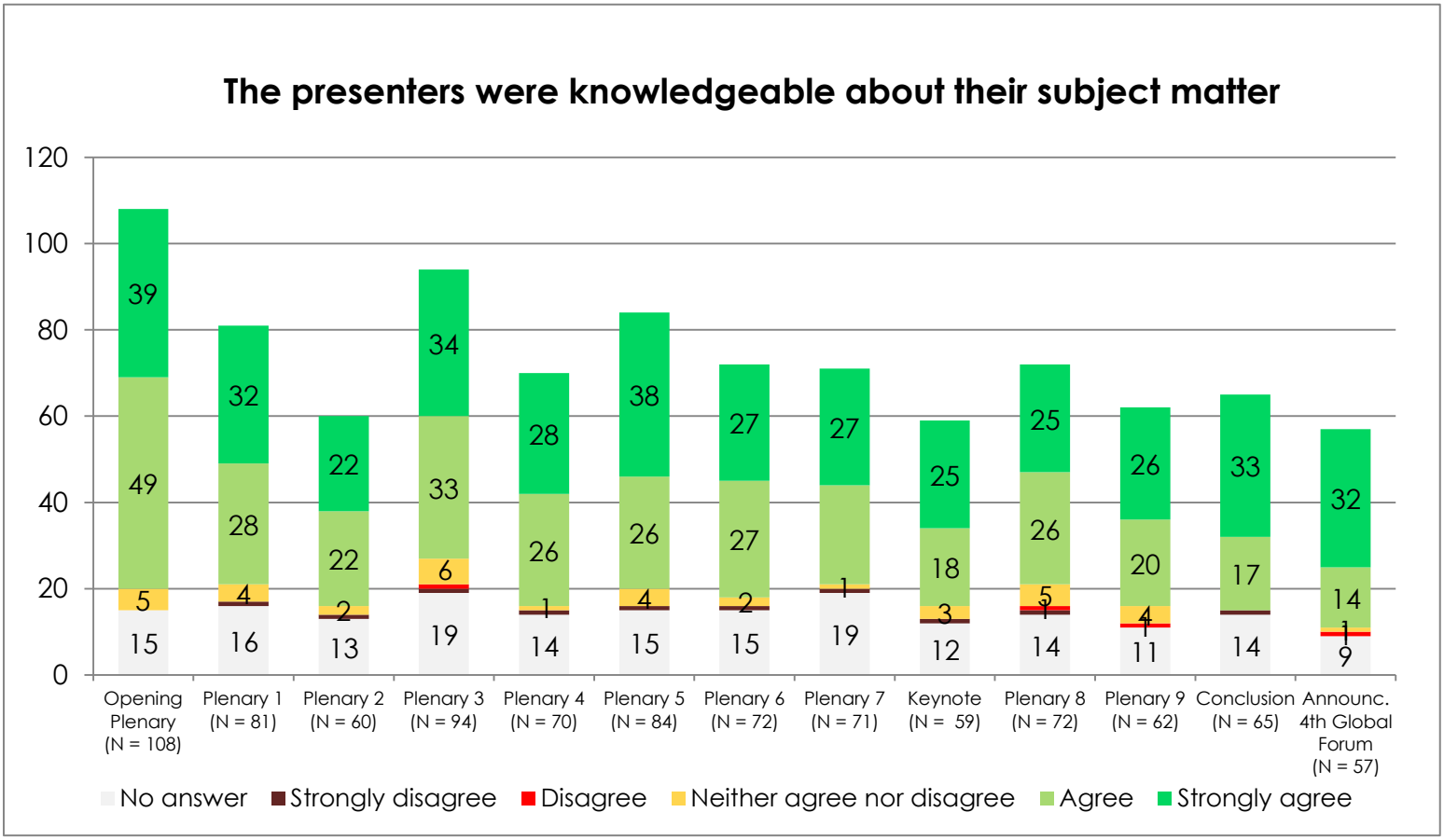

Figure A17. The presenters were knowledgeable about their subject matter

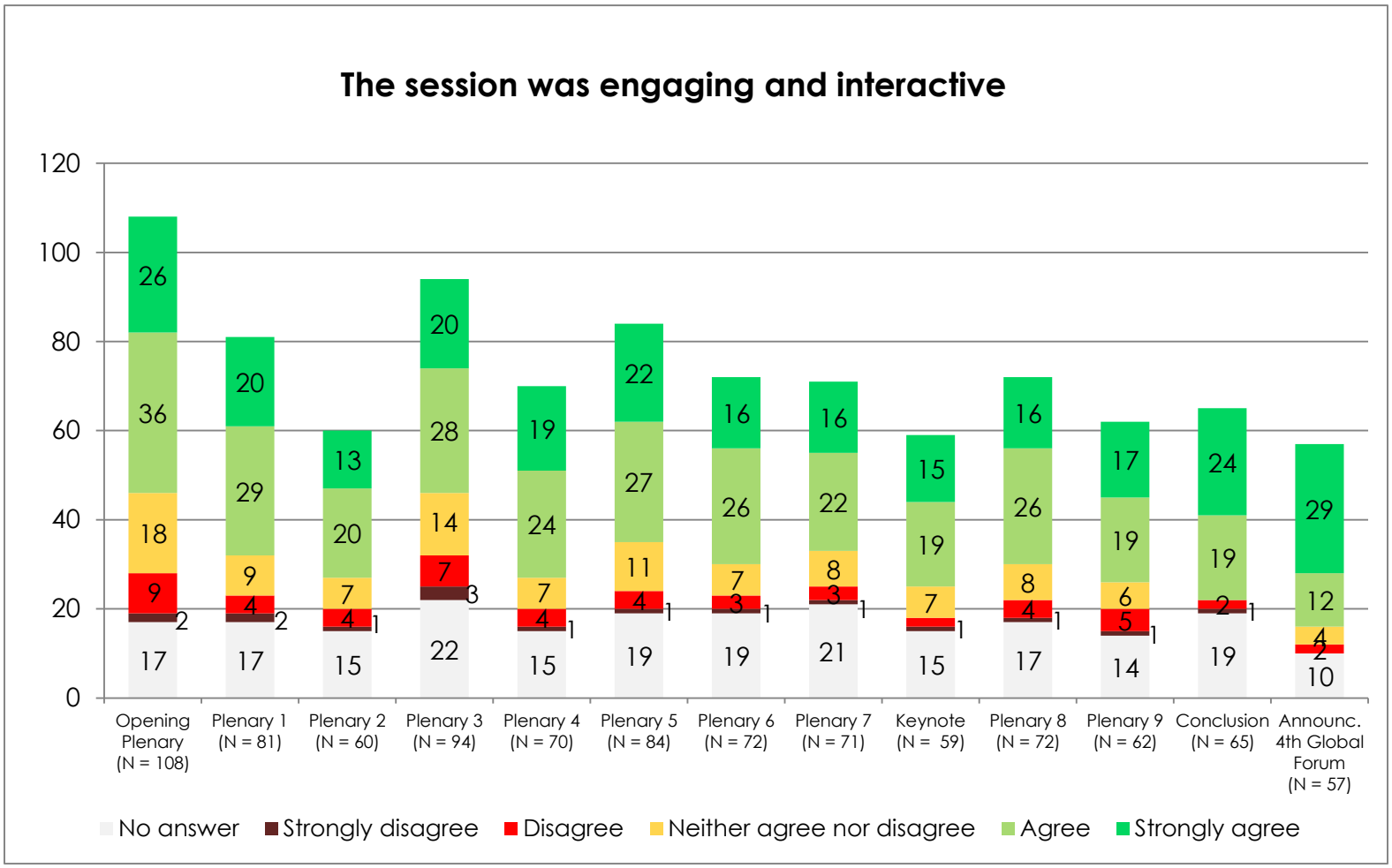

Figure A18. The session was engaging and interactive

5.4 Oral Parallel Sessions

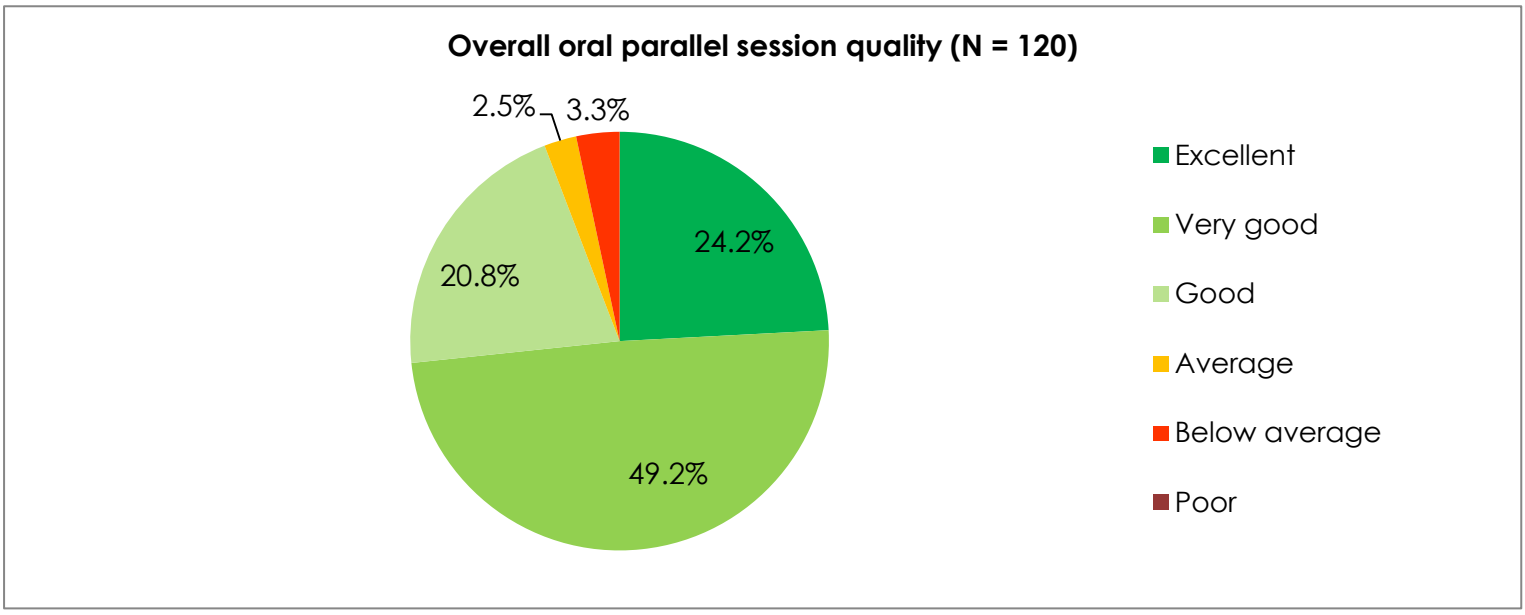

Figure A19. Overall oral parallel session quality

Comments on overall quality of Oral Parallel Sessions

Nice (Industry, Bangladesh)

Looking forward to the 4th global forum (Government, Kenya)

Wonderful! (NGO/Civil Society, Italy)

Late arrival to Geneva, otherwise I would have participated since Wednesday. Excellent presentations (Academia, Peru)

As there were several topics of interest to me, I had to leave one of the sessions and visit another on procurement - however, I believe many attendees did the same. (Independent, South Africa)

Several speakers did not show up which was somewhat disappointing. Sometimes the talks presented in the parallel sessions and in the plenary sessions where almost exactly the same (including the slides). As a result many participants started texting etc. (Academia, United Kingdom)

There is a chance of missing other parallel session that are important to hear (NGO/Civil Society, Ethiopia)

Unfortunately, oral parallel sessions with a lot of interest overlapped. This is my only comment on this excellent organisation of the event (Academia, Greece)

Too many parallel sessions at the same time. And poorly scheduled - the venue made moving from one place to the other very time-consuming. Some "salles" were 10 minutes apart from each other (Professional association, United States of America)

Far too many speakers, leaving no time for questions or discussion. Less speakers with 10 min each would have been better. Sessions were too rushed. The use of an iPhone timer was very off-putting. (UN/Intergovernmental organization, Switzerland)

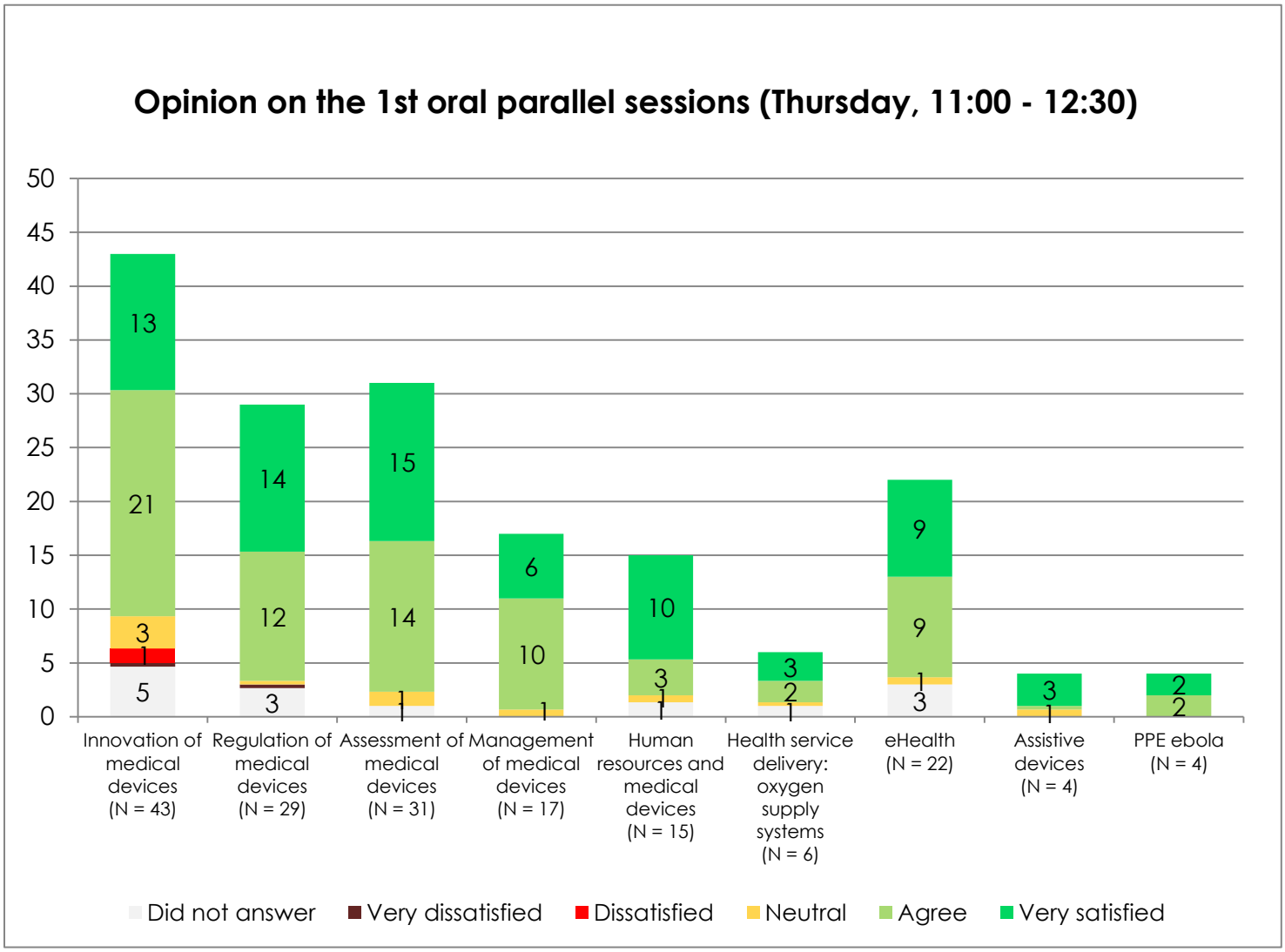

Figure A20. Opinion on the 1st oral parallel sessions

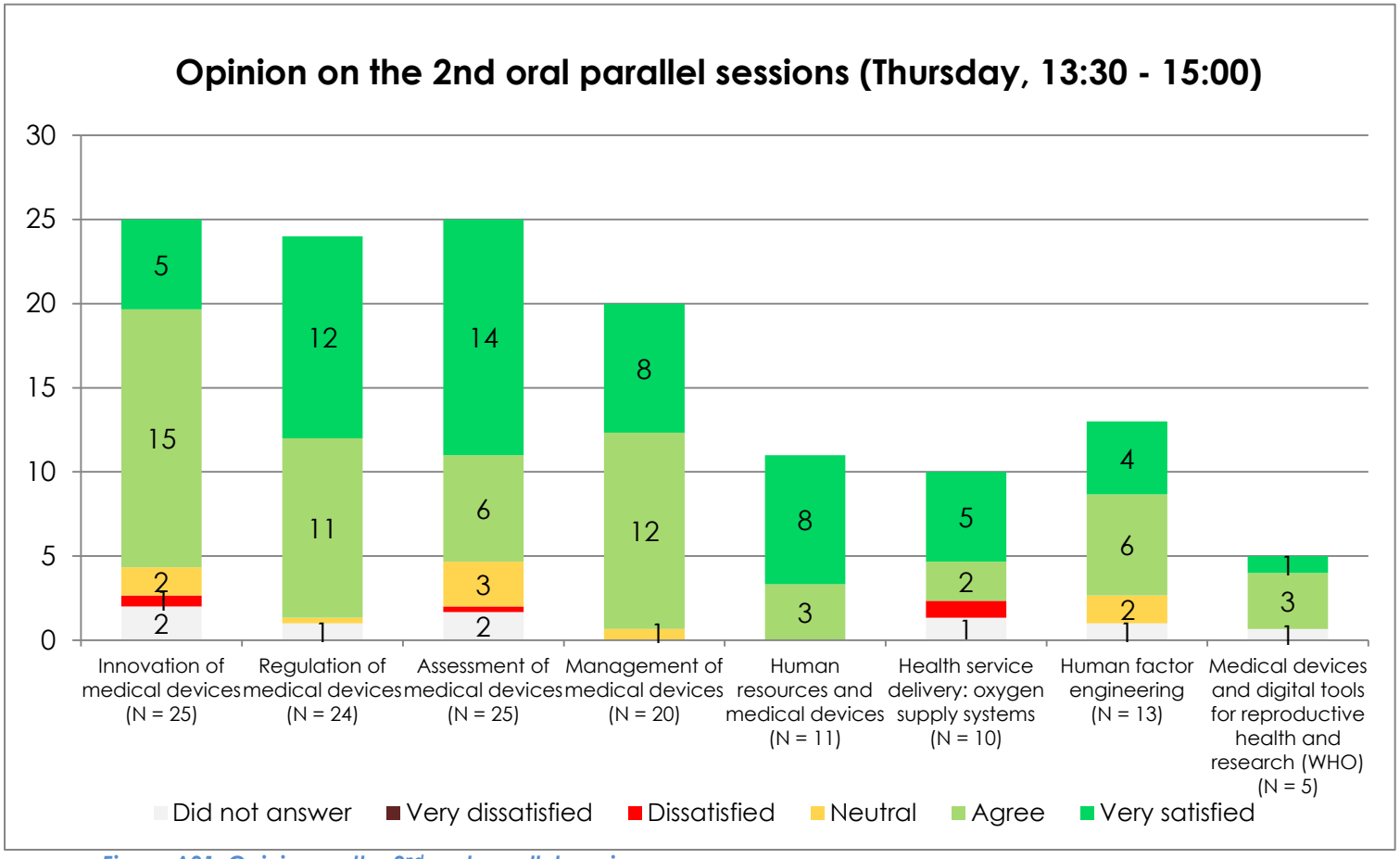

Figure A21. Opinion on the 2nd oral parallel sessions

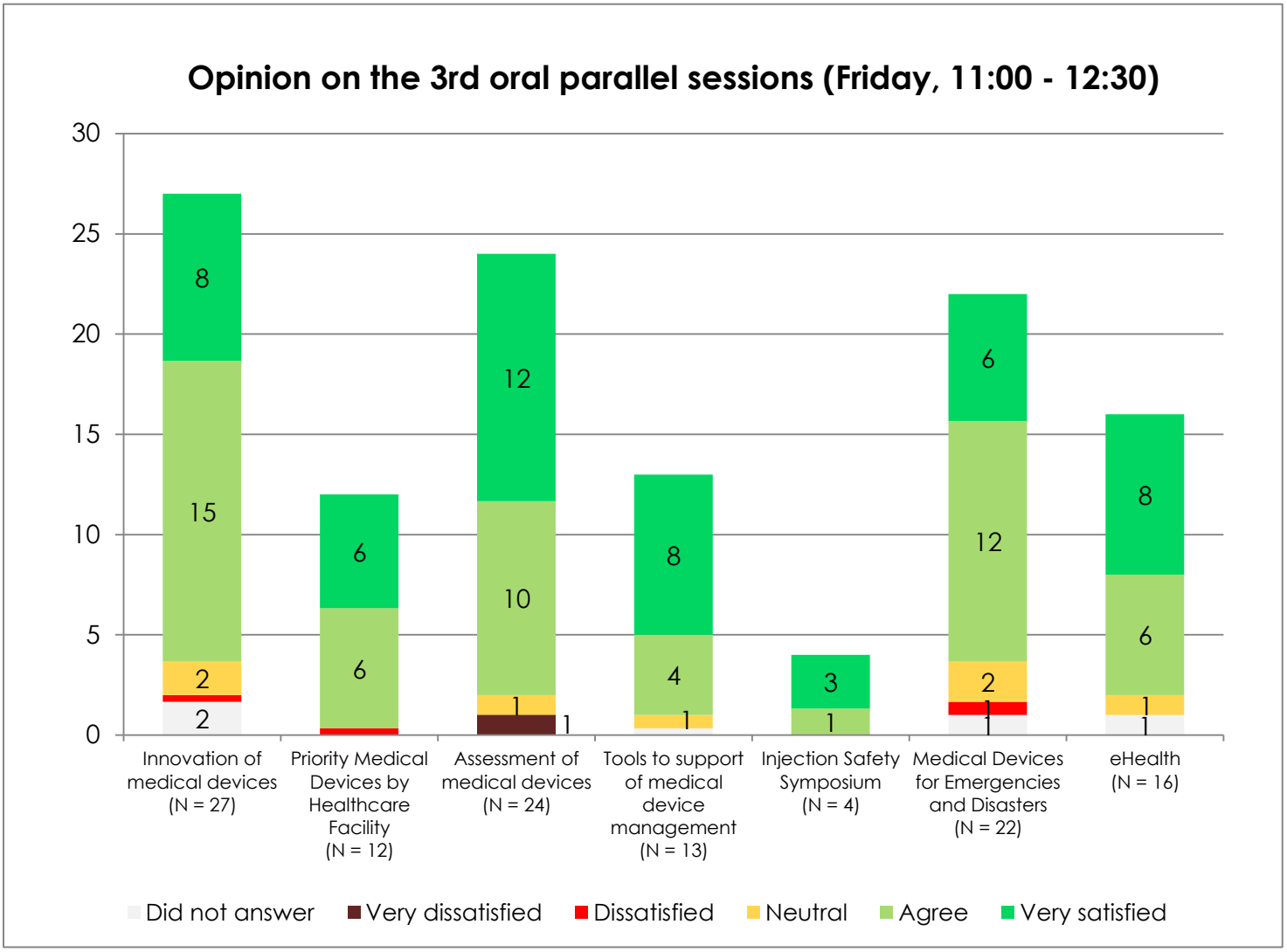

Figure A22. Opinion on the 3rd oral parallel sessions

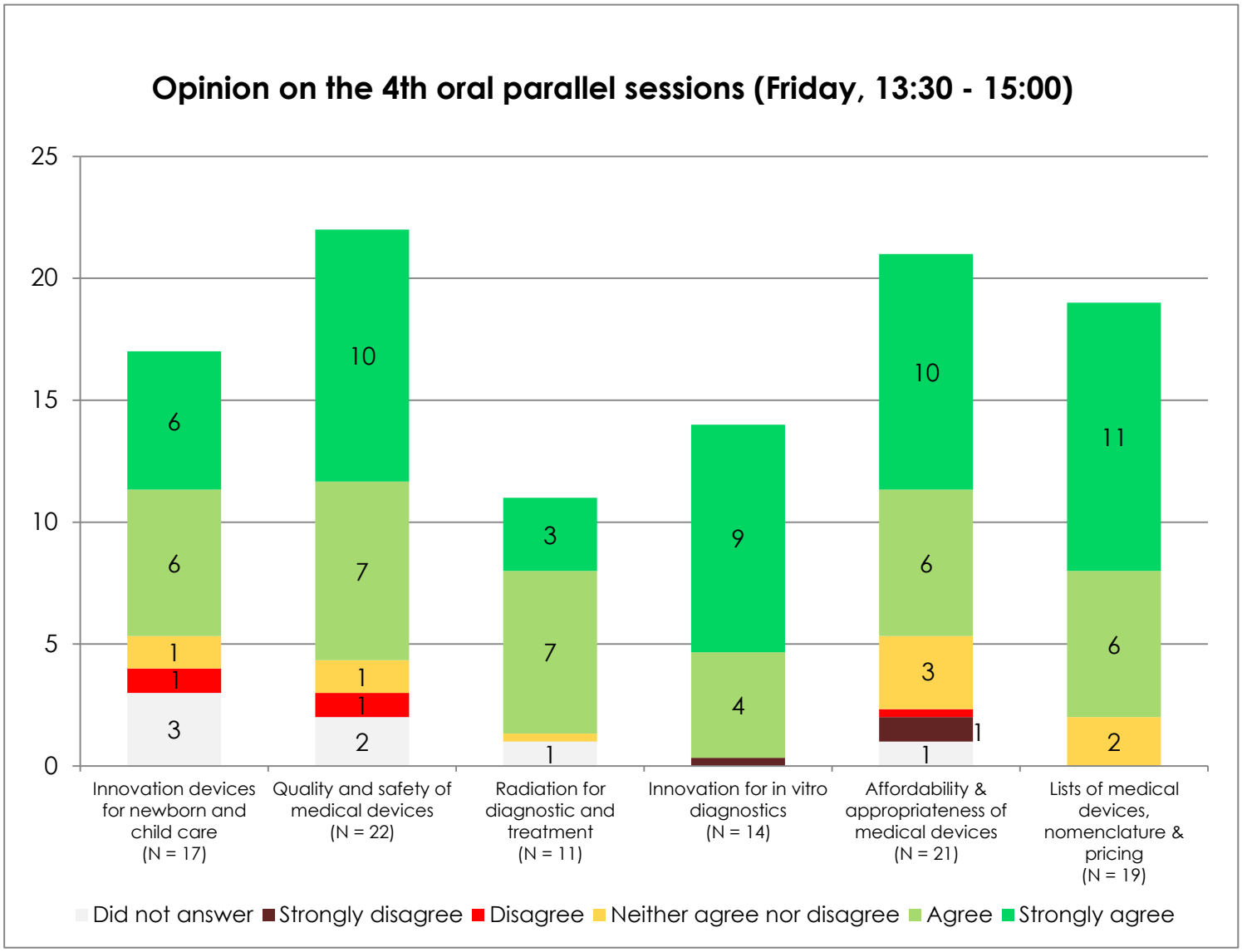

Figure A23. Opinion on the 4th oral parallel sessions

5.5 Exhibition, Poster and Video

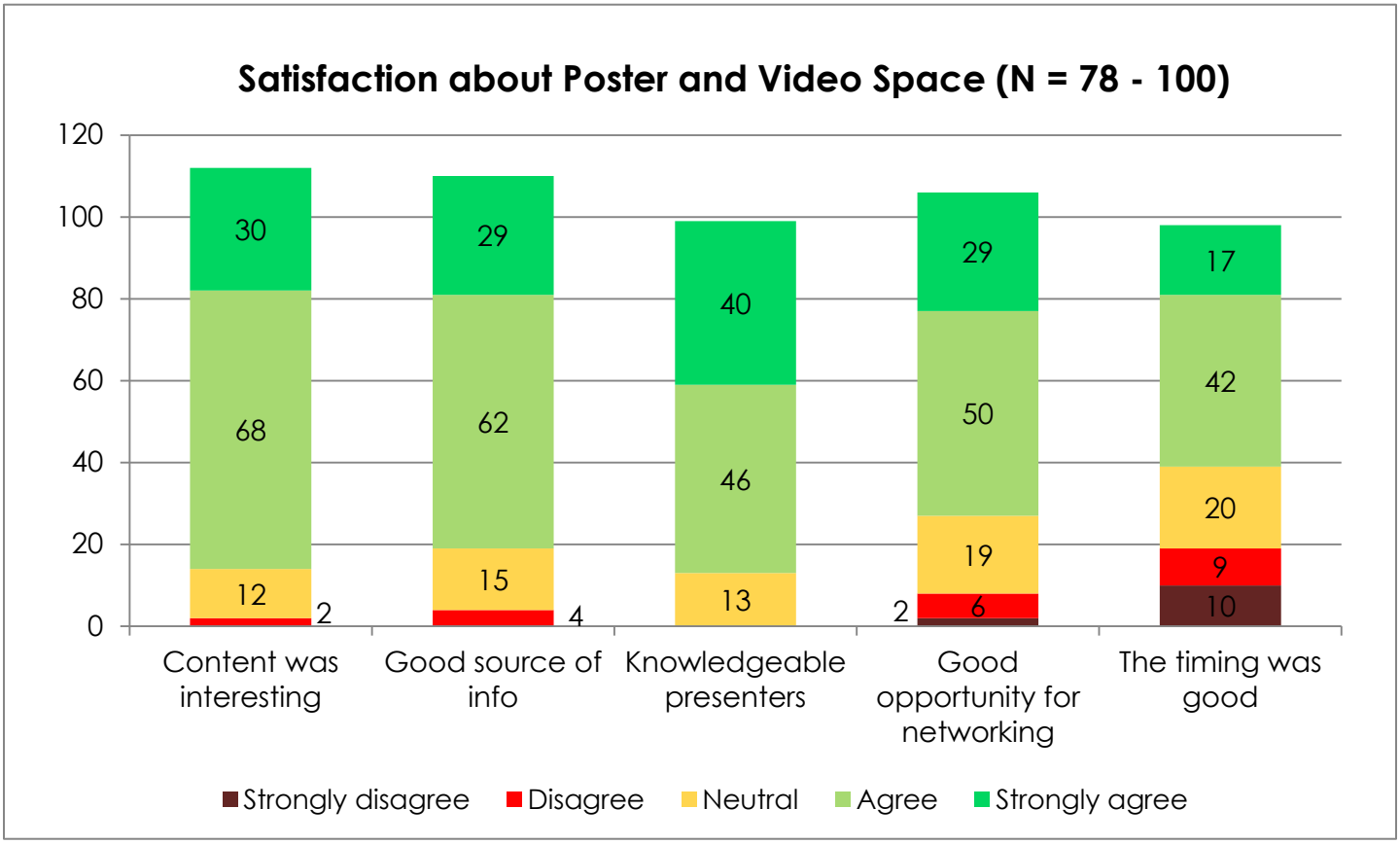

Figure A24. Satisfaction about Poster and Video Space

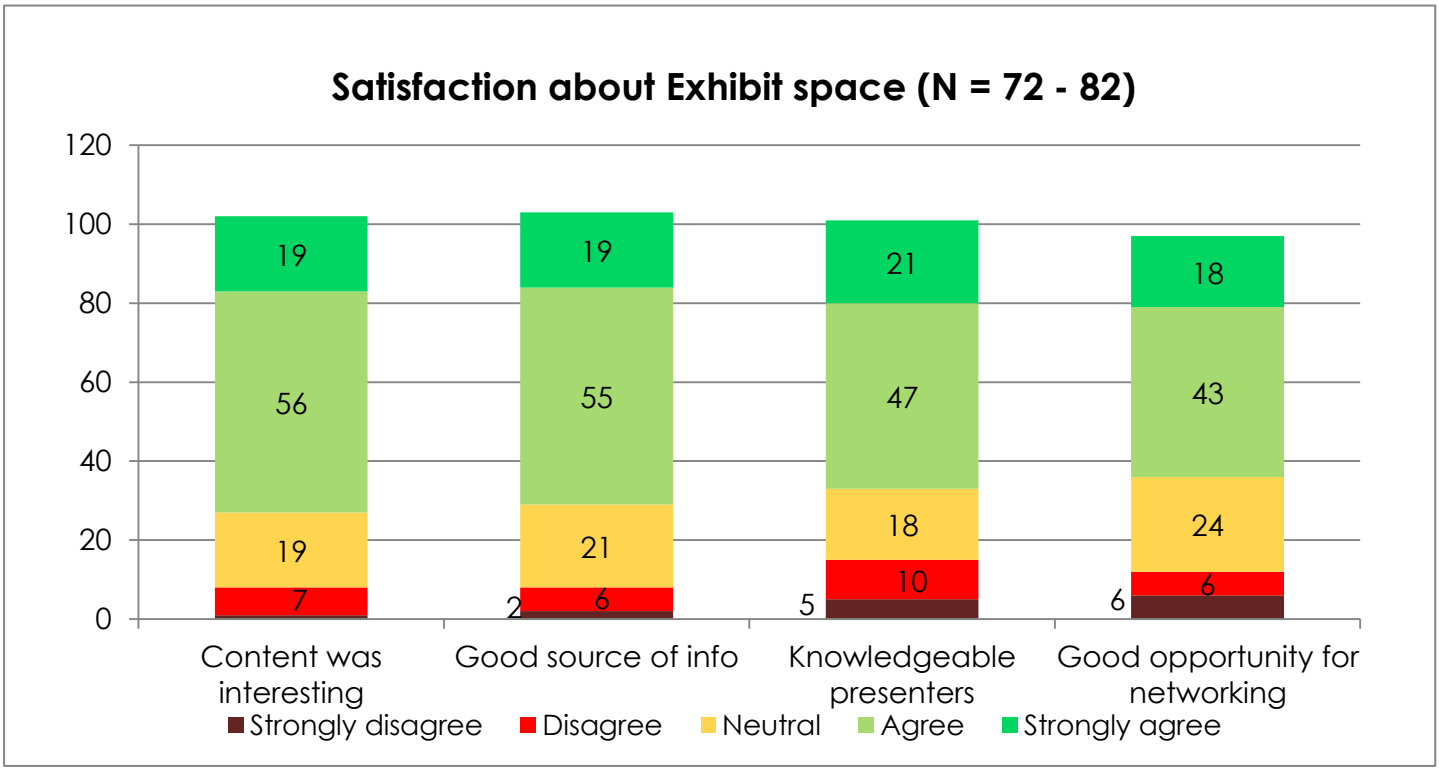

Figure A25. Satisfaction about Exhibit space

Comments on Exhibition, Poster and Video Space

Poster sessions were crammed into the end and beginning of day -- very easy to skip! Poster session needs to be more seamlessly integrated into the day and the conference space itself (Industry, United States of America)

The exhibition space was well set up and well prepared. Thank you! (Academia, United Kingdom)

I liked how the posters were right in the front and main lobby. If they had been in a special room, I would not have looked at this as much. (NGO, United States of America)

Posters were not well organized. It was hard to find a specific poster that I was looking for. (Professional association, Canada)

Unfortunately, I did not have enough time to visit the exhibit space. (Independent, South Africa)

Too bad the poster session was just 1 hour in the mornings. It would have been nice to have an ongoing session throughout the day so that people could go and see the posters and interact with the presenters when they had an opportunity throughout the day. For example, I wanted to go during the lunch break, but most of the posters were already taken down and being replaced and almost no presenters were there. (Academia, Switzerland)

Poor location of exhibit space that no one passed through. It should be located where there is foot traffic. (NGO, United States of America)

Exhibit space was small. (Academia, Greece)

It would have been nice to have the exhibits placed in a way where people had to walk through them to get to posters. They were sort of in a corner and out of the way, it felt like this deterred people from walking though. It also would have been nice to have the poster/exhibit sessions during the day to facilitate people staying and walking through and more conversation. Early morning and late evening are difficult times to have people come and have conversations. (Academia, United States of America)

Comments on Books and Bookshop

Thank you for publications on different areas. It is not always possible to carry books, so I appreciate the possibility to able to order online and/or the pdf access. (Independent, South Africa)

These books are highly instructive for the assessment, management and use of medical devices in China, and it is hope strongly to translate into Chinese. (Academia, China)

Outstanding (Industry, Bengladesh)

Excellent idea to have the "bookshop" in the Forum and a catalogue and books are really needed so to be able to download PDF gives access to all books for free, specially in LMIC. (WHO collaborating center, Switzerland)

5.6 4th Global Foum on Medical Devices

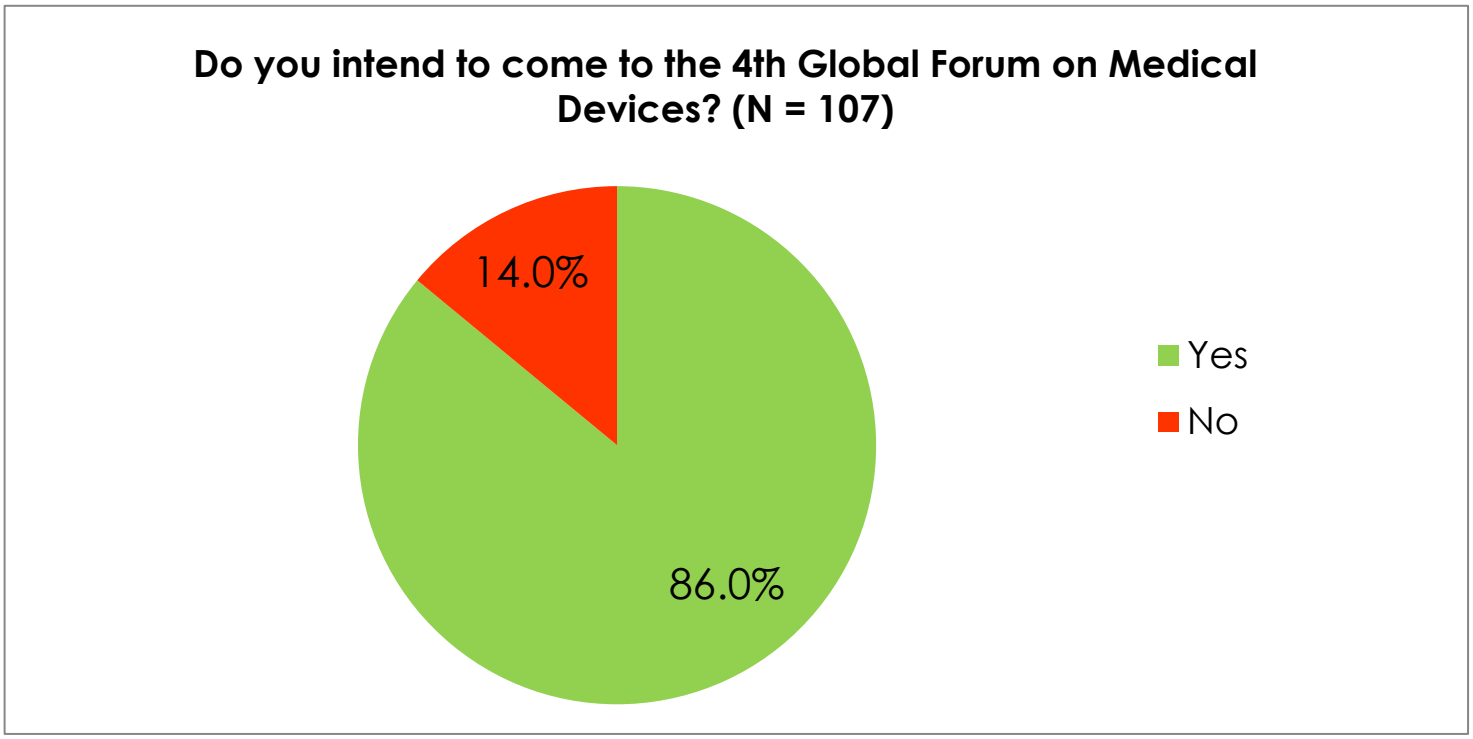

Figure A26. Do you intend to come to the 4th Global Forum on Medical Devices?

Suggestions of topics for the 4th Global Forum on Medical Devices

Impact assessment. If we are all in fact trying to address health inequities or public health problems, I'd like us to talk about how we are all measuring our progress - both with individual projects and as a community. I found that to be a glaring omission. I also think having honest dialogue about that will cut much of the marketing-speak by groups like PATH. (NGO/Civil Society, United States of America)

It was discussed, but inserted in the other topics. Price regulation is a very important issue. (UN/Intergovernmental organization, Brazil)

Decontamination practice for medical devices (Health professional, Malaysia)

The role of laboratory medicine in general and the different professions contributions to diagnostics should be highlighted in coming forums (NGO in official relations with WHO, Sweden)

Suggestions of changes for next forum

More LMIC representation (Government, United Kingdom)

Better organization so that things are geared to a specific objective (I think networking, partnership, and interdisciplinary ommunication are the best objectives). I also think the poster session needs to be improved so that attendance increases and sessions need to be much more interactive (venue selection could also help with this). (Academia, United States of America)

Less sessions, more time for the speakers and proactive break sessions to allow for networking (Industry, Canada)

At least 3 full days of Forum (UN/Intergovernmental organization, India)

The forum could be extended by half a day, so that the last day would not be too long as in previous years (Independent, South Africa)

More time to network. Dedicated table space for poster presentations so we can bring our devices. More interactivity/discussion and less lightning presentations. More engaging presentations with less highly technical text (Academia, United States of America)

More countries from the African region to be involved. Kenya would like to be involved more. (Government, Kenya)

More time to debate and discuss with presenters (NGO/Civil Society, Brazil)

I would watch the parallel section that I did not attend (streaming, web site, or something else). (NGO, Italy)

Interactive electronic platform for Q&A and comments during the presentations by assigning room coordinator that receive audience Q&A and comments during the presentation and select from the submissions to present to the speaker (NGO, United States of America)

Do you intend on attending the 4th Global Forum on medical devices?

I will try to attend. Hopefully by that time, I may have some indicators to share with colleagues on HTM implementation (Health professional, Lebanon)

It would be nice to have the exact dates the soonest possible (Academia, Greece)

Will appreciate if WHO sponsors me to the 4th Global Forum (Government, Kenya)

Depends on availability of funding (NGO, United States of America)

Take participants from organization (Professional association, Japan)

Would better attend to WHO forum for pre-qualification of IVD (Industry, Luxembourg)

I would like to see a citizen as health provider workstream (Health professional, United Kingdom)

Final decision will depend on the agenda (NGO, Switzerland)

WHO has to help undeveloped country people to attend forum (Government, Benin)

Final comments

I cannot thank the organisers enough for all their hard work and dedication. In my view this has been an inspiring conference because they made it happen! I also want to let you know that hearing our colleague speaking to us over the phone all the way from Sierra Leone was a really powerful experience and strong reminder how easy it is to end up in an academic/diplomatic/bureaucratic bubble. Thank you! (Academia, United Kingdom)

Very generous of the WHO to offer this meeting free of charge to all participants! Thank you very much (Government, Sweden)

Excellent activity, the location was accessible and the facilities were nice (Academia, Peru)

Thank you for planning and hosting the conference. I enjoyed the experience! (Industry, United States of America)

It was overall a very good session to discuss further about medical devices globally (Health professional, Malaysia)

We commend the great work done by WHO in arranging this. You have world-class overview and work capacity! I also miss finding the posters and presentations online at WHO.int. This is a bit sad, because I wanted to share the significant information with my colleagues while it is still fresh in my mind. (Industry, Norway)

A wonderful, huge job well done (Health professional, Lebanon)

It was a very interesting conference that has potential to grow much more. (NGO, Sweden)

CONGRATULATIONS!!! Incredible achievement, having the forum and launching 4 books with so minimum resources! Hopefully more funds can be available to bring more participants from low income countries and very important to have available web dissemination live and a tool to make suggestions like 1 and 2GFMD and suggest to use more social media to share ideas, discussions, publications, etc. I would suggest to have translation in the 4GFMD, to help other non-English speakers receive the information. (WHO collaborating center, Switzerland)

I wanted to thank you for the opportunity to take part in this event. The fact that it is free of charge allows also people with low income, such as students or apprentices to participate and gain knowledge. And I think this is very important. The overall organisation was excellent and the staff at the reception desk was friendly and helpful (Industry, Luxembourg)

Great forum, interesting, and with a wide range of topics surrounding medical devices (NGO/Civil Society, Syrian Arab Republic)

The forum was well organized, properly coordinated and very educative. One word!! Exceptional. (Government, Kenya)

It was excellent in spite of the limited available time to organise it. Congratulations!! (Academia, Greece)

Overall it was very nice, the few things I mentioned could have made it better for me but I really appreciate all of the work that was put into organizing and planning the event! (Academia, United States of America)

Generally OK, and we appreciate the effort of WHO to organize it despite the lack of funding. We hope Indian government will put some funding to the next forum. However, there is place for improvement (less workshop and presentation, and the one available with more evidence and stronger abstracts). (Foundation/Donor agency, China)

Need for better technical support (upload of presentations/presentation devices, computers...) or more informed chairs/co-chairs in regard to technical aspects of their sessions (presentations), earlier announcement/organization/confirmations for chairs/co-chairs (Health professional, Croatia)

I immensely appreciate the vast scope, following the entire life-cycle of a device, encompassing innovation, regulation, procurement, HTA, HT management, safety, implementation and sustainability and re-use (Government, Sweden)

Appendix 6

List of participants

The list of participants can be found in the following session.

According to the type of organization they belong to.

The total number of participants from each category is shown in Figure A27.

Number of participants per category		Page
Government	96	220-225
UN/Intergovernmental organization	76	226-228
WHO collaborating centers	11	228
NGO in official relations with WHO	50	228-229
Civil society/ NGO	30	229-230
Professional Association	19	230-231
Academia	103	231-234
Foundation/Donor agency	8	234
Health professional	17	234
Consultants	32	235
Independent	18	235-236
Medical device industry	111	236-239
Total	**571**	

Figure A27. Number of participants from each type of organization

6.1. Participants from Government

GOVERNMENT			
Armenia			
Ms. Lala MARGARYANTS	Senior Expert, Medical Device Department	Scientific Center of Drug and Medical Technologies Expertise	lalamarg@yahoo.com
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Bangladesh			
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