World Health Organization

Fourth WHO Global Forum on Medical Devices

REPORT

AMTZ-Kalam Convention Centre, Visakhapatnam, India
13 to 15 December 2018

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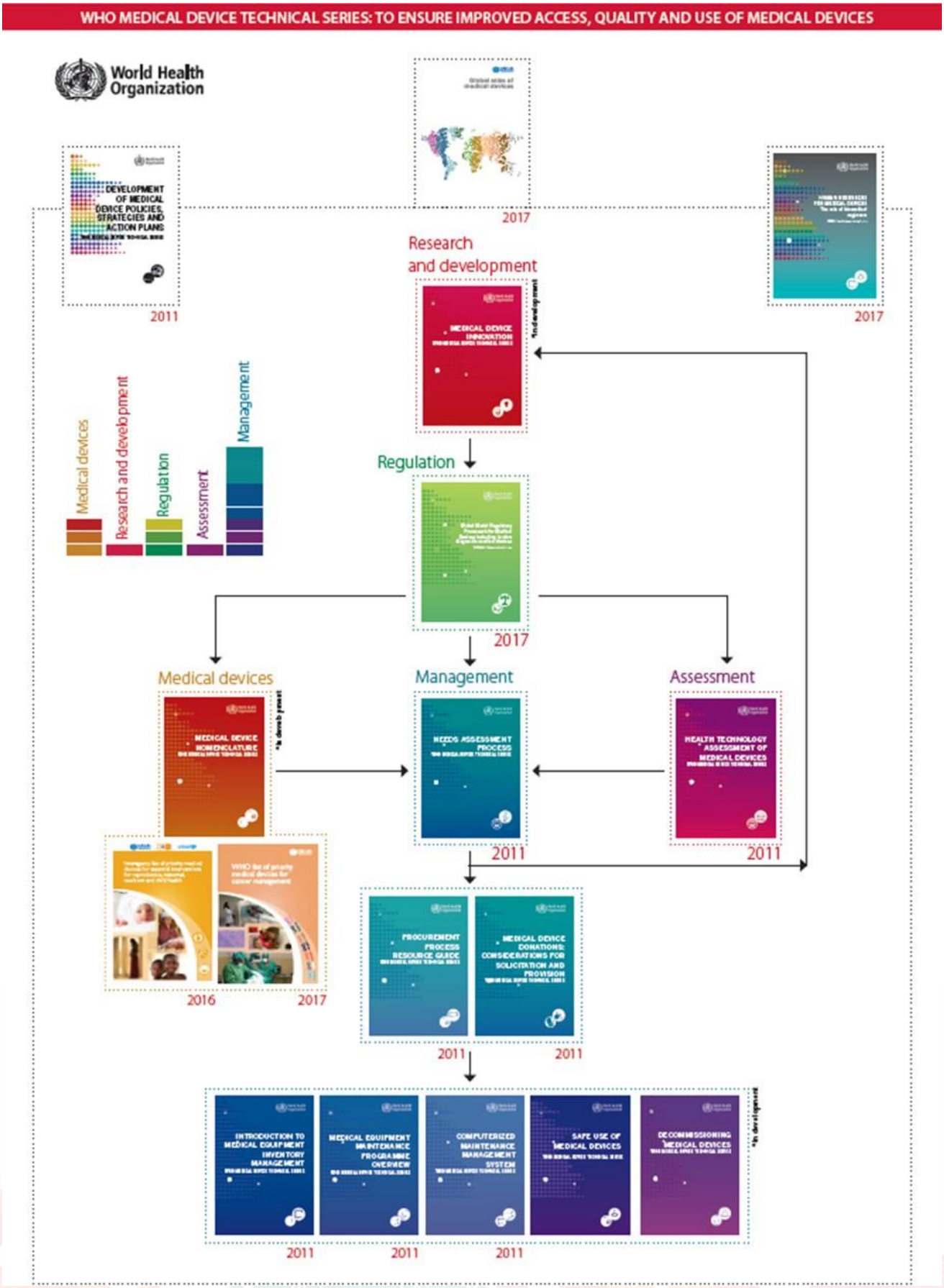
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Acronyms and abbreviations

Organizations

CED	Clinical Engineering Division of IFMBE
GMDN	Global Medical Device Nomenclature
GMTA	Global Medical Technology Alliance
HTAi	Health Technology Assessment International
Humatem	Pour l'appui à l'équipement medical des pays en développement
IAEA	International Atomic Energy Agency
IFBLS	International Federation of Biomedical Laboratory Science
IFMBE	International Federation for Medical and Biological Engineering
IMDRF	International Medical Device Regulators Forum
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& Radiological Technologists
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
UNFPA	United Nations Population Fund
UNICEF	United Nations International Children's Emergency Fund
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

WHA	World Health Assembly
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
CMMS	Computerized Maintenance Management Software
HTA	Health Technology Assessment
HTM	Health Technology Management
ICTs	Information and Communications Technologies
IT	Information Technology
LMIC	Low- and Middle-Income Countries
NCDs	Noncommunicable Diseases
NGO	Nongovernmental Organization
PoC	Point-of-Care
PPE	Personal Protective Equipment
SDG	Sustainable Development Goal
UDI	Unique Device Identification
UHC	Universal Health Coverage

Introduction

Member States recognized in World Health Assembly (WHA) resolutions WHA60.29 (2007) *(1)* and WHA 67.20 (2014) *(2)* that medical devices are indispensable for health-care delivery but that their selection, regulation and use present enormous challenges, especially for low- and middle-income countries (LMIC).

Marking eleven years since the former resolution, the Fourth WHO Global Forum on Medical Devices served as an opportunity to share WHO initiatives to support country needs on the road to Universal Health Coverage (UHC) and the achievement of the Sustainable Development Goals (SDGs).

The Forum also served as an occasion to listen to regional and country activities on medical devices issues. The Forum presented the WHO resources available to Member States in the realm of medical devices nomenclature, innovation, selection and prioritization.

The programme of the Fourth WHO Global Forum included presentations on best practices, challenges and new tools for innovation, regulation, assessment and management of medical devices (including procurement, technical specifications, donations, maintenance and appropriate safe use), as well as lists of priority medical devices for emergencies and cancer diseases, and the work in progress on such lists for primary health care and cardiovascular diseases.

Forum objectives

1. To define methods of increasing and measuring access to essential and priority medical devices under Universal Health Coverage in compliance with the Sustainable Development Goals
2. To share country 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.

Fourth WHO Global Forum on Medical Devices: Context

The First Global Forum on Medical Devices took place in Bangkok, Thailand, in September 2010, with participants coming from 107 Member States *(3)*. The event raised awareness and served as a forum to share ideas on how to increase access to safe and effective medical devices.

The Second Global Forum on Medical Devices held in November 2013 *(4)*, 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 resolution WHA 60.29.

In May 2017, the Third Global Forum on Medical Devices *(5)* considered the achievements that have been made in the field and addressed challenges in LMIC towards UHC within the framework of the SDGs.

The Fourth Global Forum on Medical Devices held in December 2018 *(6)*, addressed a range of needs communicated by Member States. Some of the main topics discussed in the Fourth Forum were the WHO first edition of the Essential In Vitro Diagnostics List (EDL) *(7)*, the first version of the International Classification of Medical Devices (ICMD) *(8)* , plus ongoing work on the selection of priority medical devices (PMD) for cardiovascular and primary health care, oxygen delivery systems and regulatory networks.

The WHO thirteenth general programme of work for 2019-2023 *(9)*, has three interconnected strategic priorities based on the SDGs, and focuses on impact in "triple billion" goals, as follows:

- 1 billion more people benefitting from universal health coverage
- 1 billion more people better protected from health emergencies
- 1 billion more people enjoying better health and well-being.

As medical devices are used to prevent, diagnose, treat, rehabilitate and palliate, they are essential to achieving the three strategic priorities. It is therefore especially important to increase access to affordable, high-quality medical devices that can be used in the context of disease and emergencies, and to maintain health and well-being.

Medical devices in WHO – overview of achievements 2017–2018

Following the Third Global Forum in 2017, WHO has continued to work to promote increased accessibility, affordability and availability of medical devices through publications, country and regional workshops and consultation meetings. The work achieved in the last year, between the third and fourth forums, has resulted in various publications and guidance across the following domains:

- medical device innovation – publication of the 2017 WHO compendium of innovative health technologies for low-resource settings *(10)*, that includes both commercially-available products and prototypes, and publication of the target product profile of Personal Protective Equipment in case of Ebola *(11)*;
- medical device selection – publication of the first WHO Model List of Essential In Vitro Diagnostics (EDL) *(7)*;
- classification and nomenclature of medical devices *(12)*;
- procurement of medical devices;

Ongoing work in the following areas, presented during the forum for input:

- development of technical specifications for oxygen delivery systems (oxygen production, monitoring and delivery), and diagnostics and treatment for precancerous lesions;
- priority medical devices for cardiovascular health, stroke and diabetes; and
- priority medical devices for primary health care.

Fourth WHO Global Forum on Medical Devices: Content

The Fourth WHO Global Forum on Medical Devices was convened from 13–15 December 2018 at the Andhra Pradesh MedTech Zone, Visakhapatnam, India.

Programme overview

In September 2018, 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 Forum. From this pool of abstracts, the committee developed a programme that included six plenary sessions with 18 presentations, 119 parallel oral presentations, 73 posters and 66 workshops. Thus, the content of the programme (see Table 1) was largely formed by submissions from the medical devices community, reflecting its priorities, activities and needs.

The Forum began on 13 December with a plenary welcome session attended by senior officials of WHO and the Government of India, followed by a series of workshops and plenary panels on the donation of medical devices as well as medical device use in non-communicable diseases. The Forum continued over the next two days with plenary and parallel sessions. Each of the main days of the conference consisted of two or three plenary sessions, plus five sessions conducted in parallel in the mornings and afternoons. Over the course of the three days, the active involvement of the participants was essential to addressing the objectives of the Forum.

Table 1. Fourth WHO Global Forum on Medical Devices: the numbers

Type	Number
Registrants	1271
Countries represented	92
Plenary ministerial sessions	3
Plenary sessions	6
Plenary session presentations	18
Parallel oral sessions	26
Parallel oral presentations	119
Poster sessions	7
Workshops	27
Workshop presentations	66
Posters	73
Exhibitions	52

General programme

An overview of the programme is provided in Fig. 1. The detailed programme is provided in Annex 1 and can be found on the WHO Medical Devices website along with all the presentations and posters (http://www.who.int/medical_devices/global_forum/4th_gfmd/en/). The official language for submission of abstracts was English. The AMTZ venue offered a large plenary room, six other meeting rooms to accommodate parallel sessions and workshops, open areas for poster presentations and exhibit spaces.

Fig. 1. Programme Overview

Thursday 13th December 2018			
8:00 – 9:00	Track	Workshops	Meeting room
	W1	Vigilance of medical devices in hospitals	Amravati
	W2	Assessment of medical devices: IFMBE HTA methods	Faraday
	W22	Biomedical engineering	Curie
	W4	National biomedical equipment maintenance program of India	Visakha
	W5	National free diagnostic service initiative in India	NTR plenary hall*
	W7	Methodology for the design of health technologies	Tesla
	W28	Nomenclature and classification of medical devices	Celsius
9:00 – 9:30	**Break**		
09:30 – 11:00	Track	Workshops	
	W8	Management of medical equipment	Celsius
	W9	Real-World data and evidence for medical devices HTA	Tesla
	W10	Open-Source medical devices: safety and reliability	Curie
	W11-W12	WHO Essential Diagnostics List: introduction and towards implementation	Amravati
	W13	Tools and resources for oxygen system planning and procurement	NTR plenary hall*
	W27	Regulation of medical devices	Faraday
	W23	Procurement and safe use of medical imaging and radiotherapy equipment	Visakha
11:00 – 11:30	**Break**		
11:30 – 13:00	WS	Welcome session Auditorium	
		Welcome session of the Fourth WHO Global Forum on Medical Devices	NTR plenary hall*
13:00 – 13:45	**Lunch break**		
13:45 – 14:30	EXP	Exhibit and poster sessions	
14:30 –16:00	Track	Plenary sessions Auditorium	
	PP1	Plenary panel session 1	
		Donations of medical devices: consequences to patients and health workers.	NTR plenary hall*
	PP2	Plenary panel session 2	
		Priority medical devices for non-communicable diseases towards Universal Health coverage	NTR plenary hall*
16:00 – 16:30	**Break**		

16:30 – 18:00	**Track**	Pre-conference workshops	
	W15	Clinical Engineering and information technology best practices	Visakha
	W16	The role of biomedical engineers in HTA	Celsius
	W17	3D printing, AI and design of medical devices for low resource settings	Celsius
	W18 - W19	WHO guidance on procurement and post-market surveillance for in vitro diagnostics (IVDs)	Amravati
	W20	Clinical and technical roll-out of oxygen therapy	NTR plenary *
	W21	Guidance on blood pressure devices	Tesla
	W14	Technologies for cervical cancer	Visakha
	W24	Regulation of medical devices	Curie
	W26	Metrology of medical devices	Curie
18:00	**Break**		
18:10 – 19:00	**W6**	WHO methodology for the selection of priority medical devices for NCDs	Faraday
	W25	BME global capacity building	Visakha
	CM1	Medical devices in African francophone countries	Curie
	CM2	Technical specifications for cervical cancer	Tesla
	CM3	Oxygen supply systems	Celsius

Friday 14 December 2018			
8:00 – 9:00	**Track**	Parallel regional sessions	
	PR1	Africa	NTR HALL
	PR2	Americas	Curie
	PR3	Eastern Mediterranean	Tesla
	PR4	Europe	Faraday
	PR5	South East Asia	Amravati
	PR6	Western Pacific	Celsius
	IN	Medical devices industry	Visakha
9:00 – 9:30	**Break**		
9:30 – 11:00	**OS**	Opening Ministerial session Auditorium	
		Inaugural session of the 4th WHO Global Forum on Medical Devices	
11:00 – 11:30	**Break**		
11:30 – 13:00	**Track**	Plenary sessions Auditorium	
	PP3	Plenary panel session 3	
		Essential in vitro diagnostics, selection and use	
	PP4	Plenary panel session 4	
		Oxygen supply systems, needs and challenges	
13:00 – 13:45	**Lunch break**		

13:45 – 14:30	**EXP**	Exhibit, poster and video sessions	
14:30 – 16:00	**Track**	Parallel oral sessions: Priority and essential medical devices by disease/facility	
	PS2F	Paths to health technology innovation	Curie
	PS16S	Pricing of medical devices	Amravati
	PS4F	Assessment of medical devices for LMIC	Tesla
	PD4F	ehealth	Faraday
	PS6F	Procurement and supply	Celsius
	PS7F	Nomenclature and classification of medical devices	NTR plenary hall
	PS11F	Regulation in South-East Asia	Visakha
16:00 – 16:30	**Break**		
16:30 – 18:00	**Track**	Plenary sessions Auditorium	
	PP5	Plenary panel session 5	
		Classification, coding and Nomenclature of medical devices, challenges and opportunities	NTR plenary hall *
	PP6	Plenary panel session 6	
		Innovation of medical devices, challenges to scale up	NTR plenary hall*
18:00	**Adjourn**		

Saturday 15 December 2018			
8:00 – 9:00	**Track**	Parallel oral sessions: Access to Medical Devices	
	PS1S	Policies on medical devices	NTR plenary hall*
	PS2S	Paths to health technology innovation	Amravati
	PD15S	Biomaterials	Curie
	PD16S	Technologies for dental applications	Tesla
	PS18S	Regulation post market	Visakha
	PS20S	Steps towards the harmonization of EU-Africa regulations	Faraday
9:00 – 9:30	**Break**		
09:30 – 11:00	**PM2**	Plenary Ministerial session Auditorium	
		Access to medical devices	
11:00 – 11:30	**Break**		

11:30 – 13:00	**Track**	Parallel oral sessions: Access to medical Devices	
	PS2S	Innovation	Celsius
	PD17S	Single-use devices	Faraday
	PS4S	Assessment of medical devices	Curie
	PS13S	Health technology management	Visakha
	PS3F	Human resources to manage medical devices	Tesla
	PS19S	Challenges in donations	Faraday
	PS17S	Regulation of medical devices	NTR plenary hall
13:00 – 13:45	**Lunch break**		
13:45 – 14:30	**EXP**	Exhibit, poster and video sessions	
14:30 – 15:30	**Track**	Parallel oral sessions: Priority and essential medical devices by disease/facility	
	PD2S	Oxygen supply systems	NTR plenary hall
	PD9S	Medical imaging for diagnostic and interventional procedures	Amravati
	PD10S	Medical devices for treatments	Visakha
	PD14S	Packages for primary health-care and emergencies	Tesla
	PD12S	Medical devices for non-communicable diseases	Curie
	PD3S	IVDs and laboratory services	Faraday
15:30 – 15:45	**Break**		
15:45 – 16:30	**Track**	Plenary sessions Auditorium	
	PM3	Plenary Ministerial session	NTR Plenary hall
		Conclusions and action plan	
	CS	Closing session	NTR Plenary hall
		Closing Ceremony	
16:30	**Adjourn (16:30)**		

Workshops

The workshops took place on Thursday 13 December. There were 66 presentations presented in the following order, on 27 topics:

- 3D printing, AI and design of medical devices
- Assessment of medical devices: IFMBE HTA methods
- Biomedical engineering
- Biomedical engineering capacity
- Cervical cancer
- Clinical and technical roll-out of oxygen therapy
- Global clinical engineering and IT best practices
- Guidance on blood pressure devices
- Management of medical equipment
- Methodology for the design of health technologies
- Metrology medical devices
- National biomedical equipment maintenance program of India
- National free diagnostic service of India
- Nomenclature and classification of medical devices
- Open-source medical devices: safety and reliability
- Oxygen supply systems
- Procurement and safe use of medical imaging and radiotherapy equipment
- Real-world data and evidence for medical devices HTA
- Regulation of medical devices
- Regulation of medical devices
- Technologies for cervical cancer
- The role of biomedical engineers in HTA
- Tools and resources for oxygen system planning and procurement
- Vigilance on medical devices in hospitals
- WHO In Vitro Essential Diagnostics List: towards implementation
- WHO guidance on procurement and post-market surveillance for IVDs
- WHO methodology for the selection of priority medical devices for NCDs

Representatives from WHO, other UN agencies, nongovernmental organizations (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 Annex 2.

Plenary sessions

Each of the six plenary sessions included brief presentations on a specific topic by experts invited as leaders in their respective fields. For each session, the presentations were followed by questions and comments from Forum participants and further discussion. The plenary session topics included:

- Donations of medical devices, consequences to patients and health workers
- Medical devices for non-communicable diseases
- The WHO Model List of Essential In Vitro Diagnostics (EDL) and its utility around the world
- Increasing access to safe oxygen therapy: country perspectives
- In search of a harmonized nomenclature of medical devices
- Innovation of medical devices, challenges to scale up

Three plenary ministerial sessions took place: the inaugural session, access to medical devices and closing session.

Parallel oral sessions

Taking into consideration the abstracts received, a programme was developed to accommodate country, academia and health-care delivery perspectives. The programme included 119 oral presentations distributed across the 26 tracks of the parallel sessions:

- Assessment of medical devices
- Assessment of medical devices for LMIC
- Biomaterials
- Challenges in donations
- eHealth
- Health technology management
- Human resources to manage medical devices
- Innovation
- IVDs and laboratory services.
- Medical device packages for primary healthcare and emergency response
- Medical devices for non-communicable diseases
- Medical devices for treatments
- Medical imaging for diagnostic and interventional procedures
- Nomenclature
- Oxygen supply systems
- Oxygen supply systems
- Paths to health technology innovation

- Paths to health technology innovation
- Policies on medical devices
- Pricing of medical devices
- Procurement and supply
- Regulation in South-East Asia
- Regulation of medical devices
- Regulation post market
- Single-use devices
- Steps towards the harmonization of EU-Africa regulations
- Technologies for dental application.

Abstracts of the parallel oral presentations can be found in Annex 3.

Posters

The abstracts that were not selected for presentations, or that were submitted for poster presentations were featured on 73 posters organized around 7 themes, namely:

- Assistive devices
- Diagnostics
- e-health
- Health Technology Management (HTM)
- Innovation
- Regulation
- Treatment

Specific times were allotted for poster viewing. There were 3 poster sessions, one per day. Poster abstracts are listed in Annex 4.

Exhibition spaces

There was also an exhibition area for Member States, NGOs and universities. Commercial branding was not allowed. There were 52 exhibitions.

Attendees

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

The total number of registered participants was 1271, from 92 countries and 10 intergovernmental organizations. Attendees represented a variety of organizations, with the largest proportion (37%) from governments or public agencies. The private medical device industry represented 20% of participants, 16% were from academia, and 13% were from non-governmental organizations. The full breakdown of participants by category is shown in Fig. 2.

The attendees came from all six WHO regions, and represented 47% of Member States. Fig. 3 shows the participating Member States per WHO region. Fig. 4 shows the distribution of participants per region. Attendees included participants from high-income countries, but there was a larger representation from LMIC. Annex 6 contains the full list of registered participants of the Forum by category and country.

Fig. 2. Participants by category

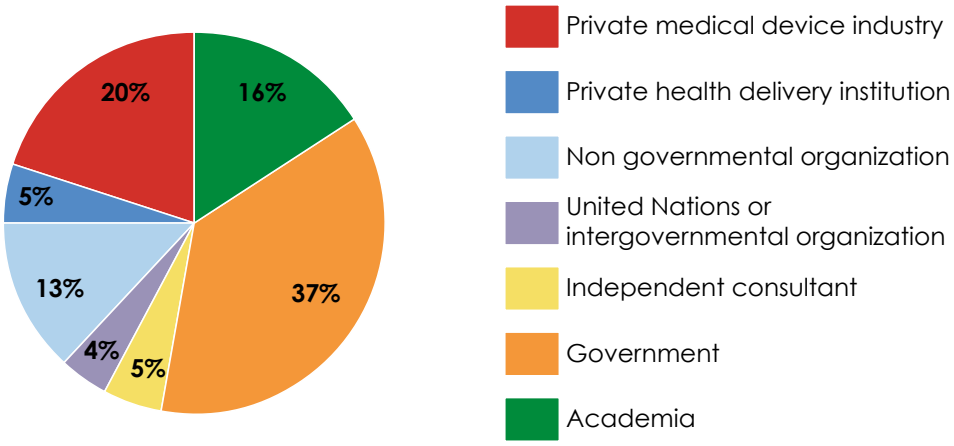


Fig. 3. Participant countries per WHO region

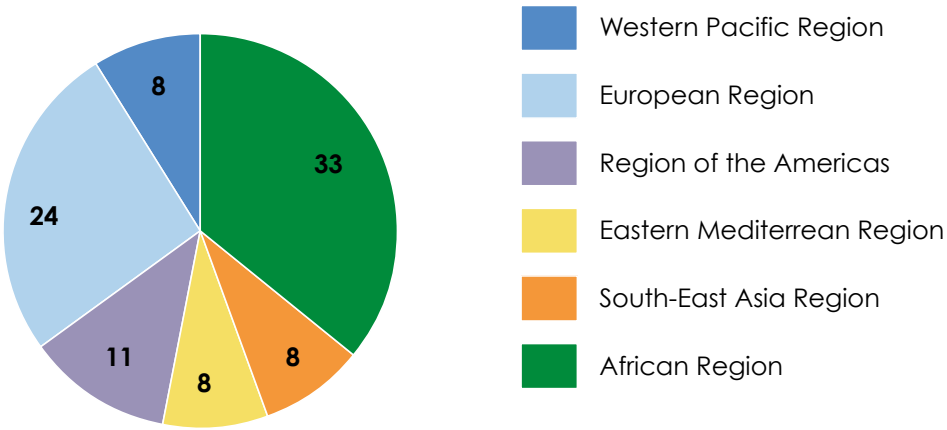
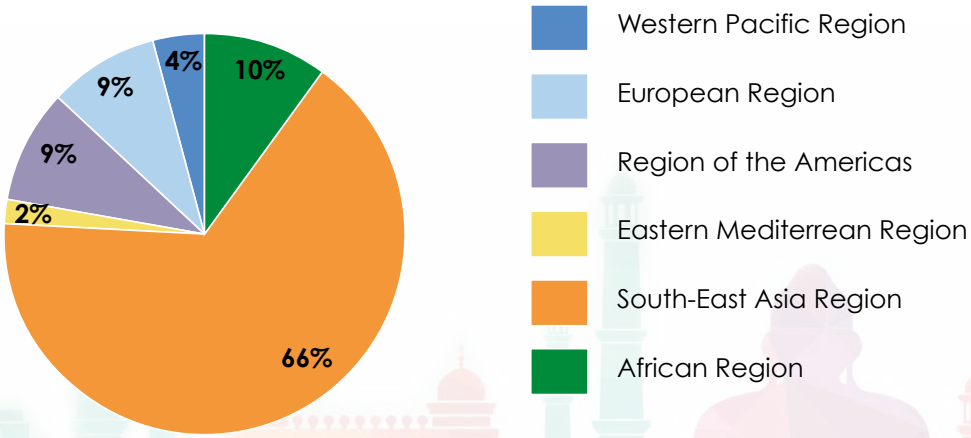


Fig. 4. Participants per WHO region



Fourth WHO Global Forum on Medical Devices: Outcomes

During the Fourth WHO Global Forum, the following planned objectives were met:

1. To define methods of increasing and measuring access to essential and priority medical devices under Universal Health Coverage in compliance with the Sustainable Development Goals;
2. To share country 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; and
4. To share WHO tools and guidelines on medical devices for better implementation.

Participants and presenters exchanged information in the areas of innovation, regulation, selection, assessment and management of medical devices; including procurement, donations, technical specifications, lists and safe use. WHO tools and guidelines were shared.

Participants highlighted an area that needs to be addressed further: the tools for measuring access to priority and essential medical devices. This will be the main objective for the Fifth Global Forum on Medical Devices.

Conclusions

The time available to prepare the Fourth WHO Global Forum on Medical Devices was just three months. However, the high interest and response, in papers submitted and workshops proposed by the medical devices community (academia, governmental bodies and professionals interested in the field), was overwhelming. The support of the local organizing team in Visakhapatnam, along with government officials of India and Andhra Pradesh government, was instrumental in ensuring an event that was smoothly organized and addressed the priorities of the global medical device community.

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

It is a pleasure to report that funding was secured through the generosity and support of various organizations that facilitated the attendance of experts from LMIC. We acknowledge the Ministry of Health and Family Welfare of India and the Andhra Med Tech Zone (AMTZ) for hosting the meeting in a new med tech zone venue. Also, there was participation and virtual attendance of persons from around the globe, made possible through online viewing portals provided by the local organizers.

Every workshop and panel presentation presented issues of great concern for participants and thus the Forum is an invitation to continue working together towards increasing access to medical devices, particularly for those who are most in need – populations in low-resource settings.

As can be seen in Annex 5, the evaluations for each type of session and the Forum overall were positive and reaffirmed that this Forum presents a unique opportunity to receive input from WHO, as well as discuss country concerns and find strategies to move forward in medical devices.

At the closing of the Forum, a statement was made by some NGOs, partners and delegates in attendance, issuing a call to all stakeholders, starting with the authorities from all Member States, to WHO itself and all supporting partners, to urgently allocate the needed additional organizational, financial and human resources to the WHO Medical Devices unit. This call for support is necessary in order for WHO and the medical devices community to face the evolving challenges described in the Forum in a continued and effective way.

n the final session, the Minister of Health and Family Welfare, government of India, suggested that WHO considers forming a Technical Expert or Advisory group to address safety, efficacy and appropriate use of medical devices and to provide guidance on assessment of medical devices including in vitro diagnostics through out their live cycle.

WHO acknowledges everyone who collaborated in the Fourth Global Forum and encourages continued progress in working towards Universal Health Coverage and the SDGs, and looks forward to presenting new outcomes at the Fifth WHO Global Forum on Medical Devices.

Next steps

The Fourth Global Forum presented an opportunity to discuss many topics, five of which stand out as critical issues to focus on in 2019. An additional seven important issues were identified, to be subsequently addressed. By providing support to countries on the following issues, progress can be made on increasing access to appropriate and good quality medical devices, as required for UHC and to implement the SDGs:

Critical issues:

- availability of a global nomenclature, classification and coding of medical devices, that can serve the Unique Device Identification (UDI) system, procurement, regulations and safe use of devices;
- guidance for the implementation of the WHO Essential In Vitro Diagnostics List;
- increased regulation of medical devices in LMIC, particularly for post-market surveillance;
- development of technical specifications for better procurement of priority medical devices;
- continuing development of guidance for oxygen supply systems, especially for pneumonia, surgery, trauma and chronic obstructive pulmonary disease;

Additional issues:

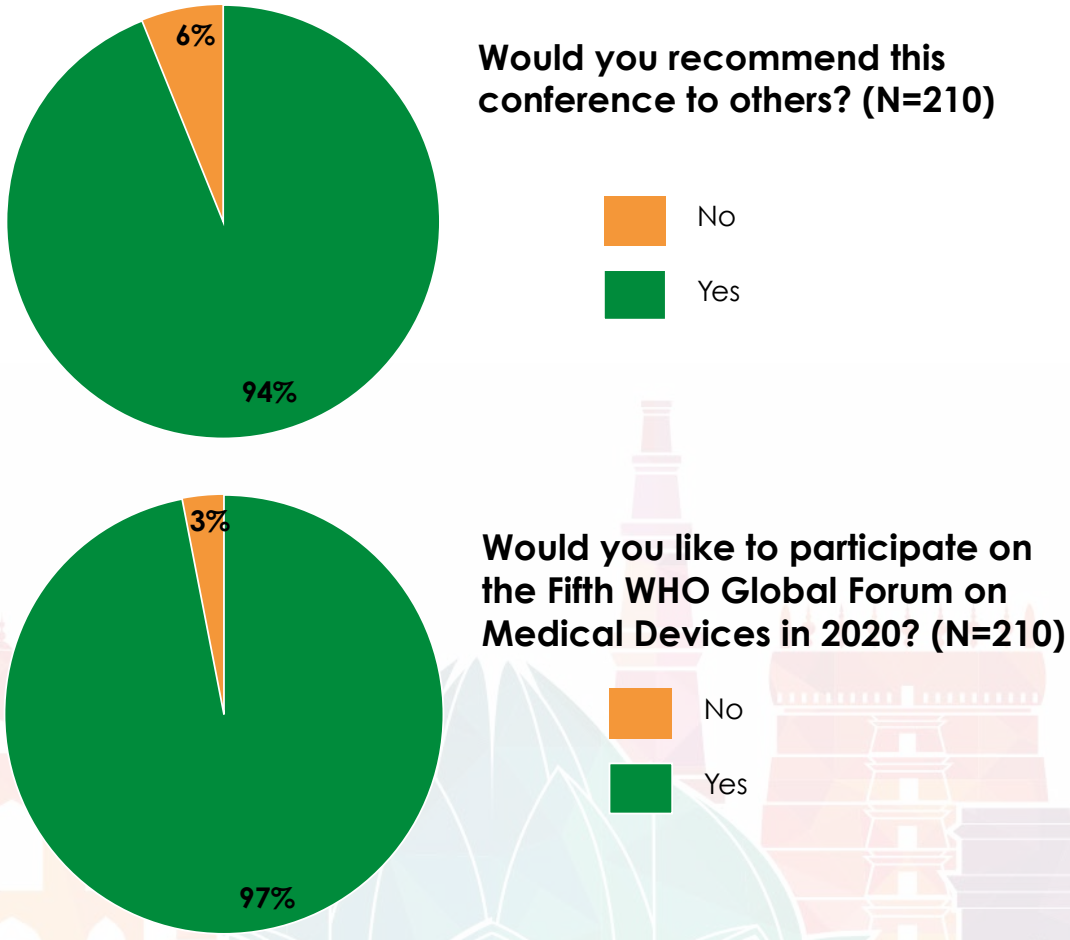
- guidance on decommissioning and disinvestment of medical devices;
- dissemination of list of priority medical devices for primary health care (PHC);
- development of lists of priority medical devices for cardiovascular diseases, diabetes and respiratory diseases;
- information on prices of medical devices;
- medical devices for emergency preparedness and response;
- need for a global web-based clearing house database of medical devices; and
- scaling up innovative medical devices.

Measurement of access to essential and priority medical devices remains a top priority for the Fifth Global Forum.

Evaluation

Following the Forum, an electronic feedback survey was sent to all participants for the evaluation of the plenary sessions, parallel oral sessions, workshops and poster sessions. Fig. 5 provides a visual representation of two very important measures of participant satisfaction. As can be seen, over 97% of participants had the intention to participate in the Fifth WHO Global Forum on Medical Devices; and 94% would recommend the conference to others.

Fig. 5. Participant satisfaction results



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Annex 1: Conference Programme

Workshops

Ref ID	Workshop sessions - Thursday 13th December 2018
Vigilance on medical devices in hospitals	
139	Global health technology regulation issues for clinical engineers
	Thomas Maxwell Judd, Mohammad Ameel, Ajai Basil, Nicolas Pallikarakis, Almir Badnjevic, Tobey Clark
161	Adverse event notification, investigation and regulatory reporting in the United States
	John Tobey Clark
173	Medical Devices post-market surveillance experiences
	Almir Badnjevic, Almir Badnjevic, Nicolas Pallikarakis, Tobey Clark, Mohammad Ameel, Ajai Basil
184	Medical Devices Vigilance: Need for a global approach
	Nicolas Pallikarakis
Assessment of medical devices: IFMBE HTA methods	
142	HTA methods for medical devices: an in-depth dialogue
	Julie Polisena, Murilo Conto, Leandro Pecchia, Oriana Ciani, Nicolas Pallikarakis
Biomedical Engineering	
238	Achieving Sustainable Development Goals in Good Health and Well-being through BME
	Ratko Magjarevic, Shankar Krishnan, Getahun Mehuria, Luis Renjifo Martinez, Tom Judd, Ichiro Sakuma, Paulo de Carvalho
National biomedical equipment maintenance program of India	
201	National biomedical equipment maintenance program of India
	Anjaney Lnu, Shashi Sinha, Ameel Mohammad, Ajai Basil, Akriti Tomar
National free diagnostic service of India	
202	National free diagnostic service initiative
	Anjaney Lnu, Yogita Kumar, Ameel Mohammad, Ajai Basil, Akriti Tomar, Shashi Sinha
Methodology for the design of health technologies	
15	Intelligent design of global heath technologies
	John Langell, Tomasz Petelenz, Shawn Fojtik, Roger Altizer
Nomenclature and classification of medical devices	
248	Towards International Harmonized Nomenclature for Medical Devices
	Adriana Velazquez Berumen, Umberto Vitale, Rebecca Baker, Laura Velez Ruiz Gaitan, Karen Kulp, Daniel Diethei
COFFEE BREAK	

Ref ID	Workshop sessions - Thursday 13th December 2018
Management of medical equipment	
42	Technical Specifications of Medical Devices for Procurement
	Mohammad Ameel, SB Sinha, Ajai Basil, Akriti Chahar, Vigneshwaran, Bharat Dahiya, Ujjwal Kumar
124	HTM best practices from, Fundacion Cardioinfantil-FCI, Colombian hospital, 5th latinamerican best hospital
	Andrea Rocio Garcia Ibarra, Diego Heredia Osorio
140	Clinical engineering-health technology management global best practices
	Thomas Maxwell Judd, Almir Badnjevic, Andrea Garcia, Yadin David, Stefano Bergamasco, Mohammad Ameel, Ashenafi Hussein
170	Role of CE in a changing healthcare. Perspectives of Mediterranean countries
	Stefano Bergamasco, Paolo Lago, Nicolas Pallikarakis, Almir Badnjevic, Mario Medvedec, Ledina Picari, Christophe Parret
175	Management of medical equipment
	Almir Badnjevic, Tom Judd, Andrea Garcia, Stefano Bergamasco, Ashenafi Hussein, Mohammad Ameel
Real-World data and evidence for medical devices HTA	
143	The use of real-world data and evidence for medical devices
	Julie Polisena, Rossella DiBidino, Dinsie Williams, Ernesto Iadanza, Carlo Federici
Open-source medical devices: safety and reliability	
18	UBORA: safety and reliability of innovating open-source medical devices
	Carmelo De Maria, Licia Di Pietro, Arti Ahluwalia
WHO Essential Diagnostics List: towards implementation	
224	The essential diagnostics list, developments to date and plans for the future
	Lucy Anne Hattingh, Adriana Velazquez Berumen, William Sewell, Magdalena Rabini
225	Building access to IVD testing worldwide
	Lucy Anne Hattingh, Adriana Velazquez Berumen, William Sewell, Magdalena Rabini
Tools and resources for oxygen system planning and procurement	
144	Tools and resources for oxygen system planning and procurement
	Michael Andrew Ruffo, Beverly Bradley, Mulugeta Mideksa, Heta Kosonen, Kathryn Geskermann, Lisa Smith
Regulation medical devices	
122	South East Asia Regulatory Network (SEARN) for access to quality, safe and affordable Medical Devices and diagnostics
	Manisha Shridhar, Madhur Gupta, V. Kalaiselvan, Ravikant Sharma, Surinder Singh
Procurement and safe use of medical imaging and radiotherapy equipment	
	The medical physicists' role of embedding safety culture
	Sunil Dutt Sharma

Ref ID	Workshop sessions - Thursday 13th December 2018
	The radiographers' role of embedding safety culture
	Stewart Whitley
	Key aspects of Nuclear Medicine: from procurement to decommissioning.
	Dong Soo Lee
	Safety culture takes a team: multidisciplinary collaborative medical imaging outreach - victories and challenges in LMIC facilities
	Miriam Mikhail
	Q&As, summary and conclusions
	Stewart Whitley
Plenary Sessions and Lunch Break	
Global Clinical Engineering and IT best practices	
141	ICTs in health: global CE-IT best practices
	Thomas Maxwell Judd, Elliot Sloane, Ricardo Silva, Steve Grimes, Shankar Krishnan
The role of biomedical engineers in HTA	
146	The role of biomedical engineers on HTA of medical devices
	Ernesto Ladanza, Leandro Pecchia, Nicolas Pallikarakis, Murilo Conto, Julie Polisena
3D printing, AI and design of medical devices	
187	3D printing, artificial intelligence and design of medical devices for low resource settings
	Leandro Pecchia, Ashenafi Hussein, Almir Badnjevic, Carmelo De Maria
WHO guidance on procurement and post-market surveillance for IVDs	
	How to use WHO guidance for better procurement of in vitro diagnostics (IVDs)
185	Anita Sands, Mercedes Perez Gonzalez
	Post-market surveillance of in vitro diagnostic medical devices (IVDs) for testing providers, IVD manufacturers, and regulators of IVDs
186	Anita Sands, Mercedes Perez Gonzalez
Clinical and technical roll-out of oxygen therapy	
216	Clinical roll-out: oxygen therapy
	Martha Lauren Gartley, Adebayo Bakare
Guidance on blood pressure devices	
220	WHO guidance and specifics on blood pressure devices
	Marc Gregory Jaffe
Technologies for cervical cancer	
45	Cancer technologies for cervical cancer detection, diagnosis, monitoring and treatment in low-resource settings
	Natalie Broutet, Martha Gartley, Cai Long, Ying Lin

Ref ID	Workshop sessions - Thursday 13th December 2018
Regulation of Medical Devices	
	Comparison of European union vs USA regulatory systems for medical devices
	Rodolphe Munoz (via Webex)
Metrology medical devices	
246	The OIML and legal metrology - international harmonisation in the regulation of measuring instruments
	Ian Ronald Dunmill
WHO methodology for the selection of priority medical devices for NCDs	
138	Priority medical devices for cardiovascular, stroke, diabetes, and chronic respiratory disease management
	Karen Kulp, Mar Perez, Adriana Velazquez
Biomedical Engineering Capacity	
240	BME Capacity Building at the Global Level
	Shankar Krishnan, Leandro Pecchia, Martha Zequera Dias, Ernesto Iadanza, Ashenafi Hussein
African francophone countries	
	Follow up to 2017 Senegal workshop on medical devices (in French)
	(closed meeting)
Cervical Cancer	
	Technical specifications for medical devices for Cervical Cancer
	(closed meeting)
Oxygen supply systems	
	Oxygen systems guidance development
	(closed meeting)

Plenary sessions

Thursday 13th December:11:30 - 13:00

Welcome Ministerial Session
Welcome session of the Fourth WHO Global Forum on Medical Devices
Mr Nara Chandrababu Naidu
Honorable Chief Minister, Government of Andhra Pradesh
Mr Ashwini Kumar Choubey
Honorable Minister of State, Health & Family Welfare, Government of India
Mr Nasyam Mohammed Farooq
Honorable Minister (Health), Government of Andhra Pradesh
Dr RK Vats
Additional Secretary and Financial Adviser, Ministry of Health & Family Welfare, Government of India
Dr Poonam Malakondaiah
Special Chief Secretary (Health), Government of Andhra Pradesh
Dr Henk Bekedam
World Health Organization Representative to India
Dr Mandeep Bhandari
Joint Secretary, Ministry of Health and Family Welfare, Government of India
Dr Jitendar Sharma
MD & CEO, Andhra Pradesh MedTech Zone, Government of Andhra Pradesh
Ms Adriana Velazquez
Coordinator Global Forum Medical Devices, World Health Organization
Dr Madhur Gupta
Technical Officer-Pharmaceuticals, World Health Organization Country Office for India
Plenary Panel Session 1
Donations of medical devices, consequences to patients and health workers
Adriana Velazquez
Senior Advisor on Medical Devices, World Health Organization
Daniel Sneddon
Australia
Vikas Meka
Global Health Innovation Consultant, Former Sr. Advisor, USAID
Cathy Blanc-Gonnet
Directrice, Humatem
Pascal Soroheye
Direction des Infrastructures, des Équipments et de la Maintenance, Ministère de la Santé, Bénin

Plenary Panel Session 2
Medical devices for non-communicable diseases
Adriana Velazquez (Chair)
Senior Advisor on Medical Devices, World Health Organization
Dr Babacar Guèye
Spécialiste en Santé Publique, Chef de la Division des Maladies Non Transmissibles, Ministère de la Santé et de L'Action Sociale, Sénégal
Dario Trapani
Consultant to WHO, European Society of Medical Oncology
Dr Nathalie Broutet
Medical Officer, Cervical Cancer, World Health Organization
Dr Marc Jaffe
Senior Vice President, Cardiovascular Health Initiative, Resolve to Save Lives - an Initiative of Vital Strategies
Dr Dong Soo Lee
Professor of Nuclear Medicine, Molecular Medicine and Biopharmaceutical Sciences, Seoul National University, President-elect, WFNMB
Trevor Gun
Chair, International Affairs Committee, MedTech Europe

Friday 14th December: 9:30 - 11:00

Opening Ministerial Session
Inaugural session of the Fourth WHO Global Forum on Medical Devices
Mr Suresh Prabhu
Honorable Union Minister, Commerce & Industry and Civil Aviation, Government of India
Mr Ashwini Kumar Choubey
Honorable Minister of State, Health & Family Welfare, Government of India
Video Address by Dr Tedros Adhanom Ghebreyesus
Director General, World Health Organization
Dr VK Paul
Member, NITI Aayog, Government of India
Dr Balram Bhargava
Secretary, Department of Health Research and Director General, Indian Council of Medical Research, Government of India
Dr RK Vats
Additional Secretary and Financial Adviser, Ministry of Health & Family Welfare, Government of India
Mr Arun Singhal
Additional Secretary, Ministry of Health and Family Welfare, Government of India
Dr Poonam Malakondaiah
Special Chief Secretary (Health), Government of Andhra Pradesh

Mr Rajiv Aggarwal
Joint Secretary, Department of Industrial Policy and Promotion, Government of India
Dr Henk Bekedam
World Health Organization Representative to India
Dr Mandeep Bhandari
Joint Secretary (Regulation) Ministry of Health & Family Welfare, Government of India
Dr Suzanne Hill
Director, Essential Medicines and Health Products, World Health Organization
Dr Jitendar Sharma
MD & CEO, Andhra Pradesh MedTech Zone, Government of Andhra Pradesh
Plenary Panel Session 3
The Essential in vitro Diagnostics List and its Utility Around the World
Dr Sue Hill (Intro)
Director of Essential Medicines and Health Products, WHO
Dr Anita Sands (Co-chair)
Technical Officer, Essential Medicines and Health Products, WHO
Mr Jesus Rueda
Global Medical Technology Alliance, IVD Industry Representative
Prof William Sewell
St Vincent's Clinical School, Faculty of Medicine, UNSW, Sydney, Australia, IVD Laboratory Representative
Dr Kamini Walia
ICMR Epidemiology and Communicable Diseases Division, EDL SAGE IVD member
Dr Valerie Wilson
Caribbean Med Labs Foundation, EDL SAGE IVD member
Ms Bintiomar Tsala
Kenya Medical Laboratory Technicians and Technologists Board
Plenary Panel Session 4
Increasing Access to Safe Oxygen Therapy: Country Perspectives
Audrey Battu (Co-Chair)
Director Essential Medecines, CHAI
Sitra Mulepo
Senior Engineer, Health Infrastructure Division, Ministry of Health, Uganda
Dr Tayo Olaleye
Pneumonia Program Manager, CHAI Nigeria
Dr Phoebe-Anne Mainland
Anaesthesiologist, World Federation of Anaesthesiology

Cheri Reynolds
Director of Program Development, Assist International
Mulugeta Mideksa
Biomedical Engineer, UNICEF/Ethiopia
Martin Owino
Medical Engineer, Ministry of Health, Kenya
Plenary Panel Session 5
In search of a harmonized nomenclature of medical devices
Adriana Velazquez
Senior Advisor on Medical Devices, World Health Organization
Mark Wasmuth
CEO of GMDN
Bayrack Tuncay
Health Expert/ Biomedical Engineer, M.Sc., Turkish Medicines and Medical Devices Agency, Ministry of Health, Turkey
Murillo Conto
IFMBE, Brazil
Salvatore Scalzo (via Webex)
Policy and Legal Officer, European Commission
Robert Jakob (via Webex)
Team Leader, International Classification, World Health Organization
Plenary Pannel Session 6
Innovation of medical devices, challenges to scale up
Adriana Velazquez
Senior advisor on medical devices, WHO
Dr Sudesh Sivarasu
Associate Professor, Head of Biomedical Engineering, Department of Human Biology, University of Cape Town, Medcial School, South Africa
Dr Shanon Kuyper
Senior Manager, Global Health Technologies, Global Good Fund, Intellectual Ventures Laboratory
Carmelo De Maria
Assistant Professor of Bioengineering, University of Pisa, UBORA Project

Saturday 15th 9:30 - 11:00

Ministerial Plenary Session
Access to Medical Devices to achieve SDG 2030 Goals
Mr JP Nadda (Address)
Union Minister, Ministry of Health & Family Welfare, Government of India

Mrs Preeti Sudan
Secretary Health, Ministry of Health & Family Welfare, Government of India
Dr Soumya Swaminathan (Video Address)
Deputy Director General, World Health Organization
Dr Poonam Malakondaiah
Special Chief Secretary (Health), Government of Andhra Pradesh
Mr Arun Singhal
Additional Secretary, Ministry of Health and Family Welfare, Government of India
Dr Henk Bekedam
WHO Representative to India
Dr Mandeep Bhandari
Joint Secretary (Regulation) Ministry of Health & Family Welfare, Government of India
Dr Suzanne Hill
Director, Essential Medicines and Health Products, World Health Organization
Dr Eswara Reddy
Drugs Controller General (India), Ministry of Health and Family Welfare
Dr Madhur Gupta
Technical Officer-Pharmaceuticals, World Health Organization Country Office for India
Ministerial Closing Session
Dr Poonam Malakondaiah
Special Chief Secretary (Health), Government of Andhra Pradesh
Dr Henk Bekedam
World Health Organization Representative to India
Dr Jitendar Sharma
MD & CEO, Andhra Pradesh MedTech Zone, Government of Andhra Pradesh
Dr Mandeep Bhandari
Joint Secretary (Regulation) Ministry of Health & Family Welfare, Government of India
Dr Suzanne Hill
Director, Essential Medicines and Health Products, World Health Organization
Dr Eswara Reddy
Drugs Controller General (India), Ministry of Health and Family Welfare
Ms Adriana Velazquez
Coordinator Global Forum Medical Devices, World Health Organization
Dr Madhur Gupta
Technical Officer-Pharmaceuticals, World Health Organization Country Office for India

Parallel oral sessions

Friday 14th December: 8:00 – 9:00

Parallel sessions
PR1 - Africa
Session chairs: Sheick Oumar Coulibaly and Christophe Rerat
PR2 - Americas
Session chair: Alexandre Lemgruber
PR3 Eastern Mediterranean, PR4 Europe and PR6 Western Pacific
Session chairs: Adriana Velazquez, Alejandra Velez
PR5 - South East Asia
Session chairs: Anjana Bhushan and Manisha Shridhar
IN - Medical Devices Industry

Friday 14th December: 14:30 – 15:30

PS2F - Paths to health technology innovation	
14	Prototyping a global health innovation registry
	Fred Walter Hosea III, Jans Aasman
72	Creating an eco-system for medical device innovation through capacity and capability building
	Joseph Mathew, Sudesh Sivarasu, Thalakkotur Mathew
76	Frugal Biodesign: A systems approach for medical devices innovation
	Sudesh Sivarasu
	Roles of clinical engineers in medical device development based on clinical needs
	Hiroki Igeta
PS16S - Pricing of Medical Devices	
9	Understanding diagnostic pricing & reimbursement: CRC case study
	Vince Salazar Thomas,
33	Medical devices market and Import: India chapter
	Pritam Datta
85	Challenges in prices, access & reimbursement policies on medical devices in Brazil
	Murilo Conto
	The price control of medical devices in India
	Pavan Choudary
	Relieve the financing constraints of medical devices industry in China: from the perspectives of innovative financial tools
	Xuedan Yuan, Shugui Zeng, Qiuping Xie, Zhenhua Mao

PS4F - Assessment of medical devices for LMIC	
3	A clearinghouse for African Health Technologies
	Vince Salazar Thomas
86	Medical devices access in Brazil - different steps using HTA & evidences
	Murilo Conto
	ISPOR international initiatives on the assessment of the value of medical technologies
	Amy Marie Pavlock, Carlo Federici, Oriana Ciani
	Health Technology Assessment in India
	Himanshu Baweja, Madhur Gupta
	Development of consumer engagement protocol in health technology assessment in public health
	Shailendra Singh Bisht, B. R. Shamanna
PD4F - eHealth	
23	Health information - Retrieval, archival, analysis on/through cloud
	Sudheer Kunkunuru, Sandeep Kunkunuru
78	E-Health tools for organisation of anesthesia services
	Philippe Mavoungou
	eHealth: Improving Health services quality & effectiveness in Peru, Chile, US
	Pilar Rossana Rivas Tarazona, Cesar Galindo, Tobey Clark
	Exploring utility of Google for prediction of disease outbreak
	Kamal Kishore, Madhur Verma
	Medical virtualism board: emerging dimension of clinical precision medicine
	Shyama Nagarajan, Amitabh Dutta
	Enhancing prevention of Coronary Heart diseases countrywide through Telediagnosis
	Pedro Galván, Jose Ortellado, Ronald Rivas, Juan Portillo, Julio Mazzoleni, Enrique Hilario
PS6F - Procurement and supply	
35	Pre-dispatch inspection of medical devices for Hospitals
	Sudesh Yadav, Dhirendra Bansal, Shashi Moitra
	Report on evaluation and rationalizing of distribution and utilization of Radiotherapy units in Greece
	Aris Dermitzakis, Silviu Domente, Nicolas Pallikarakis
	Financing supply chains for durable goods under end-user payment uncertainty
	Olumurejiwa Fatunde
	WHO, MSME survey an impetus to boost innovation for medical devices
	Manisha Shridhar, Madhur Gupta
	Health technology assessment of infusion pumps. An experience in Fundación Cardioinfantil-FCI.
	Andrea Rocio Garcia Ibarra, Jairo Bejarano Vergara, Nidia Vanegas, Diego Heredia Osorio, Soraya Almeida, Viviana Guerrero, Juan Rodriguez Rozo

PS7F - Nomenclature	
7	The Global Medical Device Nomenclature (GMDN)
	Mark Wasmuth
12	National implementation on unique device identification for medical devices in Turkey
	Tuncay Bayrak, Recep Uslu, Vemer Kuru
83	Main priorities and a Global Standard on Medical Devices Nomenclature - Latin American & Caribbean summit on HTM Results
	Murilo Conto, Thiago Santos, Fotini Toscas, Rodrigo Silvestre, Akexandre Lemgruber
	Automatic transcoding across different medical device coding and nomenclature systems
	Stefano Bergamasco
	Standardization on medical devices
	Prakash Bachani
	In Search of Harmonized Nomenclature for Medical Devices
	Adriana Velazquez Berumen, Umberto Vitale, Rebecca Lee Baker, Laura Alejandra Velez Ruiz Gaitan, Maurice Page, Karen Kulp, Daniel Diethei
PS11F - Regulation in South-East Asia	
	Leveraging regulatory networks- South East Asia Regulatory Network (SEARN)
	Manisha Shridhar, Madhur Gupta, Eswara Reddy
	Medical devices rules
	Krishanarajan Bangarurajan

Saturday 15th December: 8:00 – 9:00

Parallel sessions	
PS1S - Policies on medical devices	
41	L'accès aux dispositifs médicaux essentiels et prioritaires en RD Congo / Access to essential medical devices and priorities in Congo
	Edison Maombi, Thomas Kataba
	Development and implementation of policies for medical devices: an industry perspective
	Pavan Choudary
	Medical device reforms and the dynamic landscape in India
	Madhur Gupta, Eswara Reddy, Manisha Shridhar
	Kenya: Journey towards optimal medical devices management
	Martha Lauren Gartley, Martin Owino
PS2S - Paths to health technology innovation	
8	New frugal innovation for refugees and migrants
	David Swann, Nathan Jones
91	Translational research & medical device innovation: a clinician's perspective
	Punit Ratnakar Fulzele, Syed Quazi, Abhay Gadhane

	Creating ecosystem for biomedical technology innovations: DBT's initiatives
	Alka Sharma
PD15S - Biomaterials	
25	Medical devices and biofilms: strategies for prevention
	Kundurthy Shasank
29	Tissue-on-demand
	Ranjna Dutta, Aroop Dutta, Achintya Dutta
60	Translational research at intersection of engineering, biology and medicine: an Indian landscape
	Bikramjit Basu
70	Hydroxyapatite-chitosan nanocomposite for orthopedic applications
	Manisha Sharma, Suman Singh, Vijay Meena
PD16S - Technologies for dental applications	
26	Telemedicine in Dentistry
	Kundurthy Shasank
67	Final-impression techniques and materials for making complete and removable partial dentures
	Balendra Pratap Singh, Srinivasan Jayaraman, Balasubramanian Ramanathan, Murukan Pillai, Laura MacDonald, Richard Kirubakaran
	Multipurpose endodontic slab
	Nishi Singh
	Indian burden of orofacial diorders, workforce and policies
	Akhilanand Chaurasia, Mark Drangsholt, Jaisree Thoppay, Alexander Kerr
PS18S - Regulation post market	
69	Role of Kenya medical laboratory technicians & technologists board on implementation of point-of-care technologies (PoCT)
	Bintiomar Bakari Tsala, Abdulatif Samatar, Abel Onyango, Dorcus Abuya
71	Medical devices adverse event monitoring: the story of India
	Preeti Kharb, Madhur Gupta, V. Kalaiselvan
88	Regulatory framework of medical devices and in-vitro diagnostic kits in India
	Ravi Kant Sharma
	The impact of the passive awareness on the implementation and success of materio vigilance program in a medical institute in northern India.
	Dumpala Venkata ravi Kiran, Anil Gupta, Ashok Kumar, Vipin koushal, Navin Pandey
PS20S - Steps towards the harmonization of EU-Africa regulations	
	Harmonising medical device and medical location policies among Africa and Europe
	Leandro Pecchia, Ashenafi Hussein, Nicolas Pallikarakis, Sudesh Sivarasu, Nicola Caputo

Saturday 15th December: 11:30 – 13:00

PS2S – Innovation	
13	Wearable for Good
	David Michael Swann, Jim Reid, Christine Mushwibe, Barry Doyle, Julia Meaton
16	Smart fever screening system for health clearance
	Hiu Fai Siu, Stanley Siu, Richard So
17	Advanced hemodialysis/hemodiafiltration based on real-time individualized cardiometabolic measurements
	Fabiola Margarita Martinez Licona, Joaquin Azpiroz-Leehan, Andreus Morin-Mendoza, Miguel Cadena-Mendez, Emilio Sacriston-Rock, Gerardo Rosas-Andre
20	Transfer of technology of commoditized medical devices
	Luca Passaggio
27	Deployable wide spectrum wound care device
	Aroop Dutta, Achintya Dutta, Ranjna Dutta
	Understanding community healthcare worker adherence to iCCM guidelines when using an ARIDA device and barriers and facilitators to use
	Heta Kosonen, Charlotte Ward Ward, Kevin Baker Baker, Cindy McWhorter McWhorter, Paul LaBarre LaBarre, Hayalnesh Tarekegn Tarekegn, Karin Kyllander
PD17S - Single-use devices	
93	Reprocessing of single use devices (SUD), how to ensure safety and performance?
	Sasikala Devi Thangavelu
	Difficult to prevent reuse of single use devices: need for national policy & regulation
	Ajai Basil
	Integrating the existing infection control program with materio-vigilance program: need of an hour?
	Dumpala Venkata Ravi Kiran, Sunil Kakkar, Vipin Koushal, Manisha Biswal, Anil Gupta, Navin Pandey
PS4S - Assessment of medical devices	
	HTAi, ISPOR, INAHTA, IFMBE, IUPESM and WHO joint panel on HTA of Medical Devices
	Ernesto Iadanza, Amy Pavlock, Julie Polisena, Leandro Pecchia, Adriana Velazquez Berumen
PS13S - Health technology management	
5	Designing a medical equipment database management system
	Kemigisha Priscilla
75	Health technology management in Bhutan
	Tashi Penjore
	Virtual health technology training for Latin America & the Caribbean
	John Tobey Clark
	Health technology innovation, planning & management: improving professionals outputs in Peruvian health sector
	Pilar Rossana Rivas Tarazona, Rosa Villar, Tobey Clark

PS3F - Human resources to manage medical devices	
10	Roles of Clinical Engineer in education
	Hiroki Igeta, Takeshi Ifuku, Jun Yoshioka, Keiko Fukuta, Tomoyuki Nomura, Tadayuki Kawasaki, Takashi Honma
49	Sharing experience on biomedical skills strengthening program in South-Kivu, DRC
	Catherine Blanc-Gonnet Robach, Lieven D'haese
59	Clinical Engineers, a role under the stakeholders' perspective
	Fabiola Margarita Martínez Licona, Francisco Aceves-Aldrete, Herberth Bravo-Hernández, Elliot Vernet-Saavedra
	Recognition of Biomedical Engineers in Public Health facilities in India
	Ajai Basil
	Experiences from an academic program in Clinical Engineering
	Fabiola Martinez-Licona, Martha Ortiz-Posadas
	Clinical engineering certification in the United States
	John Tobey Clark
	Maintenance center - A solution to long-term sustainability of training programs
	Benjin Joshua
PS19S - Challenges in donations	
47	Addressing sustainability challenges in medical device donations
	Vikas Venkata Meka, Bruce Compton, David Barash, Jennifer Farrington, Cynthia Hall, Dale Herzog, Ellen Rafferty
54	Transnational donations of medical devices (in Sierra Leone and Ghana): facilitators of healthcare or white elephants?
	Dinsie Williams, Jillian Kohler, Andrew Howard, Zubin Austin, Yu-Ling Cheng
	Extending the lifespan of donated medical devices
	Stefano Bergamasco, Dinsie Williams, Leandro Pecchia, Ashenafi Hussein
	Designing a sustainable ecosystem for medical equipment
	Asha Susan Varghese
PS17S - Regulation of medical devices	
11	Status of radiological equipment used in Nepal
	Kanchan P. Adhikari
48	Centro Colaborador OPS /OMS Regulaciones Dispositivos medicos; PAHO / WHO Collaborating Center Regulations Medical Devices
	Dulce Maria Martinez Pereira
79	Addressing decade long non-compliance of radiation safety in public health facilities of India
	Ajai Basil, Mohammad Ameel, Vigneshwaran P.S., Anjaney, S.B. Sinha
	Regulation of medical devices in India
	Eswara Reddy Sanapareddy

	Regulation of Medical Devices: Main achievements and challenges in the Region of the Americas
	Alexandre Lemgruber

Saturday 15th December: 14:30 – 15:30

PD2S - Oxygen supply systems	
	Improving appropriate technologies for oxygen delivery through engineering education in Malawi
	Elizabeth Suzanne Asma, Rebecca Richards-Kortum, Maria Oden, Veronica Leautaud, Theresa Mkandawire, Matthew Petney, Brittany Allen
	UNICEF Initiatives to Increase Access To Oxygen Therapy Systems In Low-resource Settings
	Heta Kosonen, Beverly Bradley, Mulugeta Mideksa, Hayalnesh Tarekegn, Cindy McWhorter, Paul LaBarre, Kristoffer Gandrup-Marino
PD9S - Medical imaging for diagnostic and interventional procedures	
62	Improving Medical Imaging Access, in India and Globally: example partnerships, victories, and challenges
	Miriam Mikhail, Melissa Culp
	Test tool for assessing lead equivalence in protective lead apparels
	Roshan Samuel Livingstone, Anna Varghese
	Quantitative assessment of image quality in different digital radiography systems
	Roshan Samuel Livingstone, Benedicta Pearlin
	Meta-analysis on the diagnostics accuracy of different breast cancer screening modalities in low and high risk
	Akriti Chahar, SB Sinha, Mohammad Zoheb, Shashwat Sharma, Mohammad Ameel, Ajai Basil, Anjaney Shahi
	Ultrasound facilities and expertise of health care providers: A primary health care based cross sectional study
	Ashiq Rashid Mir
PD10S - Medical devices for treatments	
44	Peritoneal dialysis for developing countries
	Mohammad Ameel, SB Sinha, Ajai Basil, Anjaney, Vigneshwaran, Bharat Dahiya, Ujjwal Kumar
	Indigenous cobalt - 60 teletherapy technology - 4 years experience
	Arun Chougule
	Towards crucial oral care of long term bed ridden elderly
	Steward Gracian Sam Arjunan
	Pradhan Mantri national dialysis program
	Anjaney Lnu, Shashi Sinha, Ameel Mohammad, Ajai Basil, Akriti Tomar, Vighneshwaran S

PD12S - Medical devices for non-communicable diseases	
	Proposed module for establishment of national cardiovascular database in low and middle-income countries
	Ashrafuzzaman, Monjurul Ahsan, Sakib Abrar Hossain, Nabil Islam
	Medical technology and its role in establishing stroke care services globally: World Stroke Organisation and WHO perspective
	Jeyaraj Durai Pandian, Michael Brainin, Bo Norvving, Werner Hacke, Michel Patrik, Pooja Khatri, Adriana Velazquez Berumen
	Dialysis Outcomes in India: Feasibility of dialysis outcomes data collection in India, preliminary results of the India dialysis outcomes study
	Oommen John, Abhinav Bassi, John Knight, Vivekanand Jha
	Cancer Prioritization tool
	Dario Trapani, Andre Ilbawi
	Towards selection of WHO Priority medical devices list for Cardiovascular, Diabetes and Stroke
	Karen Kulp, Mar Elena, Adriana Velazquez
PD14S - Medical device packages for primary health-care and emergency response	
	Priority Medical Devices for the Primary Level of Care: experience from the Region of the Americas
	Alexandre Lemgruber, Alfonso Rosales, Santiago Hasdeu, Francisco Caccavo
	Health Products for Primary Healthcare
	Adriana Velazquez Berumen
	Standard List of Medical Supplies for WHO Emergency Response
	Laura Alejandra Velez Ruiz Gaitan, Antoine Delaitre, Ian Norton
	Integrated approach on HTA, Incorporation and Management of Medical Devices
	Alexandre Lemgruber
PD3S - IVDs and laboratory services	
2	Assessing optimal infectious diarrhea PoC diagnostic tests
	Vince Salazar Thomas
43	Point-of-care diagnostics for primary care
	Mohammad Ameel, Rajani Ved, SB SInha, Ajai Basil, Anjaney Shahi, Madhur Gupta, Yogita Kumar
55	National road-map on utilization of multi-disease point-of-care testing platform for HIV, TB and HPV testing in Kenya
	Dorcus Awuor Abuya, Nancy Bowen, Bintiomar Tsala, George Githuka, Richard Njoroge
	Development of the Essential Diagnostics List (EDL) for India
	Madhur Gupta, Vandana Kumar
	Building consensus for creating a National Essential Diagnostics List: Indian experience

Posters

Poster session - Thursday 13 December 2018
Diagnostics
Poster session - Friday 14 December 2018
HTM
Innovation
Poster session - Saturday 15 December 2018
Assistive devices
E-health
Treatment
Regulation

Exhibitions

Thursday 13th December 2018	
Country	Organization
Nepal	National Academy of Medical Sciences, Bir Hospital, Kathmandu, Nepal
India	Andhra Pradesh Medtech Zone (AMTZ)
Cuba	CC Centro de Control Estatal de Medicamentos, Equipos y dispositivos medicos CECMED
Turkey	Turkish Medicines and Medical Devices Agency
Nigeria	AGBOYI - KETU Local Government Area
Guinea-Bissau	Ministry of Health
Ethiopa	Jhpiego/FMHACA
Demorcratic Republic of Congo	Health Ministry / Direction de la pharmacie et du medicament
Libya	Ministry of Health
Angola	DNME/ Ministry of Health
Kenya	Ministry of Health
Malaysia	Medical Device Authority
Bosnia and Herzegovina	Medical Devices Verification Laboratory Verlab
Mali	Direction de la Pharmacie et du Medicament
Ghana	Ghana Health Service
Uzbekistan	Agency on Development of the Pharmaceutical Industry Ministry of Health
Paraguay	Ministry of Public Health and Welfare

Friday 14th December 2018	
Country	Organization
Benin	Department of Pharmacy, Drug and Diagnostic Exploration (DPMED)
Indonesia	Delhi Pharmaceuticals Science and Reseach Institute
Sri Lanka	Biomedical Engineering services
Senegal	Ministry of Health
Sudan	Nmsf
India	National Health Systems Resource Centre
Mexico	Latin American Regional Council of Biomedical Engineering
Greece	INBIT
India	PATH
India	World Stroke Organisation
Australia	World Federation of Societies of Anaesthesiologists
United Kingdom	International Society of Radiographers and Radiological Technologists
Croatia	International Federation for Medical and Biological Engineering - IFMBE
France	HUMATEM
Ethiopia	Clinton Health Access Intiative
Singapore	Global Medical Technology Alliance
United Arab Emirates	Mecomed Middle East and Africa
Belgium	Medecins Sans Vacances

Friday 14th December 2018	
Country	Organization
Malaysia	ECRI Institute
United States	Assist International
United States	Save the Children US
Mexico	Mexican Society of Biomedical Engineering
Denmark	UNICEF
Uzbekistan	GIZ/CIM
India	IPE Global / USAID
Switzerland	World Health Organization
Timor Leste	Ministry of Health, Timor-Leste
South Korea	MFDS (Ministry of Food and Drug Safety)
Ecuador	Yachay Tech University
Bangladesh	Military Institute of Science and Technology
Liberia	Liberia Medicines and Health Products Regulatory Authority (LMHRA)
Malta	Malta Medicines Authority
Brazil	IEB-UFSC-Biomedical Engineering Institute-Federal University of Santa Catarina
United States	University of Vermont, Technical Services Partnership
Nepal	Department of Health Services

Annex 2: Workshops

Workshops: Title and author(s)

Workshop session 1: 13 December 2018	
W1	**Vigilance on medical devices in hospitals**
139	Global health technology regulation issues for clinical engineers
	Mr Mohammad Ameel, Mr Ajai Basil, Dr Nicolas Pallikarakis, Dr Almir Badnjevic, Mr Tobey Clark, Thomas Maxwell Judd
161	Adverse event notification, investigation and regulatory reporting in the United States
	Mr John Clark
173	Medical devices post-market surveillance experiences
	Prof Almir Badnjevic, Prof Nicolas Pallikarakis, Prof Tobey Clark, Mr Mohammad Ameel, Mr Ajai Basil
184	Medical devices vigilance: need for a global approach
	Prof Nicolas Pallikarakis
W2	**Assessment of medical devices: IFMBE HTA methods**
142	The International Federation of Medical and Biological Engineering (IFMBE) Recommendations for HTA Methods Guidelines for Medical Devices: An In-Depth Dialogue
	Mr Murilo Conto, Dr Leandro Pecchia, Dr Oriana Ciani, Dr Nicolas Pallikarakis, Julie Polisena
W22	**Biomedical Engineering**
238	Achieving sustainable development goals in good health and well-being through BME
	Prof Shankar Krishnan, Dr Getahun Mehuria, Prof Luis Renjifo Martinez, Mr Tom Judd, Prof Ichiro Sakuma, Prof Paulo de Carvalho, Ratko Magjarevic
W4	**National biomedical equipment maintenance program of India**
201	National biomedical equipment maintenance program of India
	Mr Shashi Sinha, Mr Ameel Mohammad, Mr Ajai Basil, Mrs Akriti Tomar, Anjaney Lnu
W5	**National free diagnostic service of India**
202	National free diagnostic service initiative
	Mrs Yogita Kumar, Mr Ameel Mohammad, Mr Ajai Basil, Mrs Akriti Tomar, Mr Shashi Sinha, Anjaney Lnu
W7	**Methodology for the design of heath technologies**
15	Intelligent design of global heath technologies
	Dr Tomasz Petelenz, Mr Shawn Fojtik, Prof Roger Altizer, John Langell
W28	**Nomenclature and classification of medical devices**
248	In search of an international harmonized nomenclature for medical devices
	Mrs Adriana Velazquez Berumen, Mr Umberto Vitale, Mrs Rebecca Baker, Ms Laura Velez Ruiz Gaitan, Mrs Karen Kulp, Mr Daniel Diethei
W8	**Management of medical equipment**
42	Technical specifications of medical devices for procurement
	Mr SB Sinha, Mr Ajai Basil, Mr Akriti Chahar, Mr Vigneshwaran, Mr Bharat Dahiya, Mr Ujjwal Kumar, Mohammad Ameel

124	HTM best practices from fundacion cardioinfantil-fci colombian hospital, 5th Latinamerican best hospital.
	Mr Diego Heredia Osorio, Mrs Almeida, Andrea Rocio Garcia Ibarra
140	Clinical engineering-health technology management global best practices
	Dr Almir Badnjevic, Ms Andrea Garcia, Dr Yadin David, Mr Stefano Bergamasco, Mr Mohammad Ameel, Mr Ashenafi Hussein, Thomas Maxwell Judd
170	Role of CE in a changing healthcare. perspectives of Mediterranean countries
	Dr Paolo Lago, Prof Nicolas Pallikarakis, Prof Almir Badnjevic, Dr Mario Medvedec, Dr Ledina Picari, Dr Christophe Parret, Stefano Bergamasco
175	Management of medical equipment
	Prof Almir Badnjevic, Prof Tom Judd, Ms Andrea Garcia, Mr Stefano Bergamasco, Mr Ashenafi Hussein, Mr Mohammad Ameel
W9	**Real World data and evidence for medical devices HTA**
143	The use of real-world data and evidence for medical devices
	Dr Rossella DiBidino, Dr Dinsie Williams, Dr Ernesto Iadanza, Mr Carlo Federici, Julie Polisena
W10	**Open-source medical devices: safety and reliability**
18	UBORA: safety and reliability of open-source medical devices
	Dr Carmelo De Maria, Dr Licia Di Pietro, Prof Arti Ahluwalia
W11-12	**WHO Essential Diagnostics List: towards implementation**
224	The Essential Diagnostics List, developments to date and plans for the future
	Mrs Adriana Velazquez-Berumen, Prof Francis Moussy, Prof William Sewell, Ms Lucy Hattingh
225	Building access to IVD testing worldwide
	Mrs Adriana Velazquez-Berumen, Prof Francis Moussy, Prof William Sewell, Ms Lucy Hattingh
W13	**Tools and resources for oxygen system planning and procurement**
144	Tools and resources for oxygen system planning and procurement
	Dr Bev Bradley, Mr Mulugeta Mideksa, Ms Heta Kosonen, Ms Kathryn Geskermann, Ms Lisa Smith, Michael Andrew Ruffo
W27	**Regulation medical devices**
122	Leveraging regulatory networks - South East Asia Regulatory Network (SEARN) for access to quality, safe and affordable medical devices and diagnostics
	Dr Madhur Gupta, Dr V Kalaiselvan, Dr Ravi Kant Sharma, Dr Surinder Singh, Manisha Shridhar
W23	**Procurement and safe use of medical devices and radiotherapy equipment**
	General Introduction
	Mr Stewart Whitley
	The medical physicists' role of embedding safety culture
	Sunil Dutt Sharma
	The radiographers' role of embedding safety culture
	Stewart Whitley
	Key aspects of Nuclear Medicine: from procurement to decommissioning.
	Dong Soo Lee
	Safety culture takes a team: multidisciplinary collaborative medical imaging outreach - victories and challenges in LMIC facilities
	Miriam Mikhail

	Q&As, summary and conclusions
	Stewart Whitley
W15	**Global clinical engineering and IT best practices**
141	ICTs in Health: global CE-IT best practices
	Dr Elliot Sloane, Dr Ricardo Silva, Mr Steve Grimes, Prof Shankar Krishnan, Thomas Maxwell Judd
W16	**The role of biomedical engineers in HTA**
146	The Health Technology Assessment Division (HTAD) of the International Federation for Medical and Biological Engineering (IFMBE): the crucial role of biomedical engineers
	Prof Leandro Pecchia, Prof Nicolas Pallikarakis, Dr Murilo Conte, Dr Julie Polisena, Ernesto Iadanza
W17	**3D printing, artificial intelligence and design of medical devies for low resource settings**
187	3D printing, artificial intelligence and design of medical devices for low resource settings
	Dr Leandro Pecchia, Dr Ashenafi Hussein, Dr Almir Badnjevic, Dr Carmelo De Maria
W18-19	**WHO guidance on procurement and post market surveillance for IVDs**
185	How to use WHO guidance for better procurement of in vitro diagnostics (IVDs)
	Ms Anita Sands, Ms Mercedes Perez Gonzalez
186	Post-market surveillance of in vitro diagnostic medical devices (IVDs) for testing providers, IVD manufacturers, and regulators of IVDs
	Ms Anita Sands, Ms Mercedes Perez Gonzalez
W20	**Clinical and technical roll out of oxygen therapy**
216	Clinical roll-out: oxygen therapy
	Dr Adebayo Bakare, Martha Lauren Gartley
W21	**Guidance on blood pressure devices**
220	WHO guidance and specifics on blood pressure devices
	Marc Gregory Jaffe
W14	**Technology for cervical cancer**
45	Affordable cancer technologies for cervical cancer detection, diagnosis, monitoring and treatment in low-resource settings
	Dr Edward Trimble, Paul Charles Pearlman
W24	**Regulation of medical devices**
252	Comparison of European Union vs USA regulatory system for medical device
	Rodolphe Munoz (via webex)
W26	**Metrology medical devices**
246	The OIML and legal metrology - international harmonisation in the regulation of measuring instruments
	Ian Ronald Dunmill
W6	**WHO methodology for the selection of priority medical devices for NCDs**
138	Priority medical devices for cardiovascular, stroke, diabetes and chronic respiratory disease management
	Karen Kulp, Mar Perez, Adriana Velazquez
W25	**Biomedical engineering capacity**
239	BME Capacity Building at the Global Level
	Prof Shankar Krishnan, Prof Leandro Pecchia, Prof Martha Zequera Dias, Prof Ernesto Iadanza, Mr Ashenafi Hussein, Ratko Magjarevic

Workshops: Title, author(s) and abstract

Workshop session 1: 13 December 2018	
W1	**Vigilance on medical devices in hospitals**
139	Global health technology regulation issues for clinical engineers
	Mr Mohammad Ameel, Mr Ajai Basil, Dr Nicolas Pallikarakis, Dr Almir Badnjevic, Mr Tobey Clark, Thomas Maxwell Judd
	This Workshop will address the full spectrum of health technology regulation issues related to Clinical Engineering including: 1.Mohammad Ameel, Ajai Basil from India MOHFW regarding Health Technology Policy andRegulation Challenges (eg radiation safety and reuse of single use devices); 2.Nicolas Pallikarakis, from Greece and the EU presenting on Medical Devices Vigilance: Need for a global approach; 3.Almir Badnjevic from Bosnia & Herzegovina regarding Medical Devices Post-market surveillance experiences; and 4.Tobey Clark, from the USA University of Vermont WHO Collaborating Center giving USA FDA perspectives on Adverse event notification, investigation and regulatory reporting.
161	Adverse event notification, investigation and regulatory reporting in the United States
	Mr John Clark
	In the United States, deaths from healthcare errors which is a primary cause of adverse events is estimated to be nearly 100,000 per year. Medical devices are involved in 13% of all types of healthcare adverse events. In addition, there are high patient care and litigation costs associated with adverse events. The Safe Medical Devices Act was established requiring mandatory reporting by healthcare facilities, manufacturers, importers, and distributors for device related incidents that caused serious injury or death. The workshop presentation will review the regulatory requirements, hospital systems for adverse event notification, investigation and reporting, and the clinical engineering role.
173	Medical devices post-market surveillance experiences
	Prof Almir Badnjevic, Prof Nicolas Pallikarakis, Prof Tobey Clark, Mr Mohammad Ameel, Mr Ajai Basil
	Worldwide countries have recognized the importance of regulating assessment of medical devices (MD) that are already in use in healthcare institutions through Legal Metrology Framework. MDs that have been introduced into the legal metrology system include both diagnostic and therapeutic devices. Standardized procedures of post-market safety and performance assessment have been developed with precisely defined units of measurement for each type of MDs, their ranges and allowed output error ranges. Specific phantoms were calibrated with traceability to SI units. In this way, traceability of medical measurements, was established. This resulted with increased efficiency of diagnosis and treatments for the patients.
184	Medical devices vigilance: need for a global approach
	Prof Nicolas Pallikarakis
	Most countries have adopted medical device (MD) vigilance systems, through their market regulatory framework. Therefore, users and/or manufacturers are enforced to report to health authorities any adverse event involving MD. Thousands of user reports are submitted yearly to the health authorities worldwide. Some of them lead to corrective actions and recalls that should be implemented to avoid reoccurrence. Additionally, this huge amount of data can be used for analysis resulting to critical findings for MD technology improvement. It is therefore important to harmonise worldwide the user reporting systems and following the example of the US/FDA, provide free access on this information, in order to facilitate such studies.

W2	**Assessment of medical devices: IFMBE HTA methods**
142	The International Federation of Medical and Biological Engineering (IFMBE) Recommendations for HTA Methods Guidelines for Medical Devices: An In-Depth Dialogue
	Mr Murilo Conto, Dr Leandro Pecchia, Dr Oriana Ciani, Dr Nicolas Pallikarakis, Julie Polisena
	Objectives: In 2018, the IFMBE published recommendations to address the perceived gaps in the HTA methods guidelines for medical devices. Methods: A decision-maker will share CONITECs experiences with HTA used to adopt health technologies in the Brazilian public health system; a biomedical engineer will present the biomedical engineers role in health technology management; a HTA producer will highlight how human factors engineering can impact medical device performance; and a medical physicist will discuss the relevance of a more integrated approach in medical device assessments. Lessons learnt: A broader scope in HTA provides an important opportunity to increase its impact.
W22	**Biomedical Engineering**
238	Achieving sustainable development goals in good health and well-being through BME
	Prof Shankar Krishnan, Dr Getahun Mehuria, Prof Luis Renjifo Martinez, Mr Tom Judd, Prof Ichiro Sakuma, Prof Paulo de Carvalho, Ratko Magjarevic
	The workshop will enable information sharing across multidisciplinary teams and present the viewpoints of stakeholders and experts from different regions through their presentations and panel discussion. International Federation for Medical and Biological Engineering (IFMBE) aims to encourage research and the application of knowledge generated by researchers in biomedical engineering, to disseminate information and promote collaboration at global level in order to ensure health and promote well-being by applying the developed and emerging medical devices, technologies and ICT -based tools.
W4	**National biomedical equipment maintenance program of India**
201	National biomedical equipment maintenance program of India
	Mr Shashi Sinha, Mr Ameel Mohammad, Mr Ajai Basil, Mrs Akriti Tomar, Anjaney Lnu
	Biomedical Equipment Maintenance Program: Biomedical Equipment Maintenance Program is a comprehensive maintenance program for medical equipment supported by Government of India. Based on best practices, it was felt that outsourcing of medical equipment maintenance with payment linked to uptime of equipment would improve time bound delivery of maintenance service. The comprehensive program including provision of toll free number for equipment fault registration, preventive and corrective maintenance, supply of spares, providing for trained engineering human resource and training of users on equipment, the comprehensive equipment maintenance program could be the ideal solution when correctly operationalised. Under this program, 29 States/UTs have completed inventory mapping of equipment/ machineries and displayed the same in public domain. Pursuant to dissemination of operational guidelines for Biomedical Equipment Maintenance Program; 20 States have awarded outsourcing contracts, 6 states are providing services through in-house mechanism and 6 states have released the RFP and are under evaluation, other states are at the stage of RFP finalisation. The program ensures 95% upkeep time for all the medical equipment in public health Systems and ensures each detail to be available on a dashboard.

W5	**National free diagnostic service of India**
202	National free diagnostic service initiative

Mrs Yogita Kumar, Mr Ameel Mohammad, Mr Ajai Basil, Mrs Akriti Tomar, Mr Shashi Sinha, Anjaney Lnu

Free diagnostic initiative has been rolled in order to leverage existing institutional structures. It aims at the provision of a set of free essential quality diagnostics service at each level, which have been identified and are being provided free of cost. Such diagnostic tests are to be provided through a strengthened public health system that provides comprehensive primary and secondary care diagnostic services to patients, from the sub-center to the level of the district hospitals. Identification of technological pathways and setting up of systems for capturing, transmission and reporting of radiological tests that could be digitized

W7	**Methodology for the design of health technologies**
15	Intelligent design of global heath technologies

Dr Tomasz Petelenz, Mr Shawn Fojtik, Prof Roger Altizer, John Langell

The design of global medical technology solutions requires a integrated approach to device design and development. 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 and aligning these with a comprehensive regulatory strategy 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 are optimized to regional healthcare delivery constraints. Using our Design-Box approach we have created and launched new global device solutions for laparoscopic surgery, cervical cancer prevention, non-invasive anemia monitoring, vital sign monitoring and the treatment of postpartum hemorrhage among others.

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.

W28	**Nomenclature and classification of medical devices**
248	In search of an international harmonized nomenclature for medical devices

Mrs Adriana Velazquez Berumen, Mr Umberto Vitale, Mrs Rebecca Baker, Ms Laura Velez Ruiz Gaitan, Mrs Karen Kulp, Mr Daniel Diethei

An international, harmonised and freely available nomenclature system of Medical Devices is a requirement for standardising and improving the access to healthcare, at all levels. WHO envisions a unique system, capable of linking regulations, manufacturing, procurement, supply, management and use. WHO is developing a pilot project, based on the ICD-11 ontological database platform. The workshop will provide an overview of the concept strategy and of ICD-11 structure and potential, and will be interactive for promoting discussion. WHO Operations, Supply and Logistics department will share their experiences with the list of priority medical devices and how the nomenclature gap impacts them.

W8	Management of medical equipment
42	Technical specifications of medical devices for procurement
	Mr SB Sinha, Mr Ajai Basil, Mr Akriti Chahar, Mr Vigneshwaran, Mr Bharat Dahiya, Mr Ujjwal Kumar, Mohammad Ameel
	In states there is significant need for counselling regarding minimum specifications and requirements that should be considered before starting a process of purchase of medical devices. In this regard we have a set of 168 approved medical device specifications to support states. The approved specifications are in a process to be submitted on Government E marketplace (GEM) portal to streamline procurement of medical devices. Gem is the national public procurement portal; an end to end online market place for central and state government. Specifications of following domains are available: Laboratory and Radiology Ambulances Neonatal & Pediatric ICU Skill Laboratories Operation Theater
124	HTM best practices from fundacion cardioinfantil-fci colombian hospital, 5th Latinamerican best hospital.
	Mr Diego Heredia Osorio, Mrs Almeida, Andrea Rocio Garcia Ibarra
	FCI is JCI hospital certified. In 2018, the ranking of America economic magazine positioned FCI as the 5th best hospital in Latin-America. Clinical engineer department is a strategic FCI area. Our HTM practices which aim to ensure access to appropriate medical equipment, to correct use and proper management of them. Our HTM cycle begins understanding our needs and ends by safely and efficiently decommissioning. We want to share HTM practices: evaluation and multicriterial analysis, accepting testing, training and education, maintenance and calibration, surveillance, further, joint efforts to achieve a future with safe medical equipment, accessible and available in the world.
140	Clinical engineering-health technology management global best practices
	Dr Almir Badnjevic, Ms Andrea Garcia, Dr Yadin David, Mr Stefano Bergamasco, Mr Mohammad Ameel, Mr Ashenafi Hussein, Thomas Maxwell Judd
	Facilitator: Tom Judd, Chair, IFMBE CED Board; suggested Workshop format: 1.Almir Badnjevic - Bosnia & Herzegovina: Management of Medical Equipment in Eastern Europe 2.Andrea Garcia - Colombia/COLCINC: HTM best practices from Fundacion Cardioinfantil 3.Tom Judd, Yadin David (remote) - USA/CED: Using Global Clinical Engineering Success Stories with MOHs 4.Stefano Bergamasco - USA/ACCE: Role of CE in a changing healthcare; perspectives of Mediterranean countries 5.MohammadAmeel, Ajai Basil - India/MOHFW: Technical Specifications of Medical Devices for Procurement 6.Ashenafi Hussein - Ethiopia/AfricaWG: HTM and Africa
170	Role of CE in a changing healthcare. perspectives of Mediterranean countries
	Dr Paolo Lago, Prof Nicolas Pallikarakis, Prof Almir Badnjevic, Dr Mario Medvedec, Dr Ledina Picari, Dr Christophe Parret, Stefano Bergamasco

Problem: With new challenges and new shared regulations, European Union countries need more strict collaboration to share best practices and help each other in health technology management. Method: The I Forum of Clinical Engineering in the Mediterranean was organized in 2018 and gathered together representatives from 8 Mediterranean countries, either EU members or candidate EU members. Conclusions: A final statement has been produced with a list of points that emerged as the most important for effective and safe health technology management. The participants want to share these with the global clinical engineering community, the healthcare authorities and the public.

175 Management of medical equipment

Prof Almir Badnjevic, Prof Tom Judd, Ms Andrea Garcia, Mr Stefano Bergamasco, Mr Ashenafi Hussein, Mr Mohammad Ameel

Management of Medical Equipment in each healthcare institution needs to have a plan. This plan must defines the mechanisms for interaction and oversight of the medical equipment used in the diagnosis, treatment and monitoring of patients. The related policies and procedures govern activities from selection and acquisition to incoming inspection and maintenance of medical equipment. The mission of this workshop performed by CED IFMBE representatives is to ensure that equipment used in patient care is safe, available, accurate and affordable.

W9 Real World data and evidence for medical devices HTA

143 The use of real-world data and evidence for medical devices

Dr Rossella DiBidino, Dr Dinsie Williams, Dr Ernesto Iadanza, Mr Carlo Federici, Julie Polisena

Objectives: Real-world data and evidence(RWD/RWE) can inform the medical device lifecycle that more closely reflects real-world clinical settings.
Methods: A hospital representative will discuss RWD/RWE for effective and efficient hospital management; a researcher will present on the use of RWD/RWE for hospital procurement decisions; a clinical engineer will describe the application of sentiment analysis for data mining in web sources; and a health economist will highlight how RWD/RWE can be used throughout the medical device lifecycle.
Lessons learnt: Continued stakeholder engagement on the collection and use of RWD/RWE can maximize the benefits of their application across the product lifecycle.

W10 Open-source medical devices: safety and reliability

18 UBORA: safety and reliability of open-source medical devices

Dr Carmelo De Maria, Dr Licia Di Pietro, Prof Arti Ahluwalia

UBORA is a user-friendly, versatile, stable e-infrastructures for supporting the collaborative development of open source medical devices, compliant with European Regulation: it is a key resource for global action towards the democratization of medical technology and universal equitable healthcare. UBORA which has been funded by European Union and developed by European and African Universities and their associated technological hubs, allows to identify local clinical needs and constraints, as well as the risk class and relevant standards of the medical devices. Using UBORA, workshop participants will start from a clinical challenge and go through the collaborative development of a medical device.

W11-12	**WHO Essential Diagnostics List: towards implementation**
224	The Essential Diagnostics List, developments to date and plans for the future
	Mrs Adriana Velazquez-Berumen, Prof Francis Moussy, Prof William Sewell, Ms Lucy Hattingh
	The first edition of the Essential Diagnostics List (EDL) was completed by WHO in May 2018. It contains over 60 categories of tests, including general laboratory tests, and specific tests for high burden infectious diseases. The EDL includes tests that can be performed in primary health care facilities, as well as tests that require laboratories. The EDL will be updated each year to cover additional general tests, and tests for an expanded range of infectious diseases and non-communicable diseases. This presentation will present a review of the EDL and the process to assess tests for inclusion in future editions.
225	Building access to IVD testing worldwide
	Mrs Adriana Velazquez-Berumen, Prof Francis Moussy, Prof William Sewell, Ms Lucy Hattingh
	While the Essential Diagnostics List (EDL) provides a list of important tests required at various levels of the health care system, the EDL itself cannot have an impact without an integrated, connected, tiered laboratory system, with qualified laboratory personnel and primary care workers, laboratory infrastructure, and effective regulatory & quality management systems. The EDL acts as a guide for countries to build laboratory capacity and should be adapted to local circumstances and priorities in each country.T his workshop will provide an overview of WHO supporting materials and present the experiences of three countries with very different diagnostics delivery challenges.
W13	**Tools and resources for oxygen system planning and procurement**
144	Tools and resources for oxygen system planning and procurement
	Dr Bev Bradley, Mr Mulugeta Mideksa, Ms Heta Kosonen, Ms Kathryn Geskermann, Ms Lisa Smith, Michael Andrew Ruffo
	In this workshop, PATH and UNICEF will present tools and resources available to support oxygen system planning and procurement. PATH will begin by introducing considerations for appropriate oxygen product mix and selection and approaches to estimate the 'total cost of ownership' of oxygen systems. UNICEF will then present a preview of the technical specifications and guidance being developed with WHO for oxygen therapy products, with an update on oxygen-related products available in the UNICEF Supply Catalogue. Participants will be encouraged to discuss their challenges with oxygen equipment selection and procurement and share other useful resources they have used.
W27	**Regulation medical devices**
122	Leveraging regulatory networks - South East Asia Regulatory Network (SEARN) for access to quality, safe and affordable medical devices and diagnostics
	Dr Madhur Gupta, Dr V Kalaiselvan, Dr Ravi Kant Sharma, Dr Surinder Singh, Manisha Shridhar
	In 2016, 11 Member States of WHO South East Asia Region launched South East Asia Regulatory Network (SEARN) to enhance information sharing, collaboration and convergence of medical products regulatory practices. SEARN is led by Steering Group and five Working Groups including medical device and diagnostics. Even well-resourced authorities are hard-pressed to evaluate new products and enforce regulations. Therefore, it is envisaged SEARN would be instrumental in rapid exchange of information. Proposed workshop is to share best practices and updates on regulatory framework for medical devices and diagnostics including safety monitoring systems and enhancing capacity-building in quality control of diagnostics.

W23	**Procurement and safe use of medical devices and radiotherapy equipment**
	General Introduction
	Mr Stewart Whitley
	Embedding safety culture into the procurement, commissioning, life and use of medical imaging and radiotherapy equipment until eventual replacement/decommissioning. The procurement and commissioning of medical imaging equipment for use in diagnostic radiological procedures and image guided interventional procedures and radiotherapy equipment requires a considerable investment of time and resources to ensure that what is procured is fit for purpose and will meet agreed specification criteria and expectations. The procurement and commissioning of medical imaging equipment for use in diagnostic radiological procedures and image guided interventional procedures and radiotherapy equipment requires a considerable investment of time and resources to ensure that what is procured is fit for purpose and will meet agreed specification criteria and expectations. This workshop is designed to facilitate input from the many types of personnel involved in the procurement and use of the equipotent including representatives of the medical equipment manufacturers, radiologists, radiographers, medical physicists and patient groups.
	The medical physicists' role of embedding safety culture
	Sunil Dutt Sharma
	The radiographers' role of embedding safety culture
	Stewart Whitley
	Key aspects of Nuclear Medicine: from procurement to decommissioning.
	Dong Soo Lee
	Safety culture takes a team: multidisciplinary collaborative medical imaging outreach - victories and challenges in LMIC facilities
	Miriam Mikhail
	Q&As, summary and conclusions
	Stewart Whitley
W15	**Global clinical engineering and IT best practices**
141	ICTs in Health: global CE-IT best practices
	Dr Elliot Sloane, Dr Ricardo Silva, Mr Steve Grimes, Prof Shankar Krishnan, Thomas Maxwell Judd
	Facilitator: Tom Judd, Chair, IFMBE CED Board; suggested Workshop format: 1. Elliot Sloane, Ricardo Silva from USA, and Venezuela, representing IHE to provide a Workshop on Global ICT Best Practices: These concepts are taught by both presenters to graduate students and current industry practitioners, both in the university setting and as part of the CPHIMS certification preparation. These are the basic concepts used by clinical engineers (CE) related to interfacing medical devices with electronic health records, and in various approaches to CE involvement in creating innovative Health IT tools, and various forms of medical devices used in Digital medicine healthcare delivery. 2. Steve Grimes of USA and ACCE will provide USA Cybersecurity Best Practice approaches, and 3. Shankar Krishnan of USA and IFMBE will provide Global Cybersecurity Best Practice approaches.
W16	**The role of biomedical engineers in HTA**
146	The Health Technology Assessment Division (HTAD) of the International Federation for Medical and Biological Engineering (IFMBE): the crucial role of biomedical engineers
	Prof Leandro Pecchia, Prof Nicolas Pallikarakis, Dr Murilo Conto, Dr Julie Polisena, Ernesto Iadanza

Objectives: Biomedical Engineers role in Health Technology Assessment of medical devices is not questionable. A panorama of the activities that IFMBE is performing to foster BMEs role is provided.
Methods: Many experiences from HTAD members will be shown and discussed, illustrating most of the successful projects promoted, from training to guidelines preparation.
Lessons learnt: Creating and empowering worldwide communities of experts and professionals, where the singles can contribute and learn, is a reality. Also, thanks to current information and communication technologies.

W17	**3D printing, artificial intelligence and design of medical devies for low resource settings**
187	3D printing, artificial intelligence and design of medical devices for low resource settings

Dr Leandro Pecchia, Dr Ashenafi Hussein, Dr Almir Badnjevic, Dr Carmelo De Maria

The majority of the global population is diagnosed and treated in low-resource medical settings, yet medical devices are designed to comply with needs, markets and regulations of high-resource countries, which account for 90% of the global market share. Several models are emerging to design, manufacture and service medical devices in low-income countries, leveraging on emerging technologies such as 3D printing, cold welding, Artificial Intelligence and the wide diffusion of smart phones. An overview of those models will be given by:Leandro Pecchia, UK (moderator)-Ashenafi Hussein, Ethiopia-Almir Badnjevic, Bosnia Herzegovina-Carmelo De Maria, Italy

W18-19	**WHO guidance on procurement and post market surveillance for IVDs**
185	How to use WHO guidance for better procurement of in vitro diagnostics (IVDs)

Ms Anita Sands, Ms Mercedes Perez Gonzalez

In 2017, WHO released guidance on procurement of in vitro diagnostics (IVDs) and related laboratory items and equipment. This guidance is intended to support the procurement of quality-assured and well-performing IVDs. It may be used by national authorities, and by procurement agencies that support or conduct procurement of IVDs.
Workshop learning objectives:
1. Key topics for procurement that ares pecific for IVDs (vs. medicines and vaccines)
2. Development of specifications for IVDs
3. Specificity related to procurement of polyvalent analyzers
4. Contracting for instrument-based IVDs.

186	Post-market surveillance of in vitro diagnostic medical devices (IVDs) for testing providers, IVD manufacturers, and regulators of IVDs

Ms Anita Sands, Ms Mercedes Perez Gonzalez

Post-market surveillance of IVDs is the action of detecting, investigating, and acting on of any issue related to safety, quality, or performance of an IVD after it has been placed on the market.
Reportable complaints include:
- false negative test results
- false positive test results
- invalid/unreturnable results
- defective or missing consumables that mean the IVD can't be used.

All complaints should be reported back to the IVD manufacturer for their investigation and corrective action, if needed. As well as to the national regulatory authorities.
Learning outcomes:
1. Understanding of WHO guidance on post-market surveillance of IVDs.
2. How to report complaints for IVDs.

W20	**Clinical and technical roll out of oxygen therapy**
216	Clinical roll-out: oxygen therapy
	Dr Adebayo Bakare, Martha Lauren Gartley
	All health workers should be able to identify the clinical signs indicative of severe illness in children. However, reliance on clinical signs alone commonly results in the failure to detect or misdiagnosisof hypoxemia in children. Even when screening tools are available, use and subsequent treatment is a challenge. This workshop will explore clinical oxygen herapy and necessary screening tools, with a focus on the need to reinforce systematic utilization coupled with consistent patient monitoring. Participants will be encouraged to discuss their challenges scaling up access to safe oxygen therapy, and especially share useful resources.
W21	**Guidance on blood pressure devices**
220	WHO guidance and specifics on blood pressure devices
	Marc Gregory Jaffe
	Hypertension kills more people than any other condition globally and causes significant morbidity. Hypertension can be controlled, but detection and management rely upon accurate blood pressure monitoring devices. The WHO, with input from experts from Resolve to Save Lives, an initiative of Vital Strategies, the University of Alberta, John Hopkins University, and the International Society of Hypertension, is updating the 2005 document Blood Pressure Measurement for Low Resource Settings. The workshop goals are to present preliminary progress, solicit practical country-level input from representatives of hypertension programs, and produce a working draft of the updated guidelines for publication in 2019.
W14	**Technology for cervical cancer**
45	Affordable cancer technologies for cervical cancer detection, diagnosis, monitoring and treatment in low-resource settings
	Dr Edward Trimble, Paul Charles Pearlman
	Scope for Session: A world-wide epidemiologic shift has taken place. While the global community focused on the exemplars, such as the spread of Ebola in several West African countries in 2014 and the rise of other emerging infectious diseases, the drivers of health inequity in the majority of the world are increasingly the more subtle and slow-developing diseases commonly associated with the developed world. Of these chronic diseases, cancer, the "Emperor of all Maladies," poses unique challenges to health systems. It is estimated that nearly two-thirds of the 8.2 million annual cancer deaths in the world occur in low- and middle-income countries (LMICs). Moreover, incidence rates in LMICs are on the rise, accompanied by substantial inequalities in cancer survival. Objectives. Prevention, early detection, and treatment are vital to successful cancer control. However, much of this depends on effective technologies, as many of which are not suitable for use in low resource settings due to expense, dependency on extensive medical infrastructure, or both. This situation warrants translational efforts to develop appropriate technologies that could improve cancer prevention and control in resource-poor settings. Cervical cancer is a natural target for new interventions due to its well understood natural history with clear intervention points and the significant outcomes disparities between HICs and LMICs.

W24	**Regulation of medical devices**
252	Comparison of European Union vs USA regulatory system for medical device

Rodolphe Munoz

The approach towards the regulation of medical devices' sector varies from one State to another. The approach developed by the European Union is unique. It allows the placing on the market of medical devices without direct intervention of a State agency. Independent laboratories (notified bodies) are in charge of controlling the respect by the manufactures of the legal requirements. The aim of the presentation is to give a flavour of the specificities of this system in order to understand the methods and tools developed at the EU level to ensure the safety of patients.

W26	**Metrology medical devices**
246	The OIML and legal metrology - international harmonisation in the regulation of measuring instruments

Ian Ronald Dunmill

The International Organisation of Legal Metrology (OIML) is an inter-governmental body which develops International Recommendations to promote the worldwide harmonisation of technical legislation for regulated measuring instruments. These Recommendations are then implemented by Member States through type approval and verification systems. These ensure consumer protection by establishing an appropriate level of confidence in measurement results. This presentation also demonstrates that metrology is a significant part of an effective Quality Infrastructure, enhancing the quality and safety of goods and services. It is also a critical element in promoting and sustaining economic development, as well as environmental and social well being.

W6	**WHO methodology for the selection of priority medical devices for NCDs**
138	Priority medical devices for cardiovascular, stroke, diabetes and chronic respiratory disease management

Karen Kulp, Mar Perez, Adriana Velazquez

Non-communicable diseases such as cardiovascular, stroke, diabetes, and chronic respiratory diseases have topped global lists of mortality causes for the past fifteen years. Country-level efforts to provide universal healthcare coverage and keep populations health rely on access to safe, affordable, effective medical devices. In addition, countries need to know which medical devices should be prioritized for health interventions at each stage of treatment: from community-level preventative initiatives through diagnosis, treatment, ongoing monitoring, m/health or e/health, rehabilitation, and palliative or end-of-life care. Cross-referencing the diseases and intervention to existing WHO codification systems increases the practicality of the proposed reference publication.

W25	**Biomedical engineering capacity**
239	BME Capacity Building at the Global Level

Prof Shankar Krishnan, Prof Leandro Pecchia, Prof Martha Zequera Dias, Prof Ernesto Iadanza, Mr Ashenafi Hussein, Ratko Magjarevic

The workshop will focus on biomedical talent and capacity building from the perspective of the International Federation for Medical and Biological Engineering (IFMBE). IFMBE is an international non-governmental organization with scientific, technological, literary and educational objectives including capacity building for the development and strengthening of human and institutional resources. The mission of IFMBE is to encourage, support, represent and unify the world-wide Medical and Biological Engineering Community and to promote health and quality of life through advancement of research, development, application and management of technology.

Annex 3: Parallel oral sessions

Parallel oral sessions: Title and author(s)

Parallel oral session 1: 14 December 2018	
PS2F	**Paths to health technology innovation**
14	Prototyping a global health innovation registry
	Mr Jans Aasman, Ph.D., Fred Walter Hosea III
72	Creating an eco-system for medical device innovation through capacity and capability building.
	Dr Joseph Matthew, Dr Sudesh Sivarasu, Prof Thalakkotur Matthew
76	Frugal Biodesign: A systems approach for medical devices innovation
	Dr Sudesh Sivarasu
176	Roles of clinical engineers in medical device development based on clinical needs
	Hiroki Igeta
PS16S	**Pricing of medical devices**
9	Understanding diagnostic pricing and reimbursement: CRC case study
	Vince Salazar Thomas
33	Medical devices market and import: India chapter
	Pritam Datta
85	Challenges in Prices, Access & Reimbursement Policies on Medical Devices in Brazil
	Murilo Conto
108	The price control of medical devices in India
	Pavan Choudary
130	Relieve the financing constraints of medical devices industry in China: from the perspectives of innovative financial tools
	Ms Shugui Zeng, Mrs Qiuping Xie, Mr Zhenhua Mao, Xuedan Yuan
PS4F	**Assessment of medical devices for LMIC**
3	A clearinghouse for African health technologies
	Vince Salazar Thomas
86	Medical Devices Access in Brazil - Diferent Steps using HTA & Evidences
	Murilo Conto
109	ISPOR International Initiatives on the Assessment of the Value of Medical Technologies
	Dr Leandro Pecchia, Dr Julie Polisena, Amy Marie Pavlock
165	Health technology assessment in India
	Himanshu Baweja, Dr Madhur Gupta
193	Development of consumer engagement protocol in health technology assessment in public health
	Prof B R Shamanna, Shailendra Singh Bisht
PD4F	**eHealth**
23	Health Information - Retrieval, Archival, Analysis on/through cloud
	Dr Sudheer Kunkunuru, Mr Sandeep Kunkunuru

78	E-health tools for organisation of anesthesia services
	Dr Philippe Mavoungou
163	Ehealth: Improving Health Services Quality & Effectiveness in Peru, Chile, US
	Pilar Rossana Rivas Tarazona, Prof Cesar Galindo, Prof Tobey Clark
188	Exploring utility of Google for prediction of disease outbreak
	Dr Madhur Verma, Kamal Kishore
189	Medical virtualism board: emerging dimension of clinical precision medicine
	Dr Shyama Nagarajan, Dr Amitabh Dutta
192	Enhancing prevention of coronary heart diseases countrywide through telediagnosis
	Dr Pedro Galvan, Dr Jose Ortellado, Mr Ronald Rivas, Dr Juan Portillo, Dr Julio Mazzoleni, Dr Enrique Hilario
PS6F	**Procurement and supply**
35	Pre-dispatch inspection of medical devices for hospitals
	Ms Sudesh Yadav, Mr Dhirendra Bansal, Ms Shashi Moitra
110	Report on evaluation and rationalizing of distribution and utilization of radiotherapy units in Greece
	Dr Aris Dermitzakis, Mr Silviu Domente, Dr Nicolas Pallikarakis
114	Financing supply chains for durable goods under end-user payment uncertainty
	Ms Olumurejiwa Fatunde
118	WHOs MSME survey an impetus to boost innovation for medical devices
	Dr Manisha Shridhar, Dr Madhur Gupta
125	Health technology assessment of infusion pumps. an experience in fundacin cardioinfantil-fci.
	Andrea Rocio Garcia Ibarra, Mr Jairo Bejarano Vergara, Mrs Nidia Vanegas, Mr Diego Heredia Osorio, Mrs Soraya Almeida, Mrs Viviana Guerrero, Mr Juan Rodriguez Rozo
PS7F	**Nomenclature**
7	The Global Medical Device Nomenclature (GMDN)
	Mark Wasmuth
12	National implementation on unique device identification for medical devices in Turkey
	Mr Recep Uslu, Mr Amer Kuru, Tuncay Bayrak
83	Main priorities and a global standard on medical devices nomenclature - Latin American & Caribbean summit on HTM results
	Mr Murilo Conto, Mr Thiago Santos, Mrs Fotini Toscas, Mr Rodrigo Silvestre, Mr Akexandre Lemgruber
172	Automatic transcoding across different medical device coding and nomenclature systems
	Stefano Bergamasco
210	Standardization on medical devices
	Prakash Bachani
243	In Search of an International Harmonized Nomenclature for Medical Devices
	Mrs Adriana Velazquez Berumen, Mr Umberto Vitale, Mrs Rebecca Baker, Mrs Laura Velez Ruiz Gaitan, Mrs Karen Kulp, Mr Daniel Diethei

PS11F	Regulation in South-East Asia
121	Leveraging regulatory networks- South East Asia Regulatory Network (SEARN)
	Dr Madhur Gupta, Dr Eswara Reddy, Manisha Shridhar
207	Medical devices rules
	Krishanarajan Bangarurajan
Parallel oral session 2: 15 December 2018	
PS1S	Policies on medical devices
41	L'acces aux dispositifs medicaux essentiels et prioritaires en RD Congo
	Dr Thomas Katba, Edison Maombi
107	Development and implementation of policies for medical devices an industry perspective
	Pavan Choudary
119	Medical device reforms and the dynamic landscape in India
	Madhur Gupta, Dr Eswara Reddy, Dr Manisha Shridhar
222	Kenya's journey towards optimal medical devices management
	Matha Lauren Gartley, Mr Martin Owino
PS2S	**Paths to health technology innovation**
8	New frugal innovation for refugees and migrants
	Prof David Swann, Mr Nathan Jones
91	Translational research & medical device innovation: a clinician's perspective.
	Dr Syed Quazi, Dr Abhay Gadhane, Punit Ratnakar Fulzele
228	Creating ecosystem for biomedical technology innovations: DBT's initiatives
	Alka Sharma
PD15S	**Biomaterials**
25	Medical Devices and Biofilms: Strategies for Prevention
	Dr Kundurthy Shasank
29	Tissue-on-demand
	Ranjna Dutta, Dr Aroop Dutta, Mr Achintya Dutta
60	Translational research at intersection of engineering, biology and medicine: an Indian landscape
	Bikramjit Basu
70	Hydroxyapatite-chitosan nanocomposite for orthopedic applications
	Manisha Sharma, Dr Suman Singh, Mr Vijay Meena
PD16S	**Technologies for dental applications**
26	Telemedicine in Dentistry
	Dr Kundurthy Shasank
67	Final-impression techniques and materials for making complete and removable partial dentures
	Balendra Pratap Singh, Dr Srinivasan Jayaraman, Dr Balasubramanian Ramanathan, Dr Murukan Pillai, Mrs Laura MacDonald, Mr Richard Kirubakaran
127	Multipurpose endodontic slab
	Dr Nishi Singh, Prof Balendra Singh

131	Indian burden of orofacial diorders, workforce and policies
	Akhilanand Chaurasia, Dr Mark Drangsholt, Dr Jaisree Thoppay, Dr Alexander Kerr
PS18S	**Regulation post market**
69	Role of Kenya medical laboratory technicians & technologists board on implementation of point-of-care technologies.
	Mr Abdulatif Samatar, Mr Abel Onyango, Ms Dorcus Abuya, Bintiomar Bakari Tsala
71	Medical devices adverse event monitoring: The story of India
	Pretti Karb Dr Madhur Gupta, Dr V Kalaiselvan
88	Regulatory framework of medical devices and in-vitro diagnostic kits in India
	Ravi Kant Sharma
183	The impact of the passive awareness on the implementation and success of materio vigilance program in a medical institute in northern India.
	Prof Anil Gupta, Prof Ashok Kumar, Prof Vipin Koushal, Dr Navin Pandey, Dumpala Venkata Ravi Kiran
PS20S	**Steps towards the harmonization of EU-Africa regulations**
182	Harmonising medical device and medical location policies among Africa and Europe
	Dr Leandro Pecchia, Dr Ashenafi Hussein, Prof Nicolas Pallikarakis, Mr Nicola Caputo
PS2S	**Innovation**
13	Wearable for good
	David Michael Swann, Dr Jim Reid, Prof Christine Mushwibe, Prof Barry Doyle, Dr Julia Meaton
16	Smart fever screening system for health clearance
	Hiu Fai Siu, Mr Stanley Siu, Prof Richard So
17	Advanced hemodialysis/hemodiafiltration based on real-time individualized cardiometabolic measurements
	Dr Joaquin Azpiroz-Leehan, Mr Andrs Morn-Mendoza, Dr Miguel Cadena-Mendez, Dr Emilio Sacristn-Rock, Mr Gerardo Rosas-Andreu
20	Transfer of technology of commoditized medical devices
	Luca Passaggio
27	Self deployable wide spectrum wound care device
	Dr Aroop Dutta, Mr Achintya Dutta, Dr Ranjna Dutta
154	Understanding community healthcare worker adherence to iCCM guidelines when using an ARIDA device and barriers and facilitators to use
	Heta Kosonen, Mrs Charlotte Ward, Mr Kevin Baker Baker, Mrs Cindy Mcwhorter Mcwhorter, Mr Paul Labarre, Dr Hayalnesh Tarekegn, Mrs Karin Kãlander
PD17S	**Single use devices**
93	Reprocessing of single use devices (SUD), how to ensure safety and performance?
	Mrs Sasikala Thangavelu
111	Difficult to prevent reuse of single use devices, need for national policy & regulation.
	Ajai Basil
178	Integrating the existing infection control program with materio-vigilance program: need of an hour?
	Dumpala Venkata Ravi Kiran, Dr Sunil Kakkar, Prof Vipin Koushal, Dr Manisha Biswal, Dr Anil Gupta, Dr Navin Pandey

PS4S	Assessment of medical devices
232	HTAi, ISPOR, InHTA, IFMBE, IUPESM and WHO join panel on HTA of medical devices
	Dr Amy Pavlock, Dr Julie Polisena, Prof Ernesto Iadanza, Prof Leandro Pecchia, Dr Adriana Velazquez Berumen
PS13S	**Health technology management**
5	Designing a medical equipment database management system
	Priscilla Kemigisha
75	Health technology management in Bhutan
	Tashi Penjore
160	Virtual health technology training for Latin America & the Caribbean
	Mr John Clark
162	Health technology innovation, planning & management: improving professionals outputs in Peruvian health sector
	Pilar Rossana Rivas Tarazona, Mrs Rosa Villar, Prof Tobey Clark
PS3F	**Human resources to manage medical devices**
10	Roles of Clinical Engineer in Education
	Hiroki Igeta, Mr Takeshi Ifuku, Mr Jun Yoshioka, Ms Keiko Fukuta, Mr Tomoyuki Nomura, Mr Tadayuki Kawasaki, Mr Takashi Honma
49	Sharing experience on biomedic al skills strengthening program in South Kivu-DRC
	Catherine Blanc-Gonnet Robach, Mr Lieven D'haese
59	Clinical Engineers role under the stakeholders' perspective
	Fabiola Margarita Martinez Licona, Mr Francisco Aceves-Aldrete, Mr Herberth Bravo-Hernandez, Mr Elliot Vernet-Saavedra
112	Non-recognition of biomedical engineers in public health facilities in India
	Ajai Basil
126	Experiences from an academic program in clinical engineering
	Prof Fabiola Martinez-Licona, Dr Martha Ortiz-Posadas
159	Clinical engineering certification in the United States
	Mr John Clark
221	Maintenance center - a solution to long-term sustainability of training programs
	Benjin Joshua
PS19S	**Challenges in donations**
47	Addressing sustainability challenges in medical device donations
	Vikas Venkata Meka, Mr Bruce Compton, Dr David Barash, Ms Jennifer Farrington, Ms Cynthia Hall, Mr Dale Herzog, Ms Ellen Rafferty
54	Transnational donations of medical devices (in Sierra Leone and Ghana): facilitators of healthcare or white elephants?
	Dr Dinsie Williams, Dr Jillian Kohler, Dr Andrew Howard, Dr Zubin Austin, Dr Yu-Ling Cheng
171	Extending the lifespan of donated medical devices
	Stefano Bergamasco, Dr Dinsie Williams, Prof Leandro Pecchia, Dr Ashenafi Hussein
212	Designing a sustainable ecosystem for medical equipment
	Asha Susan Varghese

PS17S	**Regulation of medical devices**
11	Status of radiological equipment used in Nepal.
	Kanchan P. Adhikari
48	Centro colaborador OPS/OMS regulaciones dispositivos medicos
	Dulce Maria Martinez Pereira
79	Addressing decade long non-compliance of radiation safety in public health facilities of India
	Ajai Basil, Mr Mohammad Ameel, Mr Vigneshwaran PS, Mr Anjaney, Mr SB Sinha
208	Regulation of emdical devies in India
	Eswara Reddy Sanapareddy
244	Regulation of medical devices in the Americas: achievements and challenges
	Mr Alexandre Lemgruber
PD2S	**Oxygen supply systems**
113	Improving appropriate technologies for oxygen delivery through engineering education in Malawi
	Elizabeth Suzanne Asma, Prof Rebecca Richards-Kortum, Prof Maria Oden, Prof Veronica Leautaud, Prof Theresa Mkandawire, Mr Matthew Petney, Ms Brittany Allen
128	UNICEF initiatives to increase access to oxygen therapy systems in low-resource settings
	Heta Kosonen, Dr Beverly Bradley, Mr Mulugeta Mideksa, Dr Hayalnesh Tarekegn, Mrs Cindy Mcwhorter, Mr Paul Labarre, Mr Kristoffer Gandrup-Marino
PD9S	**Medical imaging for diagnostic and interventional procedures**
62	Improving medical imaging access, in India and globally: example partnerships, victories, and challenges
	Dr Miriam Mikhail, Mrs Melissa Culp
134	Test tool for assessing lead equivalence in protective lead apparels
	Roshan Samuel Livingstone, Mrs Anna Varghese
135	Quantitative assessment of image quality in different digital radiography systems
	Ms Benedicta Pearlin, Roshan Samuel Livingstone
145	Meta-analysis on the diagnostics accuracy of different breast cancer screening modalities in low and high risk of breast cancer.
	Akriti Chaha, Mr SB Sinha, Mr Mohammad Zoheb, Mr Shashwat Sharma, Mr Mohammad Ameel, Mr Ajai Basil, Mr Anjaney Shahi
219	Ultrasound facilities and expertise of health care providers in far flung, hard to reach district of kashmir: a primary health care based cross sectional study
	Ashiq Rashid Mir
PD10S	**Medical devices for treatments**
44	Peritoneal dialysis for developing countries
	Mohammad Ameel, Mr Sb Sinha, Mr Ajai Basil, Mr Anjaney, Mr Vigneshwaran, Mr Bharat Dahiya, Mr Ujjwal Kumar
129	Indigenous cobalt-60 teletherapy technology- 4 years experience
	Prof Arun Chougule
136	Towards crucial oral care of long term bed ridden elderly
	Steward Gracian, Sam Arjunan

204	Pradhan mantri national dialysis program
	Anjaney Lnu, Mr Shashi Sinha, Mr Ameel Mohammad, Mr Ajai Basil, Mrs Akriti Tomar, Mr Vighneshwaran S
PD12S	**Medical devices for non-communicable diseases**
153	Proposed module for establishment of national cardiovascular database in low middle-income countries
	Md Ashrafuzzaman, Mr Monjurul Ahsan, Mr Md. Sakib Abrar Hossain, Mr Nabil Islam
200	Medical technology and its role in establishing stroke care services globally: World Stroke Organisation and WHO perspective
	Jeyaraj Durai Pandian, Prof Michael Brainin, Prof Bo Norvving, Prof Werner Hacke, Dr Michel Patrik, Dr Pooja Khatri, Ms Adriana Velazquez-Berumen
240	Dialysis outcomes in India: feasibility of dialysis outcomes data collection in India preliminary results of the India dialysis outcomes study
	Oommen John, Mr Abhinav Bassi, Prof John Knight, Prof Vivekanand Jha
242	Cancer prioritization tool
	Dr Dario Trapani
138	Priority medical devices for cardiovascular, stroke, diabetes, and chronic respiratory disease management
	Karen Kulp, Mrs Mar Perez
PD14S	**Medical device packages for the primary health care and emergency response**
245	Priority medical devices for the primary level of care: experience from the Region of the Americas
	Mr Alexandre Lemgruber, Mr Alfonso Rosales, Mr Santiago Hasdeu, Mr Francisco Caccavo
247	Standard list of medical supplies for WHO emergency response
	Laura Alejandra Velez Ruiz Gaitan, Mr Antoine Delaitre, Dr Ian Norton
PD3S	**IVDs and laboratory services**
2	Assessing optimal infectious diarrhea PoC diagnostic tests
	Vince Salazar Thomas
43	Point-of-care diagnostics for primary care
	Mohammad Ameel, Dr Rajani Ved, Mr SB SInha, Mr Ajai Basil, Mr Anjaney Shahi, Dr Madhur Gupta, Dr Yogita Kumar
55	National road-map on utilization of multi-disease point-of-care testing platform for HIV, TB and HPV testing in Kenya
	Dorcus Awuor Abuya, Ms Nancy Bowen, Ms Bintiomar Tsala, Dr George Githuka, Dr Richard Njoroge
120	Development of the Essential Diagnostics List (EDL) for India
	Madhur Gupta, Dr Vandana Kumar, Dr Sonam Vijay, Dr Sandhya Kabra, Dr Kamini Walia
209	Building consensus for creating a national essential diagnostics list: Indian experience
	Sonam Vijay, Madhur Gupta, Sandhya Kabra, Kamini Walia

Parallel oral sessions: Title, author(s) and abstract

Parallel oral session 1: 14 December 2018	
PS2F	**Paths to health technology innovation**
14	Prototyping a global health innovation registry
	Mr Jans Aasman Ph.D., Fred Walter Hosea III Currently, the fragmentation, complexity and interdependency of innovations in healthcare creates costly uncertainty, inefficiency and clinical risk for investors, regulators, insurers, government planners, health professionals, and care delivery organizations. Successful healthcare innovations must incorporate multi-disciplinary and multi-stakeholder expertise across the entire lifecycle of the innovation and the systems they interact with. Currently, no single global informational and organizational resource exists to promote such successful innovations at the design stage. We propose creating a Global Health Innovation Registry, using semantic web data science, to promote convergence among innovators worldwide through multidiscipinary team collaborations and designs based on system-lifecycle expertise.
72	Creating an eco-system for medical device innovation through capacity and capability building.
	Dr Joseph Matthew, Dr Sudesh Sivarasu, Prof Thalakkotur Matthew Despite immense diversity, developing countries share commonchallenges in the field of medical device innovation. In particular, there islack of a clear pathway to channel novel ideas of individual innovators throughthe successive stages (Technology Readiness Levels TRLs] of innovation, leading to production of clinically usable technologies. This panel sessionwill highlight challenges to medical device innovation in developing countriesand propose appropriate way forward through individual capacity building, institutional capability building and organizational eco-system building. Concomitant development of each of these prongs is essential to realize thegoal of producing useable devices that are safe, efficacious, and affordable.
76	Frugal Biodesign: A systems approach for medical devices innovation
	Dr Sudesh Sivarasu Understanding the local context is vital not only for the research and development of appropriate medical technology but also for ensuring that the knowledge and skills associated with R&D are sustainably transferred and commercialized in a way which further uplifts the plight of those who need it most in developing countries, these communities often consist of smaller demographic groups which have been further disempowered or disadvantaged through cultural and societal structures groups such as women, young scientists or young entrepreneurs.The novel 'Frugal Biodesign' approach meets the need for affordable, high-quality, context-appropriate MedTech in developing countries, by innovators and potential entrepreneurs within these countries (examples of which are showcased). This in turn promotes new knowledge advancement through cross-cutting research which will contribute to developing the capacity for innovation and the translation of research to innovation.
176	Roles of clinical engineers in medical device development based on clinical needs
	Hiroki Igeta Collaboration projects on medical device development between medicine and industry have been gathering public attention in Japan. Japan Association for Clinical Engineers also established a “clinical-industrial-academic collaboration committee” in 2016. At Aso Iizuka Hospital, there is an office called Innovation Promotion Office (IPO) which specialises in medical device development based on clinical needs. IPO and its staff, including clinical engineers, work as a bridge between the hospital and manufacturers. IPO has also started a programme called “iizuka medicolabo” which provides manufacturers with an environment for the observation of clinical sites in hospitals in the Iizuka region to support their developments.

	Pricing of medical devices
9	Understanding diagnostic pricing and reimbursement: CRC case study
	Vince Salazar Thomas Despite a range of CRC screening programs in use across the world, current screening methods have several drawbacks. Moreover, there is a distinct lack of compliance with these tests. There is a need for a non-invasive, less unpleasant, more sensitive and more specific CRC screening method. The development of new approaches and the variation in costs of the different approaches and their position within formal guidelines and recommendations poses additional challenges. Optimising the value proposition, as well as identifying the appropriate price represent core insights necessary to successful commercialisation. This study details considerations in developing and pricing a new diagnostic.
33	Medical devices market and import: India chapter
	Pritam Datta Key objective ofthis research is to estimate size of the market for medical devices in India and its dependence on import. This study uses twodatabases on Domestic Production and International trade provided by Central StatisticalOrganisation and Ministry of Commerce & Industry, Government of India.These two databases are harmonised at product level following methodology UN-statisticaldivision for the period from 2010-11 to 2013-14. Indian market for medicaldevices has grown from 2.7 to 4 billion US$ during the study period, wheredomestic production contributes only 30% of this market. Indian industry is improving its coverageamong sophisticated medical devices (e.g. apparatus based on the use of X-raysor alpha, beta or gamma radiations in recent years).
85	Challenges in Prices, Access & Reimbursement Policies on Medical Devices in Brazil
	Murilo Conto Since the manufacturing to the patient access, medical devices pass through a complex chain. Brazil MoH, ANVISA and theRegulated Sector (Hospitals, Health Insurances and Industries) created aworking group to establish an effective tool and system to monitoring theaccess and prices on medical devices. This presentation has the objective toshow how the process to guarantee the universal coverage and technology accessto the population over the country have impacts over the prices and the strategies that will be implementing to assure the Brazilian price monitoringon medical devices with accuracy and interchange capacity.
108	The price control of medical devices in India
	Pavan Choudary To ensure the affordability/accessibility of medical devices, it is crucial to identify areas of improvement on the mechanism that ultimately leads to fixing of prices. The presentation will cover the following major points: 1. The appropriateness of the drug price fixing mechanism for devices 2. Price control of cardiac stents and coronary knee implants 3. Trade Margin Rationalization (TMR) as a long-term solution in controlling prices. To summarize, a few suggestions from industry point-of-view will be given for the government to consider while it implements its pricing mechanisms.
130	Relieve the financing constraints of medical devices industry in China: from the perspectives of innovative financial tools
	Ms Shugui Zeng, Mrs Qiuping Xie, Mr Zhenhua Mao, Xuedan Yuan There exist several drawbacks in current approaches to financing of medical device industry in China, such as small scale, single channels with large potential risks, etc. Based on the experience of European and American countries, this article explores several ways to relieve the financing constraints of medical devices industry including set up of corporate bond support programs for small-scale companies, innovate financial management tools of supply chain such as accounts receivable management, domestic L/C (Letter of credit) approachm, a combination of venture investment and loan, etc.

PS4F	**Assessment of emdical devices for LMIC**
3	A clearinghouse for African health technologies
	Vince Salazar Thomas
	OBJECTIVE: Building on our previous work setting out a plan for the regional assessment of affordable and high-quality medicines and medical technologies across Africa, an HTA "Clearinghouse" is proposed as a preparedness mechanism enabling access to tests and devices. METHOD: A situational analysis of extant regulatory and procurement system(s), population health needs, as well as current best practices. CONCLUSION: Given ongoing efforts to provide universal health insurance, an Health Technology "clearinghouse" utilising an evidence base for technology assessment simultaneously serves as a passive broker of innovative technologies and informs the uptake of critical technologies to enhance health system functioning.
86	Medical Devices Access in Brazil - Diferent Steps using HTA & Evidences
	Murilo Conto
	The process to guarantee the access of medical devices into Brazilian market has four main steps. The first one is the ANVISA register and after adopting into Public Health System and into the Private Sector for reimbursement purposes. This presentation has the main goal to clarify how the HTA tools and scientific evidences are used to approval the medical devices during the all access chain in different perspectives.
109	ISPOR International Initiatives on the Assessment of the Value of Medical Technologies
	Dr Leandro Pecchia, Dr Julie Polisena, Amy Marie Pavlock
	OBJECTIVES: Identify rolesof Health Technology Assessments (HTAs) and other tools/ instruments in assessingvalue of medical technologies throughout their lifecycles. METHODS: ISPOR and several international organizations are collaborating to perform a gap analysis. Systematic and grey literature searches have been completed. Additional plans include a survey of relevant stakeholders and authorship of a paper. RESULTS: Data will include the types of study, medical technology, value assessment, reporting organization, evidence collected, region in which study was performed, and lifecycle stage(s) analyzed. LESSONS: There is a need to improve the process and appropriate use of value assessment specific for medical technologies.
165	Health technology assessment in India
	Himanshu Baweja, Dr Madhur Gupta
	There is a growing recognition of the need for priority setting in India as it aims to achieve universal health coverage (UHC). These efforts have gained prominence in view of the recently launched initiative by the Government of India, Pradhan Mantri Jan Aarogya Yojana (AB-PMJAY), which aims to strengthen primary health care (through health and wellness centres) with a vision to provide the poorest of the poor, and the underprivileged sections of society, with better healthcare. Health Technology has emerged as an important tool for supporting core functions of health care system. These activities in the country help to facilitate the process of transparent and evidence informed decision making in the field of health. The Health Technology Assessment in India aims to maximize access to quality healthcare at minimum cost to the people of the country.

193	Development of consumer engagement protocol in health technology assessment in public health
	Prof B R Shamanna, Shailendra Singh Bisht
	Involving health technology consumers in Health Technology Assessments (HTAs) help in highlighting patient's view and social contexts. Consumers in HTA context could be "patients, carers, patients' organisations & potential recipients of health programs and may involve in three activities in HTAs: "prioritising, commissioning and reporting research". Traditional HTAs tend to "concentrate on clinical procedures, pharmaceuticals, etc" and thus fail to incorporate public health interventions involving use of medical devices which are important for Universal Health Coverage and Health Specific SDGs achievements. HTAs in India are very nascent and establishment of Medical Technology Assessment Board (MTAB) is an encouraging sign.
PD4F	**eHealth**
23	Health Information - Retrieval, Archival, Analysis on/through cloud
	Dr Sudheer Kunkunuru, Mr Sandeep Kunkunuru
	Introduction: A person's health data is usually - spread across physical location is various data formats generated by different device over time. A cost-effective and performant way to archive, retrieve and analyse this data is valuable for both individual and other stakeholders.This poster aims to revisit this need and address it using web/cloud based platforms, devices/apps and techniques. Objectives:DataCloud : a web and cloud based solution aims to collect directly directly and point-of-care health information through following features: - individuals can upload directly to cloud through app/browser using guided workflows. - bulk data sync from devices at health care facilities to cloud in near realtime. - synchronize data on time and enrich it using location, event and therapeutic area. - full text search on reports, annotations, images using standards e.g. DICOM, HL7 - individuals can share data to stakeholders with time/access controls. Methods: DataCloud leverages AWS S3 to sync data, APIs for on-demand collection and collaboration, big-data technologies to analyse and report.Lessons:Non-intrusive collection and timely online and offline access are necessary to be effective.
78	E-health tools for organisation of anesthesia services
	Dr Philippe Mavoungou
	The WFSA works to achieve universal access to safe anaesthesia, directly contributing to SDG3. Supervision by an anaesthesiologist is essential for optimal anaesthesia care. Modern e-health tools may help to improve this supervision, and even allows local, or online expertise, and organisation of logistics and procurement whilst bringing some kind of relief to the shortage of anaesthesiologists. The presentation will browse some benefits of ane-department of anaesthesia. The WFSA urges the industry to include communications capabilities, among the specifications of equipment for LMICs,in accordance with the agenda item 12.4 of the WHA 71.7 about Digital Health.

163 Ehealth: Improving Health Services Quality & Effectiveness in Peru, Chile, US

Pilar Rossana Rivas Tarazona, Prof Cesar Galindo, Prof Tobey Clark

MoH of Peru implemented the Reference and Counter Reference Unit with the Integrated Health Networks-IHN they will improve: a) hospitals effectiveness and b) health services of primary levels organizations. IT is a component of IHN, theposter will bring the results of Telehealth in Peru. Chile is developing "Digital Hospital Project" based on series of services set in the cloud to improve the health systems capacity. The Office of the Nationa lCoordinator (ONC) of Health Information Technology (IT) was created on 2004. Later, government called for EMRs to be incorporated; this was known as theHealth Information Technology for Economic and Clinical Health Act (HITECH). The poster provides evidences in Peru, Chile and US, a discussion of differences in national systems and prospects for the future.

188 Exploring utility of Google for prediction of disease outbreak

Dr Madhur Verma, Kamal Kishore

Introduction: An Internet-based novel surveillance system led by internet search behaviour of the community has recently emerged as a promising technique in few countries. A pertinent question in this regard can be: Can we replace traditional data collection methods with internet search data in an Indian setting?
Methodology: IDSP programme data was used to investigate the relationship with internet generated data. For initial exploration, Malaria, Dengue, Chikungunya and enteric fever were selected to compare data.
Conclusion: Internet-generated data has huge potential especially in resource constraint settings where it can supplement the existing surveillance systems without the extra burden of logistics and manpower.

189 Medical virtualism board: emerging dimension of clinical precision medicine

Dr Shyama Nagarajan, Dr Amitabh Dutta

Digital medicine has revolutionized health care. Physicians today need to understand the physics behind a technology to provide optimal, effective, and ethical care in this “Medical Virtual World”. According to an estimate, tele-medicine has the potential of tackling 30% to 50% of visits virtually. All this has made “Combination Science” a need of the hour.
Journal of American Medical Association has vouched the need for qualified “Medical Virtualists”. SahaManthran goes a step further to suggest a “Medical Virtualism Board” to foster “Holistic Precision Medicine”. This would create a group of experts who can understand science as a whole, using technology as an aid for virtual care.

192 Enhancing prevention of coronary heart diseases countrywide through telediagnosis

Dr Pedro Galvan, Dr Jose Ortellado, Mr Ronald Rivas, Dr Juan Portillo, Dr Julio Mazzoleni, Dr Enrique Hilario

Coronary Heart Diseases (CHD) cause worldwide 12.7% of total deaths in 2008. CHD causes 15.7%of total deaths in Paraguay in 2017 (WHO). This descriptive study evaluates the results of a teleelectrocardiography (Tele-EKG) program in remote public hospitals in Paraguay as tool to improve access to a prevention program for CHD between 2014-18. Type of CHD and adherence to medications and lifestyle modifications was determined. 246,217 remote EKG diagnoses were performed, 80.6% corresponded to adults and 19.4% to children. The mean adherence rate to the prevention program was 2.3. Telemedicine is powerful for EKG screening and prevention program for CHD.

PS6F	**Procurement and supply**
35	Pre-dispatch inspection of medical devices for hospitals
	Ms Sudesh Yadav, Mr Dhirendra Bansal, Ms Shashi Moitra
	Hospitals being the majorend user of medical devices can ensure that the quality of received devices is consistent with their specifications through pre-dispatch inspection by third party. Objective:To perform pre-dispatch inspection of medical devices for Hospitals Methods:Inspection involves site identification, sample size selection, specification verification, identification of deviation from specifications, deviations categorisation, preparation and submission ofinspection report. Lessons Learnt: Observed deviationsvarying from minor to major in user specification and features available inselected medical device. It helped users to allow dispatch of quality product thereby ensuring improvements in the healthcare system.
110	Report on evaluation and rationalizing of distribution and utilization of radiotherapy units in Greece
	Dr Aris Dermitzakis, Mr Silviu Domente, Dr Nicolas Pallikarakis
	Report is conducted in order to evaluate and rationalize distribution and utilization of Radiotherapy units in Greece. Situation: Until 2016, the majority of RT equipment in public sector was older than 15 years. This changed in 2017 following a donation of 10 new LINACs. RT centers are widely spread since most haveonly one or two RT machines and understaffed. Results: In total 57 RT units are available, resulting in 0.53units/100K inhabitants making Greece meet EU recommendations. Data on purchase and maintenance costs, downtime and use are lacking, thus evidence-based decisions are impossible. Adequate stuffing and reorganization into bigger RT centers should be considered.
114	Financing supply chains for durable goods under end-user payment uncertainty
	Ms Olumurejiwa Fatunde
	Supply chains for medical devices and other durable goods featureretrospective customer payments, often paid in installments. In emergingmarkets, such supply chains are typically characterized by payment uncertainty. To decouple supply chain processes from customer revenue, each actor must developpolicies to mitigate cash shortages resulting from working capital (WC)uncertainty. This study presents a model of the payment uncertainty problem fora simple medical device supply chain consisting of a manufacturer, agent, and customer. I determine a WC policy for manufacturers and recommend a policy for agentsto minimize risk of bankruptcy, given payment uncertainty originating from customers.
118	WHOs MSME survey an impetus to boost innovation for medical devices
	Dr Manisha Shridhar, Dr Madhur Gupta
	Survey of Indian Pharmaceutical Enterprises for Meeting National and Global Health Needs, provides an overview of supply of affordable medical products by Indian enterprises. It examines measures necessary to ensure continuity and augment supply of quality medical products at affordable prices to meet public health goals. It is envisaged that data from survey will help guide policy interventions and identify specific areas of support by different Ministries of Government of India and WHO. The recommendations of report would provide useful policy inputs for government, industry and academia especially at this juncture where government is dynamically changing regulatory landscape.

125	Health technology assessment of infusion pumps. an experience in fundacin cardioinfantil-fci.
	Andrea Rocio Garcia Ibarra, Mr Jairo Bejarano Vergara, Mrs Nidia Vanegas, Mr Diego Heredia Osorio, Mrs Soraya Almeida, Mrs Viviana Guerrero, Mr Juan Rodriguez Rozo
	Being part of a health system with universal coverage, broad benefits packages and limited resources, brings challenges for economic investments and medical equipment procurement. Clinical engineering can face it. Medical equipment procurement, must be based on epidemiological needs, assessments, multi-criteria decision analysis, human resources engineering, the FCI experience wants to share. Infusion pumps are used to administer medications, in some critical cases and may have high risk and implications for the safety of patients. Assessment of infusion pumps procurement was a successful case. This experience leads us to include clinical engineering in the construction of scenarios to make better decisions.
PS7F	**Nomenclature**
7	The Global Medical Device Nomenclature (GMDN)
	Mark Wasmuth
	The GMDN Agency fully supports the need foran international classification, coding and nomenclature system of Medical Devices (ICMD) to support the access to medical devices for better health care delivery in line with the Sustainable Development Goal #3 and the WHO Thirteenth General Programme of Work(2019–2023). This presentation will provide a background to the development of the nomenclature for medical devices, why it is needed and the main features of the GMDN and how it is used by regulators of medical devices around the world today to support patient safety.
12	National implementation on unique device identification for medical devices in Turkey
	Mr Recep Uslu, Mr Amer Kuru, Tuncay Bayrak
	Objectives: We are planning to implement UDI on medical devices inorder to increase patient safety and traceability in Turkey. Methods: We have introduced a stepwise approach to implement UDI. We have working groups including stakeholders from NGOs, health careproviders, and suppliers and published guidelines and procedures involving road-maps. Results: UDI was initiated for active implantable medical devices in 2 July 2018 and then Class III devices in 1 October 2018. Other devices will be handled in 2019. Lessons learnt: Hospital IT systems should be integrated to National Tracking System. More qualified staff shouldbe employed in hospitals.
83	Main priorities and a global standard on medical devices nomenclature - Latin American & Caribbean summit on HTM results
	Mr Murilo Conto, Mr Thiago Santos, Mrs Fotini Toscas, Mr Rodrigo Silvestre, Mr Alexandre Lemgruber
	The LA & Caribbean Summit on Health Technologies Management was promoted by PAHO-WHO, Brazilian MoH and IFMBE, with 96 representatives from 18 countries counted with 27 presentations about challenges and successful cases on medical devices. The main conclusion was the need for a greater engagement of organizations and governments to work in the entire life cycle of technology. A list with priorities was defined and the key element to advance in the prioritizedtopics, was to establish a global standard of nomenclatures. After the meeting, Brazilian MoH sent a request to prioritize this task in the next WHA in 2019.

172	Automatic transcoding across different medical device coding and nomenclature systems
	Stefano Bergamasco
	Problem: Many different coding and nomenclature systems exist for medical devices, used globally, nationally or locally in individual companies and institutions. Sharing information is difficult, though new international standards are proposed as a global solution. Method: A software platform is conceptualized that will be able to interpret the identification of any specific MD in an asset management system, map it to any existing or new coding and nomenclature system and link any asset management system to external databases of information. Results: A dynamic mapping system, based on AI and semantic analysis, has been designed and a first prototype was made.
210	Standardization on medical devices
	Prakash Bachani
	Bureau of Indian Standards (BIS) is National Standards Body of India, under which Medical Equipment & Hospital planning Department (MHD) is one of 15 Departments for formulation of Indian Standards. MHD has formulated more than 1200 Indian Standards on Medical Devices under its 19 Sectional Committees. BIS is 'P'-(participating) member in 14 Technical and 9 Sub-committees of ISO & one technical and four sub-committee of IEC for medical devices. Medical Device Rules 2017 gave first priority for conformance of medical devices to Indian Standards. BIS is continuing to provide quality eco-system through formulation and harmonization of standards on medical devices.
243	In Search of an International Harmonized Nomenclature for Medical Devices
	Mrs Adriana Velazquez-Berumen, Mr Umberto Vitale, Mrs Rebecca Baker, Mrs Laura Velez Ruiz Gaitan, Mrs Karen Kulp, Mr Daniel Diethei
	The Health Sector is aware of the need of a harmonized nomenclature/coding system for medical devices, encompassing their entire lifespan.From development through testing, approval, manufacture, procurement, use, maintenance and finally disposal or recycling, WHO envisions unique nomenclature and device identification codes, freely and entirely available for all.WHO launched a survey in 2018, whose results confirmed the global intention of progressing in this direction.A pilot project has been undertaken to create a nomenclature system inspired by current systems, based on ICD-11 ontological database platform.Stakeholders are encouraged to join this initiative on the freely available medical devices nomenclature.
Parallel oral session 2: 15 December 2018	
PS11F	**Regulation in South-East Asia**
121	Leveraging regulatory networks- South East Asia Regulatory Network (SEARN)
	Dr Madhur Gupta, Dr Eswara Reddy, Manisha Shridhar
	South East Asia Regulatory Network (SEARN) was launched in 2016 by 11 Member States of WHO South East Asia Region to enhance information sharing, collaboration and convergence of regulatory practices across region for access to high-quality medical products (medicines, vaccines, diagnostics, devices). Regulatory authorities in several countries lack sufficient technical capacity, staff and resources to perform effectively. Therefore, it is envisaged SEARN would be instrumental in encouraging collaboration, effective use of resources and rapid exchange of information on medical products. SEARN is led by Steering Group comprising Medical Products regulatory agencies of Member states and five Working Groups.

207	Medical devices rules
	Krishanarajan Bangarurajan
	Medical Devices Rules 2017 has been notified by MoHFW, GOI dated 31.01.2017 under the provisions of the Drugs and Cosmetics Act, 1940 to regulate the Clinical Investigation, Manufacture, Import, Sale and Distributionof Medical Devices in the Country. In Rules, Devices are categorized into 4 classes A,B,C and D on basis of risk. Import of all classes of Medical Devices is under provision of CLA and for sale, SLA is regulatory authority. License to manufacture Class A and B will be given by SLA and QMS verification by Notified bodies only and for Class C and D will be given by CLA.
PS1S	**Policies on medical devices**
41	L'acces aux dispositifs medicaux essentiels et prioritaires en RD Congo
	Dr Thomas Katba, Edison Maombi
	Introduction: Pour améliorer l'accès aux dispositifs médicaux, le Gouvernement Congolais a lancé un projet d'équipement des structures sanitaires PESS ensigle. Objectif:Redynamiser le système sanitaire et revitaliser les formations sanitaires enfin d'améliorer la santé de la population. Méthodologie/stratégies Financement 100% Gouvernement. Contribution de l'expertise des partenaires (UNICEF, FEDECAM). Exécution en plusieurs phases Résultats Après 5 ans: 132 Hôpitaux Généraux et 1000 Centres de Santé sont équipés et approvisionnés en médicaments,100 Centres de Santé sont construits, équipés et approvisionnés en médicaments. Conclusion Ce projet est entré d'améliorer la couverture en dispositif médicaux et infrastructures de soins de qualité.
107	Development and implementation of policies for medical devices an industry perspective
	Pavan Choudary
	Medical devices are characteristically very different from pharmaceuticals. As such, Medical Devices industry has been constantly requesting for a separate Act which will fill gaps and remove ambiguity arising from clubbing of 'drug' and 'device'. Introducing measures such as Medical Device Rules, 2017 are a step in the right direction; however medical devices requirea separate governance and regulatory mechanism of their own. The presentation will be on process of developing policies: 1. Drafting the policy 2. Testing draft policy (inviting feedback fromstakeholders). 3. Implementing policy 4. Post implementation changes (Government Orders to ironout the wrinkles)
119	Medical device reforms and the dynamic landscape in India
	Madhur Gupta, Dr Eswara Reddy, Dr Manisha Shridhar
	The Government of India (GoI) has taken various steps to make India hub for medical devices. The National Health policy 2017 recommends strengthening regulation and establishing regulatory body to unleash innovation and entrepreneurial spirit for manufacture of medical devices in India. Some highlights are Medical Device Rules 2017, MVPI, Medical Technology Assessment Board (MTAB), strengthened Health Technology Management, enabling landscape created to foster research and innovation under Make in India vision to enable access to affordable, safe and effective medical devices globally, as a contribution to UHC and SDGs. It is in this context current landscape and updates are shared.

222	Kenya's journey towards optimal medical devices management
	Matha Lauren Gartley, Mr Martin Owino
	The Ministry of Health in Kenya is developing a policy intended to guide the health sector on management of medical devices. This has been occasioned bythe following: i)Under-utilization of availablemedical devices ii)Idle/non-functioning equipmentdue to lack of maintenance plans and spare parts iii)Investment in medical devices thatdo not meet priority health needs iv)Acquisition/donation of devices which are incompatible with existing infrastructure v)Investment in poor quality medicaldevices.The policy is expected to provide direction and guidanceon medical devices/equipment management and this will be expounded in duringthe session.
PS2S	**Paths to health technology innovation**
8	New frugal innovation for refugees and migrants
	Prof David Swann, Mr Nathan Jones
	This three-year study investigates the operational challenges faced by the volunteer group Kos-Solidarity (KS) who provided daily, frontline humanitarian care to support and sustain the lives of hundreds of new refugee arrivals in 2015. Field trips to Kos in 2016-2018 documented abandoned refugee sites that lead to the preservation of 90 objects. These material witnesses guided a series of object-based interviews with KS volunteers to capture their oral testimonies and the improvised solutions they created. The research is on going with findings informing a programme of frugal innovation to develop a suite of 21st century UNHCR health and well-being products.
91	Translational research & medical device innovation: a clinician's perspective.
	Dr Syed Quazi, Dr Abhay Gadhane, Punit Ratnakar Fulzele
	Introduction: Translational research, translates the findings in basic research quickly and efficiently into medical practice, and thus into meaningful health outcomes. Medical device innovation being a part of translational research should focus on unmet clinical needs. Clinicians often define unmet clinical needs, but seldomly tryto bridge the gap. Method: DMIMS(DU) is supporting an ecosystem for encourage clinicians & engineers to learn about medical devices innovation and to team-up for creating innovative solutions for unmet clinical needs using translational research methodology. Conclusions: The ecosystem and interdisciplinary approach has helped in development of devices for effective monitoring and treatment ofpatents.
228	Creating ecosystem for biomedical technology innovations: DBT's initiatives
	Alka Sharma
	The demand for biomedical technology is growing rapidly in the country. Many of the technologies are being developed successfully at very early stage but there is difficulty in translating these technologies into clinical applications. Realizing the need for creating a complete ecosystem for promoting end-to-end process i.e. ideation to commercialization, DBT has taken a number of initiatives for creating pool of med-tech innovators and entrepreneurs; establishing infrastructure and facilities; promoting public private partnership (PPP) to foster and promote med-tech innovation in India. DBT has also set up BIRAC to act as an interface agency for promoting PPP in the country.

PD15S	Biomaterials
25	Medical Devices and Biofilms: Strategies for Prevention
	Dr Kundurthy Shasank
	Objective: Strategies for prevention of biofilm-based infections in medical devices Methods: Biofilms are a major medical issue which cause of 60 80% of microbial infections . There are two approaches to control biofilm formation in healthcare settings: one is the development of biofilm inhibitors based on the understanding of the molecular mechanism of biofilm formation, and the other is to modify the biomaterials which are used in medical devices to prevent biofilm formation. Results:Changing physical properties of biomaterials (nanotechnology), biofilm inhibition by quorum quenchingLessons learnt: The current strategies and future perspectives for developing improved therapeutics for controlling biofilm-based infections
29	Tissue-on-demand
	Ranjna Dutta, Dr Aroop Dutta, Mr Achintya Dutta
	In order to engineer human tissues as an alternative to ever widening demand-supply gap for surgical transplantations, we must resort to a faster and reliable tissue engineering method unlike current paradigm. A tissue manufacturing method and business model are needed similar to FMCG products as effective solution. We have developed a process to create specific cells and corresponding extracellular matrix composites. The method is compatible with typical manufacturing processes like extrusion, molding, casting etc. TRL of proof-of-concept is 4. We expect this novel process shall be a paradigm shift for future clinical and market challenges.
60	Translational research at intersection of engineering, biology and medicine: an Indian landscape
	Bikramjit Basu
	Against the backdrop of the ever-increasing unmet clinical needs, significant efforts have been invested to innovate new bioengineering approaches for medical applications or to develop patient-customized implantable biomedical devices to accomplish the bedside-bench-bedside translation cycle. Against the above perspective, this talk will describe a few case studies illustrating the most recent research findings from our group to illustrate how to take labscale research to biomedical device development. This will be followed by our recent research program on biomedical device development through under the framework of the 'Translational center of excellence on biomaterials for orthopedic and dental applications'.
70	Hydroxyapatite-chitosan nanocomposite for orthopedic applications
	Manisha Sharma, Dr Suman Singh, Mr Vijay Meena
	Trauma, bone diseases, infection and corrosion have increased the need of biomaterials for orthopedics. Hydroxyapatite-chitosannano composite is one of the biomaterials that can be used for different orthopedic applications. Both materials are highly biocompatible. HA-CH help toenhance osseointegration. In this study HA-CH nanocomposite is synthesizedthrough in-situ hybridization method. The material was characterized using FTIR, XRD, AFM, and FESEM. Wettability was studied using Contact Angle. Biocompatibility study was also done. Results confirmed the formation of biocompatible HA-CH with a size range of 154-225 nm. The prepared material will be further electrospunned on implant material.

PD16S	Technologies for dental applications
26	Telemedicine in Dentistry
	Dr Kundurthy Shasank
	Objective: Increasing awareness of the healthcare specialist for remote telemedicine in dentistryMethods: Teledentistry is a new area of dentistry that integrates electronic health records, telecommunications technology, digital imaging, and the Internet to improve access to care for patients in remote settings. Results: Through collaborative hygienists in remote areas, patients can have improved access to preventive dental care. Through teleconsultation with specialists in larger communities, a dentist in a nearby community can provide access to specialty care for their patients more easily. Lessons learnt: Teledentistry allows the specialist located many miles away to make a diagnosis and recommend treatment options and/or referral for patients who otherwise would find it difficult to see them. clinical decision support, quality and safety assessment, consumer home use, medication e-prescribing, and simulation training.
67	Final-impression techniques and materials for making complete and removable partial dentures
	Balendra Pratap Singh, Dr Srinivasan Jayaraman, Dr Balasubramanian Ramanathan, Dr Murukan Pillai, Mrs Laura MacDonald, Mr Richard Kirubakaran
	Brief summary: Edentulism is relatively common and is often treated with the provision of complete or partial removable dentures. Clinicians make final impressions of complete dentures (CD) and removable partial dentures (RPD) using different techniques and materials. Applying the correct impression technique and material, based on an individual's oral condition, improves the quality of the prosthesis, which may improve quality of life. Objectives: To assess the effects of different final-impression techniques and materials used to make complete dentures, for retention, stability, comfort, and quality of life in completely edentulous people. To assess the effects of different final-impression techniques and materials used to make removable partial dentures, for stability, comfort, overextension, and quality of life in partially edentulous people. Methods: Database has been searched and two review authors independently, and in duplicate, screened studies for eligibility, extracted data, and assessed the risk of bias for each included trial. We included nine studies in this review. Eight studies involved 485 participants with CD. We assessed six of the studies to be at high risk of bias, and two to be at low risk of bias. We judged one study on RPD with 72 randomised participants to be at high risk of bias. Conclusion: Overall, the quality of the evidence for each comparison and outcome was either low or very low, therefore, results should be interpreted with caution, as future research is likely to change the findings.
127	Multipurpose endodontic slab
	Dr Nishi Singh, Prof Balendra Singh
	Background: Mixing and cross contamination are always an issue with dental materialswhich is taken care by this innovation. Design: Inventionconsists of two equal dimension and design parts made up of plastic andglass. Each part consists of two well dispensers, two slanting coating drainsand small mixing table on one side. Other side is flat surface used to mix large amount of material. Plastic mixing slab is used forthe adhesive dental restorative and endodontic materials; and glass mixing slabis used for non-adhesive restorative and endodontic materials.

131 Indian burden of orofacial diorders, workforce and policies

Akhilanand Chaurasia, Dr Mark Drangsholt, Dr Jaisree Thoppay, Dr Alexander Kerr

Health care is a critical need and right to humans and it is one of the largest costs to society. Understanding the burden of diseases to society and ascertaining the societal need for the number and types of health care providers is of paramount importance to improve health and maximize economic efficiency. In dentistry and orofacial health, many disorders occur in the orofacial region which are usually non-surgically managed (at least initially), including temporomandibular disorders, dry mouth/xerostomia, oral malignant/premalignant lesions, oral lichen planus and lichenoid lesions. The prevalence of these disorders and stratification by disease severity is largely based on crude estimates from small studies. Accurate estimates of the number of providers to the general population, or to the number of people afflicted with these disorders are not known. There is variability in the prevalence of these disorders across the india, and the types of providers that do diagnose and manage these conditions also vary greatly. This paper focuses on the burden of oral diseases in India, Workforce and Policies to be applied to handle it.

PS18S Regulation post market

69 Role of Kenya medical laboratory technicians & technologists board on implementation of point-of-care technologies.

Mr Abdulatif Samatar, Mr Abel Onyango, Ms Dorcus Abuya, Bintiomar Bakari Tsala

BACKGROUND: Point-of-care technologies (PoCT) that test at or near patient care has been vouched for to mitigate most of the challenges experienced by the centralized testing. However, before PoC implementation manufacturers or vendors of PoCT are required to be registered by the regulatory body, in this case KMLTTB. In view of this, we seek to highlight the role of KMLTTB in the national implementation of the PoCTs. METHODS: KMLTTB led the laboratory method validation process by providing clear guidance documents to manufacturers or vendors on obtaining registration approvals. In collaboration with NPHLS, we also perform lot to lot verification/validation of reagents to be used for PoC testing. RESULTS: KMLTTB only validated PoCtechnologies on condition that they have a mandatory WHO pre-qualification. Two EID and one VL PoC platform have been registered to date. Lot to lot validation of reagents, is a continuous process that will allow for quality of resultsfrom PoCTs.CONCLUSION: The role of KMLTTB was very key inimplementation of the PoC as it provided a gateway to their utilization at selected facilities. Consistent monitoring of the different lots also provides a better platform of assessing the manufacturers competence in producing quality reagents that can give consistent results.

71 Medical devices adverse event monitoring: The story of India

Pretti Karb Dr Madhur Gupta, Dr V Kalaiselvan

With increase in number and variety of medical devices, there has been an increase in number of adverse events associated with medical devices. To monitor these adverse events, India launched Materiovigilance Programme of India (MvPI) on 6 July 2015, a robust scientific platform that provides valuable information on safety of medical devices and contributes to regulatory decisions. Recent changes in the regulation of the devices via Medical Devices Rules 2017 in the approval processes, vigilance of undesired effects have strengthened materiovigilance in India. An overview of MVPI structures, practices, regulatory context, recent initiatives, challenges and way forward will be presented.

88	Regulatory framework of medical devices and in-vitro diagnostic kits in India
	Ravi Kant Sharma
	The medical device industry in India is growing at 15.8% compound annual growth rate and India tops among the 20 medical devices market across the world. Government of India has overhauled the regulatory framework for medical devices in 2017 which is effective from 1st January 2018 with International norms by introducing the concept of 'risk-based' regulation for fifteen categories of notified medical devices at present. The regulatory licenses issued for import, manufacture or sale of medical devices have been made perpetual in nature to shorten the duration of regulatory procedures and fasten the business in India.
183	The impact of the passive awareness on the implementation and success of materio vigilance program in a medical institute in northern India.
	Prof Anil Gupta, Prof Ashok Kumar, Prof Vipin Koushal, Dr Navin Pandey, Dumpala Venkata Ravi Kiran
	Since the decades medical fraternity and the society knows that drugs can cause the adverse events but many people from medical fraternity also don't know the various adverse events of medical devices. This study is conducted with an aim to assess the impact of background knowledge on implementing the program in the hospital and attitude of the staff towards it. The status of MvPI and PvPI were compared with the initial three years after their launch and results were concluded that the preexisting knowledge has a positive impact on reporting the adverse event and implementing the program.
PS20S	**Steps towards the harmonization of EU-Africa regulations**
182	Harmonising medical device and medical location policies among Africa and Europe
	Dr Leandro Pecchia, Dr Ashenafi Hussein, Prof Nicolas Pallikarakis, Mr Nicola Caputo
	Sub Saharan Africa (SSA) lack of harmonised regulations on medical devicesand medical locations (e.g., hospital settings). This causes inappropriateinterventions, donations, healthcare programmes scaling-up, resulting in effectiveness/ safetydetriment. This hinders African economic growth: medical device manufacturersstruggle to flourish in SSA healthcare systems, which are the fast growing inthe world. IFMBE, EAMBES, European Parliament and Africa Union started discussing howto facilitate harmonisation. Updates on the ongoing discussion will be given by panellists:- Leandro Pecchia, UK- Ashenafi Hussein, Ethiopia- Nicolas Pallikarakis, Greece- Nicola Caputo, European Parliament
PS2S	**Innovation**
13	Wearable for good
	David Michael Swann, Dr Jim Reid, Prof Christine Mushwibe, Prof Barry Doyle, Dr Julia Meaton
	This research study explores the visual communication opportunities for the chitenge as a wearable public health education/ training tool in Zambia and beyond. Traditionally, the universal chitenge has fourteen uses such as a skirt, a baby carrier and a blanket. Our exploratory engagement meetings in Zambia showcased a proof of concept demonstrator to stakeholders to explore its potentiality, transferability and acceptability. Our initial findings will guide the advancement of design interventions that will address three global public health concerns: reducing malaria in pregnancy, safeguarding homeless children and APGAR education to reduce neonatal mortality.

16	Smart fever screening system for health clearance
	Hiu Fai Siu, Mr Stanley Siu, Prof Richard So
	This is a novel system for enhancing the feverscreening capability for health clearance service at boundary control points toprevent the spread of infectious diseases in public. It uniquely combinesthermal imaging, computer vision and pattern recognition, machine intelligence,and contextual design and ergonomics. Screening efficiency is raised byshortening response time of detecting febrile travelers and optimising manpowerdeployment, as well as digitising fever screening information for big dataanalysis and improved decision making process. The system sets a reference model for quarantine service in boundary control points to protecting the public from spreading of infectious diseases.
17	Advanced hemodialysis/hemodiafiltration based on real-time individualized cardiometabolic measurements
	Dr Joaquin Azpiroz-Leehan, Mr Andrs Morn-Mendoza, Dr Miguel Cadena-Mendez, Dr Emilio Sacristn-Rock, Mr Gerardo Rosas-Andreu
	Objectives: Reduce lethality rates and increase patients' quality of life undergoing hemodialysis/hemodiafiltration by using the on-line measurement of cardiometabolic variables to control the hemodialytic processes. Methods: Measurementof the patient's intra-dialytic hemodynamic stability, which is highly related to the occurrence of adverse events. A multi-factor control which is adaptable to the specific needs of each patient is applied to preserve homeostasis. Results and Lessons learnt: The protocols have been applied for 6 months and after more than 700 therapy sessions we have found that intradialytic monitoring heart rate variability is a predictor for hypotensive events. Other results are expected shortly.
20	Transfer of technology of commoditized medical devices
	Luca Passaggio
	Objectives: To organize the transfer of technology of life-saving, commoditized medical devices. No intellectual property involved. Methods:There are three main channels of transfer of manufacturing technology: joint ventures; licensing agreements; turn-key plants. Results: When a recipient country or organization is adopting and replicating the technology, skills and knowledge from another country or organization, then the whole country receives social and economic benefits from the technology transfer. Lessons learnt:The human factor and the standard of living are a priority if we want to start the whole process of social and economic development in a society.
27	Self deployable wide spectrum wound care device
	Dr Aroop Dutta, Mr Achintya Dutta, Dr Ranjna Dutta
	Wound care, irrespective of types (acute, chronic, second/third degree) need convenient intervention on-the-spot, particularly among diabetic, aging or bedridden population. We have developed a novel solution and proposed business models for a cost constrained economy. Our solution involves a novel biomaterial platform and smart devices design for instant intervention by untrained bystanders or the victim him/herself. We have undertaken beta-test to validate devices concept. A pilot scale manufacturing is underway to be followed by clinical studies. specific business models will be tested soon after.We expect our solution and business model is conducive for worldwide market.
154	Understanding community healthcare worker adherence to iCCM guidelines when using an ARIDA device and barriers and facilitators to use
	Heta Kosonen, Mrs Charlotte Ward, Mr Kevin Baker, Mrs Cindy Mcwhorter, Mr Paul Labarre, Dr Hayalnesh Tarekegn, Mrs Karin Kalander

UNICEF in partnership with Malaria Consortium and "la Caixa" Foundation is conducting acceptability studies for two Acute Respiratory Infection Diagnostic Aid (ARIDA) technologies, Philips ChARM (an automated respiratory rate counter) and Masimo Rad G (a multimodal respiratory rate counter and pulse oximeter) at the community level in Ethiopia and Nepal. Acceptability studies will assess community health worker compliance to iCCM guidelines using ARIDA and understand barriers and facilitators of using ARIDA. Data collection will be completed end of 2018. Methods, preliminary results, learnings and evidence gaps to be shared. Funding is provided by "la Caixa" Foundation.

Single use devices

93 Reprocessing of single use devices (SUD), how to ensure safety and performance?

Mrs Sasikala Thangavelu

There is a growing trend to reprocess and reuse SUDs. This practice carries significant risks to the patient and compromises safety and performances. Survey and workshops have been conducted among the healthcare institutions to study the reprocessing activity of SUDs in Malaysia. This paper highlights the outcome of the survey and workshops. The measures taken to regulate this activity include identification of SUDs that can be reprocessed, quality management system for reprocessing activity in healthcare institutions and to regulate third party re-processors as manufacturers. These shall regulate reprocessing of SUDs in Malaysia.

111 Difficult to prevent reuse of single use devices, need for national policy & regulation.

Ajai Basil

Problem: Manufactures desire to produce single-use devices and clinicians judgement to reuse the device multiple times when there is a lack of national policy or regulation to assure safety and performance of reprocessed medical device. Method:Study on the Indian Medical device and hospital regulation/policy on medical device reuse and reprocessing. Understanding the driving factors on reuse of device and international recommendation or practices on curb reuse of medical devices. Also, analyzing possibility to ensure device affordability without compromising safety by controlled reprocessing at hospital. Conclusion:India need for policy and regulation to prevent reuse of single-use medical device.

178 Integrating the existing infection control program with materio-vigilance program: need of an hour?

Dumpala Venkata Ravi Kiran, Dr Sunil Kakkar, Prof Vipin Koushal, Dr Manisha Biswal, Dr Anil Gupta, Dr Navin Pandey

Medical devices can cause many adverse events and Hospital Acquired Infection (HAI) is one of them which deteriorate patient health, increase burden on hospital and society as well. Aim of the study is to emphasize the need of integrating the Infection control program and MvPI. Nursing staff (n=105) were evaluated before-after training program in providing patient care (n=959) with respect to catheter associated infection. Results have concluded that timely and repetitive training of hospital staff and integration of the existing programs is needed to combat AMDE and to strengthen the objectives of MvPI

PS4S	Assessment of medical devices
232	HTAi, ISPOR, InHTA, IFMBE, IUPESM and WHO join panel on HTA of medical devices

Dr Amy Pavlock, Dr Julie Polisena, Prof Ernesto Iadanza, Prof Leandro Pecchia, Mrs Adriana Velazquez-Berumen

There is clear consensus that assessing medical devices is more complex than assessing other healthcare technologies. This panel aims to report on the ongoing discussion around challenges and opportunities arising from the HTA of medical devices. Representative speakers from HTAi (J. Polisena), ISPOR (A. Pavlock), InHTA (t.b.d.), IFMBE (E. Iadanza), IUPESM (L. Pecchia), WHO (A. Velazquez) will:1) report on the ongoing discussion within those associations and among their representatives, 2) discuss common initiatives aiming to profit from mutual and complementary competences to face such a complex challenge. After a brief introduction, panelists will open the discussion with the attendees.

PS13S	Health technology management
5	Designing a medical equipment database management system

Priscilla Kemigisha

Objectives: The implementation of the design will efficiently improve the operations of health facilities, management of equipment immediately and continuously. The information can be used to increase health care facility profitability, improve audit accuracy, reviewing upcoming maintenance of medical equipment, and eliminate errors in manual processing (paper work) and hence improving the healthcare delivery to the public and hence the World Health Organisation (WHO) goal of having a healthy and happy population isachieved.Methods: Equipmentmanagement is a very important issue for safety and cost in hospital operation.The use of an effective and efficient information system effectively improvesthe managing performance. The design of a Medical Equipment Database ManagementSystem (MEDBMS) used for better equipment management. The design incorporatesthe use of Local Area Network (LAN), internet or wireless network and consists of work ordermanagement, contract management, hospital equipment inventory management, equipment life-cycle management, breakdown maintenance and preventivemaintenance (PM) among others. A user friendly web interface is available forsecure and easy access to the system. Results: The MEDBMS isused for improving on medical equipment management.Lessons learnt:Medical equipment is a veryimportant component of modern health services, but the related management ormaintenance is particularly weak in the health centers. The growth incapabilities to manage or maintain medical equipment has lagged far behind therate of deployment of equipment. In addition to the traditional operationperformance in cost/efficient analysis and control are the important issues forusing medical equipment in hospital. A medical equipment database managementsystem has been designed to help the hospital technicians and health serviceproviders early to confront the potential risks.

75	Health technology management in Bhutan

Tashi Penjore

Bhutan had embraced the advances in health technologies for improving the healthcare services to the citizen which is evident from the increasing procurement and supply of medical equipment to health facilities in the country. Until early 1980s, medical supplies were managed by the State Trading Corporation of Bhutan (STCB). During this period, medical equipment after sale services such as preventive as well as ad hoc maintenance were managed through suppliers and dealers of neighbouring countries. The Health Department took over the medical supplies management in the late 1980s. At the same time, the need for in-house maintenance team was realised. This was compounded by the choice and capabilities of health workers to switch from clinical acumens based healthcare services to technology based services. Accordingly, HERM (Health Equipment Repair and Maintenance) unit was established in June 1985 with 5 technicians to provide after sale services from installation to regular preventive maintenance of medical equipment. The capacity of the unit was enhanced with the recruitment of 1 UNV engineer in March 1989. In 2007, the Unit was renamed as Biomedical Engineering Services (BES) which was further upgraded into Bio-Medical Engineering Division with mandate to manage medical equipment of the entire country comprising of over 135 health centres of different levels. The division currently has 5 biomedical engineers with a few technicians maintaining and managing functionality of medical equipment in the country. This paper will describe the health technology management vis-a-vis biomedical engineering practices in Bhutan and its future plans.

160	Virtual health technology training for Latin America & the Caribbean

Mr John Clark

To provide accessible training and education to the low and middle income countries, two 100% virtual courses, Introduction to Biomedical Technology and Health Technology Management, were developed to teach students about the best practices to follow in supporting and managing devices over the healthcare technology lifecycle. The bi-lingual courses were first taught on the PAHO Virtual Campus for Public Health to participants from the Caribbean and Latin America countries in 2014, again in 2015 and 2017 with the next course to be conducted in 2019. The course development process, overview, evaluation, and results will be discussed in the presentation.

162	Health technology innovation, planning & management: improving professionals outputs in Peruvian health sector

Pilar Rossana Rivas Tarazona, Mrs Rosa Villar, Prof Tobey Clark

In 2016, College of Chemical and Pharmaceutical led by Villar, implemented a strategic program for: MoH Directorate of HealthAuthorizations-DIGEMID, Social Security System, Univ. San Marcos PharmaceuticalSchool, health laboratories and enterprises. Main objectives: To provide basicknowledge of HT Innovation, Planning and Managements principles; and toimprove HT Quality. Based on an online course developed by Clark and Rivas taught on the PAHOs Virtual Campus, the achievements included four proposalsand a 2017s post course learning which involved the Univ. of Vermont (UVM) andAlbany College of Pharmacy & Health Sciences in USA. UVMs areas:Instrumentation and Technical Services Department, Regenerative Medicine Lab.,Molecular Physiology & Biophysics Lab. and Bailey/Howe Library. Goals, capacity building methods, partnership, achievements and impact will bedescribed.

	Human resources to manage medical devices
10	Roles of Clinical Engineer in Education
	Hiroki Igeta, Mr Takeshi Ifuku, Mr Jun Yoshioka, Ms Keiko Fukuta, Mr Tomoyuki Nomura, Mr Tadayuki Kawasaki, Mr Takashi Honma
	Japanese clinical engineering system is unique as itis a national licence system and it allows them not only maintaining and managingmedical equipment, but also operating it especially life support equipment suchas heart-lung machines and respirators etc. Recently the demand of professionsin clinical and biomedical engineering is increasing in developing countries. From the viewpoint of education, Japan Association forClinical Engineers (JACE) collaborates with other organisations such as Clinical EngineeringGlobal Promotion Foundation and Japan International Cooperation Agency (JICA), andcooperates in the fields of dispatching lecturers or intermediary for clinicalengineers on international cooperation programmes.
49	Sharing experience on biomedic al skills strengthening program in South Kivu-DRC
	Catherine Blanc-Gonnet Robach, Mr Lieven D'haese
	Objectives: In South-Kivu, DRC, hospital technicians are struggling to maintain medical equipment due to lack of training, recognition and resources. This seriously impacts the quality of care. To improve the situation two European NGOs (MSV Belgium ; Humatem, France) have collaborated to carry out a biomedical skills strengthening program. Methods: 12 training modules (120 days) combining theory and practice were given collectively on health technology management, maintenance and basic technical knowledge. Results: 42 hospital technicians were trained from 2016 to 2018. Lessons learnt: it was very relevant to opt for pairs of North/South trainers and to supplement training with two awareness-raising seminars on HTM and biomedical strategy for political and hospital decision-makers.
59	Clinical Engineers role under the stakeholders' perspective
	Fabiola Margarita Martinez Licona, Mr Francisco Aceves-Aldrete, Mr Herberth Bravo-Hernandez, Mr Elliot Vernet-Saavedra
	Objectives: Evaluate the role of the clinical engineers in the medicaltechnology assessment process from the point of view of some stakeholders. Methods: Several meetings with biomedical and clinical engineers (CE),academic researchers, economists, architects, public policy advisors, medicaldevices businessmen, regulatory affair experts and clinic staff were carriedout in the last years. It was discussed the role of the CE in the medical devices assessment processes. Results and Lessons learnt: Most of thestakeholders recognize the CEs role as important, but are unsure of the scopeof their functions. Dissemination of the CE strategic role remains a priority.
112	Non recognition of biomedical engineers in public health facilities in India
	Ajai Basil
	Problem or challenge: Biomedical Engineers are neither recognized by public health facilities in Indianor roles to be given to them are fully understood at National or State policymaking level. Method followed: Study on the various clinical establishment act, National hospital accreditation guideline, Indian public health standard and Medical college guideline. Analyzing availability of human resource, along with roles and responsibilities given to biomedical engineers at global hospitals. Conclusion: India need to update existing guideline and incorporate role of biomedicalengineers to skeleton of clinical establishment.

126	Experiences from an academic program in clinical engineering
	Prof Fabiola Martinez-Licona, Dr Martha Ortiz-Posadas
	Objectives: To analyze the results obtained from clinical engineering (CE) academic projects and teaching-learning model at Metropolitan Autonomous University (UAM) from Mexico. Methods: The review of CE program updates at UAM biomedical engineering academic program and the projects developed in terms of the impact on healthcare. Results and Lessons learnt: The four updates of the academic program and over the 120 finished and on progress projects show that the changes on the academic program are reflected on the topics and approaches of the projects that are developed. The teaching-learning process has also evolved into a more dynamic, multidisciplinary, problem-oriented one.
159	Clinical engineering certification in the United States
	Mr John Clark
	Certification of clinical engineers began in the 1970's primarily through the Association for the Advancement of Medical Instrumentation (AAMI). The American College of Clinical Engineering (ACCE) took charge of the clinical engineering certification process in 2002. The current qualifications include an application with basic educational and experience requirements, a written test, and an oral exam. In the US, certification also exists for healthcare technology managers and biomedical equipment technicians. The presentation will discuss the development of clinical engineering certification in the US, other related certifications, and the current status and future plans. (For CE/BME Credentialing Best Practices submitted by IFMBE)
221	Maintenance center - a solution to long-term sustainability of training programs
	Benjin Joshua
	73% of hospitals in Africa have difficulty locating a BMET. Training BMETs is essential to improve healthcare in sub-Saharan Africa. However, long-term sustainability is a problem for training programs. Establishing maintenance centers as social business at training institutions can help sustain programs. BMET Trainers and students provide services to hospitals that cannot run an in-house BMET department. Maintenance center at an Ethiopian technical college has increased the number of functional devices by 18% and has the potential to generate revenue for the training program. Providing maintenance services through social business models have the potential to sustain local BMET training programs.
PS19S	**Challenges in donations**
47	Addressing sustainability challenges in medical device donations
	Vikas Venkata Meka, Mr Bruce Compton, Dr David Barash, Ms Jennifer Farrington, Ms Cynthia Hall, Mr Dale Herzog, Ms Ellen Rafferty
	Objectives: To address sustainability challenges in medical device donations. Methods: The National Academy of Sciences convened experts from academia, private industry, public and NGOs involved in medical equipment donations to identify key barriers for high-quality donations and to make recommendations for improvement. Results: Participants identified three areas for further exploration that was published in a paper "Access to Medical Devices in Low-Income Countries", NAM 2018. Lessons learnt: Additional research is needed in the quality and appropriateness of the donations, sustainability after donation is made, and visibility of the flow of donations globally to increase the impact of medical device donations.

54	Transnational donations of medical devices (in Sierra Leone and Ghana): facilitators of healthcare or white elephants?
	Dinsie Williams, Dr Jillian Kohler, Dr Andrew Howard, Dr Zubin Austin, Dr Yu-Ling Cheng
	Background: In 2000, the WHO published Guidelines for Health Equipment Donations underscoring that despite transnational funders providing 80% of financing for medical devices in resource-limited settings, 72% are abandoned. Method: Interviewed 66 public healthcare and funding staff in Sierra Leone and Ghana, to characterize policies and practices involving donations of medical devices. Conclusions: Some donated devices enhance healthcare delivery, yet in the absence of technical leadership on hospital management teams, many funders continue to donate white elephants. A comprehensive device acquisition and leadership framework in Sierra Leone and Ghana will ensure that donations facilitate sustainable access to medical devices in public hospitals.
171	Extending the lifespan of donated medical devices
	Stefano Bergamasco, Dr Dinsie Williams, Prof Leandro Pecchia, Dr Ashenafi Hussein
	Problem: Almost 20 years after the WHO first published guidelines to foster good medical equipment donation practices, researchers continue to observe donated equipment being abandoned in large quantities in recipient countries. Method: The panelists will discuss how establishing a comprehensive acquisition framework and introducing technical leadership on hospital management teams can help recipients optimize the value of donations. These solutions build and expand on WHOs 2011 Considerations for Solicitation and Provision of Medical Device Donations.Lessons: Members of international organizations will learn how they can apply the framework to improve short- and long-term public health care initiatives in any setting.
212	Designing a sustainable ecosystem for medical equipment
	Asha Susan Varghese
	Estimates point to 70% of donated medical devices not functioning in low- and middle-income countries. GE Foundation contextualizes donation by tracing Health Technology Management (HTM) issues in health systems at the country level. Donations are coupled with strategic investments in capacity building for clinical users and technicians, social business enterprise solutions for maintenance, and supply chain and clinical engineering workflow innovations. Equipment donated by GE Foundation is starting to achieve 95% uptime in low-resource settings. Some of the innovative solutions are being considered for scaling by local governments and aid agencies. Medical device donations should be executed with local healthcare technology ecosystem in view and long-term sustainability.
PS17S	**Regulation of medical devices**
11	Status of Radiological Equipment used in Nepal.
	Kanchan P. Adhikari
	In Nepal, newer modalities of radiological equipment are being introduced and the latest radiological equipment are being imported. This quantitative increment may have a positive impact on the health service system; but the lack of control can create serious problem. Study was done to find out status of radiological equipment being used at health service. No acceptance testing, radiation monitoring, QA/QC program except radiation-therapy. After becoming a member country of IAEA has enabled us for the support and speed up of the creation of appropriate conditions. Time to establish radiation regulatory body for developing and monitoring of essential radiological safety, security and radiation control infrastructure in the country.

48	Centro colaborador OPS/OMS regulaciones dispositivos medicos

Dulce Maria Martinez Pereira

PAHO / WHO Collaborating Center Regulations Medical devices. Objective: To present the results obtained as part of the Program with the Collaborating Center taking into account a descriptive method by mapping to develop the Regional Regulator profile. The progress of the strategies contributes to the development of regulatory programs, combining the essential principles efficacy, quality and safe with the concept of medical devices and their risk categories. The legal technical base and relations with the regulatory environment lead to an analysis of the impact on the market, the assessment of conformity, post market surveillance and the effective use of medical devices obtaining an impact analysis on health.

79	Addressing decade long non-compliance of radiation safety in public health facilities of India

Ajai Basil, Mr Mohammad Ameel, Mr Vigneshwaran PS, Mr Anjaney, Mr SB Sinha

Problem or challenge:
In India, Atomic energy act and environment protection act is enacted to ensure radiation safety. A survey conducted in 7 States (Approx. Population: 198 million) reveals, even after 3 decades public hospital running medical diagnostic facilities are not registered with Atomic energy regulatory board or full compliance with radiation safety laws.
Method followed:
Analyze the inventory of radio-diagnostic devices across all the States in India and map with AERB to identify non-compliance. One time solution to incorporate compliance and educate healthcare professionals.
Conclusion:
Policy "AERB compliance on public health facilities" in India was formulated.

208	Regulation of e-medical devices in India

Eswara Reddy Sanapareddy

Central Drugs Standard Control Organization (CDSCO) exercises regulatory control over the safety, performance and qualityof notified medical devices under provision of the Drugs and Cosmetics Act,1940. Ministry of Health & Family Welfare, Government ofIndia has notified the Medical Devices Rules 2017 dated 31.01.2017 under the provisions of the Drugs and Cosmetics Act, 1940 to regulate the Clinical Investigation, Manufacture, Import, Sale and Distribution of the medical devices in the country. Only fifteen Medical Devices has been notified till date. The rules are in line with the regulation being followed across the globe.

244	Regulation of medical devices in the Americas: achievements and challenges

Mr Alexandre Lemgruber

The presentation aims to show the main achievements and challenges of the regulation of medical devices in the Region of the Americas. The role of the Regional Working Group on Medical Device Regulation will be described, as well as the topics that have been addressed by the technical groups: Exchange of Adverse Events Information; Personalized Medical Devices; Software as a Medical Device; Reuse and reprocessing of Medical Devices. Other important components of the Regional Working Plan will be highlighted: Capacity building, Regional Profile with basic indicators and the launch of the REDMA Program for the exchange of reports of adverse events.

	Oxygen supply systems
113	Improving appropriate technologies for oxygen delivery through engineering education in Malawi
	Elizabeth Suzanne Asma, Prof Rebecca Richards-Kortum, Prof Maria Oden, Prof Veronica Leautaud, Prof Theresa Mkandawire, Mr Matthew Petney, Ms Brittany Allen
	Over the last three years, withsupport from the Lemelson Foundation, Rice 360° introduced real worldengineering design projects into curriculum at University of MalawiPolytechnic. Supported by an Innovation & Design Studio, student teams carriedout needs assessment in neonatal wards across hospitals in Malawi. Theyidentified maintenance and repair of oxygen concentrators as high profileneeds. For the last two years, students have worked on projects ranging from on-siteregeneration of molecular sieves, to building low-cost external filters toprevent dust damage, and low-cost refurbishing of key compressor parts mostaffected by dust entering into the oxygen concentrators.
128	UNICEF initiatives to increase access to oxygen therapy systems in low-resource settings
	Heta Kosonen, Dr Beverly Bradley, Mr Mulugeta Mideksa, Dr Hayalnesh Tarekegn, Mrs Cindy Mcwhorter, Mr Paul Labarre, Mr Kristoffer Gandrup-Marino
	UNICEF will present current progress towards a UNICEF-WHO collaboration to increase access to and utilization of oxygen therapy systems in low-resource settings, including: 1.Interagency specifications and technical guidance for oxygen therapy products; 2.Updating of the UNICEF catalogue with specifications and products; 3.A prototype decision-assist tool for more efficient and informed oxygen system decision-making. This project will be presented within a broader portfolio of pneumonia initiatives at UNICEF, including: the ARIDA diagnostic aid project and SPRINT, a new $4M UNICEF initiative to develop a model for scaling a package of pneumonia innovations - including AmoxDT, oxygen, and POx.
PD9S	**Medical imaging for diagnostic and interventional procedures**
62	Improving medical imaging access, in India and globally: example partnerships, victories, and challenges
	Dr Miriam Mikhail, Mrs Melissa Culp
	Epidemiology and UHC discussions highlight the evidence-base for medical imaging in population-based healthcare planning - essentialfor diagnosis, management, image-guided interventions, treatment, andpalliation of prevalent conditions. RAD-AID International improves these servicesin > 25 countries. In India a focus is mobile outreach. Asha Jyoti ("Ray of Hope") has provided consolidated point-of-care service to >16,000 women: patient education, screening provision, andfollow-up for breastcancer, cervical cancer and osteoporosis, with seamless referral to specialists. Radiology is a focal point for addressing healthcare disparities and poverty. RAD-AIDalliances are led by in-country professionals. Global partnershipsare described.
134	Test tool for assessing lead equivalence in protective lead apparels
	Roshan Samuel Livingstone, Mrs Anna Varghese
	Knowledge on integrity and leadequivalence radiation protection apparels is necessary for radiation workers. Leadand lead-free aprons from 6 manufacturers were assessed using a simplecopper step wedge test tool. The percentage attenuation values were determinedat 100 kVp using an ionization chamber and the pixel intensities of test tooland apron were analyzed from digital radiographic images. Pixel intensityincreased with increase in the thickness of copper step wedge indicating acorresponding increase in lead equivalence in aprons.

135 Quantitative assessment of image quality in different digital radiography systems

Ms Benedicta Pearlin, Roshan Samuel Livingstone

Assessment of image quality from radiological images isgenerally qualitative and subjective. Differences in the flat panel detectors, output of the machine and software algorithms have a direct effect on imagequality. Quantitative assessment of image quality was performed for 5 digitalradiography systems using a perspex block and aluminium step wedge. Alldetectors exhibited wide exposure latitude to accommodate low and high radiationexposures. This method serves as aquality control tool to evaluate the efficiency of the detector over a period of time.

145 Meta-analysis on the diagnostics accuracy of different breast cancer screening modalities in low and high risk of breast cancer.

Akriti Chaha, Mr SB Sinha, Mr Mohammad Zoheb, Mr Shashwat Sharma, Mr Mohammad Ameel, Mr Ajai Basil, Mr Anjaney Shahi

Objective: To assess diagnostics accuracy of different screening methods in woman at low and high risk of breast cancer. Methods: Reviewers performed a literature search using PubMed & Cochrane database for the studies published between January 1, 2000, to February 28, 2018. Initially title and abstract of various studies were reviewed by the reviewer. Those study fulfilling the eligibility criteria were included in the study, the non-relevant or duplicate studies were reviewed and excluded from the study. Result: A total of (N=496) studies were identified through database search of which meta-analysis was carried out on 11 studies. Mammography as an intervention for breast cancer screening had sensitivity ranged from 0.33 to 0.93 while specificity ranged from 0.15 to 1.0. In ultrasonography as an intervention for breast cancer screening. The sensitivity for the included studies ranged from 0.17 to 0.92 and specificity ranged from 0.38 to 0.97. Magnetic resonance imaging as an intervention for breast cancer screening the sensitivity ranged 0.64 to 0.98 and specificity ranged 0.40 to 0.97. In case of Mammography & MRI as a combined intervention for breast cancer screening the sensitivity ranged 0.93 to 0.98 and specificity ranged 0.44 to 0.96. MRI & Ultrasonography as a combined intervention had sensitivity of 0.90 & specificity was 0.88. In case of Piezoelectric finger as an intervention of breast cancer screening the sensitivity was found to be 0.83 & 0.85 and the specificity was 0.75 & 0.93. Conclusion: During various stages of breast cancer the screening methods used in various studies are different. One of the study suggests breast MRI for routine breast cancer evaluation in women with dense breast parenchyma. In case of high risk group MRI along with mammography was found to have greatest potential to detect breast cancer. The highest sensitivity & specificity value was identified when mammography & MRI were used as a combined intervention.

219 Ultrasound facilities and expertise of health care providers in far flung, hard to reach district of Kashmir: a primary health care based cross sectional study

Ashiq Rashid Mir

Aims and objectives. To assess USG Doppler equipment and expertise availability at primary health care level. To identify lacunae in USG Doppler use at primary health care level. To give recommendations for improvements in USG Doppler utilization. Methodology: Study Area: Kupwara district of J&K India which has 2 district hospitals,6 CHCs and 31 PHCs. Study Design: Cross sectional study. Tools: District health data, interviews and pre-structured questionnaire. Sample size: All district hospitals, CHCs and PHCs in district Kupwara of Kashmir Valley. Conclusion: There is a dearth of Ultrasound Doppler machines and personnel to use them in primary health care system.

PD10S	Medical devices for treatments
44	Peritoneal dialysis for developing countries
	Mohammad Ameel, Mr Sb Sinha, Mr Ajai Basil, Mr Anjaney, Mr Vigneshwaran, Mr Bharat Dahiya, Mr Ujjwal Kumar
	The Government of India announcedthe National Dialysis Program in the budget 2016. The first phase of this program envisaged setting up of haemodialysis (HD) centers in all districts, which is being implemented. Peritoneal dialysis (PD), which is another form of standard dialysis therapy, was not included in this phase. However, dialysis programs around the world are developed on a combination of haemodialysis and peritoneal dialysis. Given that peritoneal dialysis avoids the substantial costs of infrastructure set up and maintenance and staffing, reduces the demand on healthcare system and offers patient autonomy, inclusion of peritoneal dialysis in the ambit of the National Dialysis Program is being considered. PD allows therapeutic intervention at home (or nearest to the community) which in turn reduces overall Out of pocket expenditure by saving the wage loss of the patient and his attendant which was not possible in HD patients requiring to travel to the district level twice/thrice weekly. Moreover young children especially those below 5 years of age are often unsuitable for HD. Such patients are preferably initiated on PD, home-based PD is better suited to their flexible lifestyle, including education, schooling and other childhood activities.
129	Indigenous cobalt-60 teletherapy technology- 4 years experience
	Prof Arun Chougule
	About 0.6 million require radiotherapy treatment roughly needing 1200- 1400 teletherapy units but have only 400 teletherapy units which is 0.3 per one million population. BARC developed indigenous Co-60 teletherapy machine and technology transferred for commercial production. Currently, Bhabhatron-II is most successful telecobalt unit. We are using Bhabhatron machine for over 4.5 years and treating more than 140 cancer patients daily with an uptime of 95%. Bhabhatron with MLC for conformal therapy developed. Bhabhatron has eight hours of battery backup and therefore the no treatment interruption in case of power failure. Further, it has asymmetric jaws and computerized patient registration data.
136	Towards crucial oral care of long term bed ridden elderly
	Steward Gracian, Sam Arjunan
	Challenge: Healthcare-associated Pneumonia is one of the leading causes of morbidity and mortality in dependant bedridden elderly residing in hospitals or long-term care facilities across India. Observation: In spite of the good evidence in the literature to support meticulous oral hygiene for reducing the progression of aspiration pneumonia in high risk elderly, oro-dental care is still a highly neglected aspect of bedside care. For already overburdened nurses, providing oral care for uncooperative elderly patients becomes a highly challenging task. Conclusion: Thus, there is an imminent need for developing an advanced assistive oral care device which can address this crucial challenge.

204	Pradhan Mantri national dialysis program
	Anjaney Lnu, Mr Shashi Sinha, Mr Ameel Mohammad, Mr Ajai Basil, Mrs Akriti Tomar, Mr Vighneshwaran S
	The Pradhan Mantri National Dialysis Programme Guidelines envisage provision of dialysis services under NHM in PPP (Public Private Partnership) mode. The model guidelines ensure comprehensive dialysis services delivery including pre and post diagnostics, drugs, surgical procedures, emergency care and the dialysis sessions etc at District & Sub district health facilities level. Financial supports are also given to all States who have engaged service providers for dialysis service in PPP mode and in-house mode prior to the launch of national guidelines. The Status of national dialysis program in State under CRM-11 are: Program has already been implemented in 7 States and in process of selection of service provider in 5 states through NHM guidelines in PPP-mode. The services are being delivered in-house in 2 States. The rate received per session are in range from Rs 870 to Rs 1450 per dialysis session.
PD12S	**Medical devices for non communicable diseases**
153	Proposed module for establishment of national cardiovascular database in low middle income countries
	Md Ashrafuzzaman, Mr Monjurul Ahsan, Mr Md. Sakib Abrar Hossain, Mr Nabil Islam
	Cardiovascular Disease (CVD) is an increasingly important cause of morbidity and mortality inlow middle income countries. This research objective is to develop module for identifyingactual number of cardiovascular patients for indexing. Module brings abundant populationwithin survey and impending CVD patients will be identified with risk factors. Byusing 3 leads ECG connected with IT platform, designed database will analyze CVDpatients' data of individual country. Assessment and intervention using suchmodule can be explored for proper diagnosis and treatment of CVD patients whichcan improve the patients' indexing, safety and health care management in thesedeveloping countries.
200	Medical technology and its role in establishing stroke care services globally: World Stroke Organisation and WHO perspective
	Jeyaraj Durai Pandian, Prof Michael Brainin, Prof Bo Norvving, Prof Werner Hacke, Dr Michel Patrik, Dr Pooja Khatri, Ms Adriana Velazquez-Berumen
	Stroke is the major cause of death and disability globally. However, stroke care services are not well developed in Low- and middle-income countries (LMICs). World Stroke Organisation (WSO) had published a road map and action plan for stroke care services across all levels of health care (minimal, essential and advanced). The objectives were to merge the WSO action plan with World Health Organisation (WHO) stroke intervention list and prepare a document which could be used by member nations in incorporating medical devices and technology in stroke care in both high income and LMICs. The merged document is being prepared jointly.
240	Dialysis outcomes in India: feasibility of dialysis outcomes data collection in India preliminary results of the India dialysis outcomes study
	Oommen John, Mr Abhinav Bassi, Prof John Knight, Prof Vivekanand Jha
	Haemodialysis is the main modality of renal replacement therapy in India. Electronic Health Records are not routinely available. The outcomes of those starting dialysis is not known as there is no national dialysis registry in India.We developed an online dialysis outcomes data collection portal, defining a minimum data set for measuring clinical and socio economic outcomes, and describe here the results of the feasibility study for establishment of a national dialysis registry in India from a cohort of 1000 dialysis patients from 9 Indian states.

242	Cancer prioritization tool
	Dr Dario Trapani
	In response to the Cancer Resolution Mandate(WHA71) and the UN SDG 3, our work is addressing a comprehensive 3-tier resource- adapted framework to set priorities in countries for cancer care (cancer prioritization tool), in a health system approach. Cancer interventions, defined per ICHI nomenclature and ICD-convention, are linked to medical devices, nomenclated as per WHO priority medical devices for cancer and identified by GMDN codes, as there is no WHO nomenclature; also, the required workforce is encompassed, as per ISCO and ILO, interlinked to cancer medicines (WHO EML). UHC is also addressed, considering the essential packages of cancer interventions to provide cancer care to all, ensuring financial risk protection.
138	Priority medical devices for cardiovascular, stroke, diabetes, and chronic respiratory disease management
	Karen Kulp, Mrs Mar Perez
	Non-communicable diseases such as cardiovascular, stroke, diabetes, and chronic respiratory diseases have topped global lists of mortality causes for the past fifteen years. Country-level efforts to provide universal healthcare coverage and keep populations health rely on access to safe, affordable, effective medical devices. In addition, countries need to know which medical devices should be prioritized for health interventions at each stage of treatment: from community-level preventative initiatives through diagnosis, treatment, ongoing monitoring, m/health or e/health, rehabilitation, and palliative or end-of-life care. Cross-referencing the diseases and intervention to existing WHO codification systems increases the practicality of the proposed reference publication.
PD14S	**Medical device packages for the primary health care and emergency response**
245	Priority medical devices for the primary level of care: experience from the Region of the Americas
	Mr Alexandre Lemgruber, Mr Alfonso Rosales, Mr Santiago Hasdeu, Mr Francisco Caccavo
	The presentation aims to highlight the results of a Regional project on Priority Medical Devices for the Primary Level of Care. The project team applied the same methodology used by WHO in publications such as Prioritymedical devices for cancer management and Medical devices for reproductive, maternal, newborn and child health. The clinical practice guidelines recognizedby WHO were used as the main reference to identify the products to be in the list. The first version of the list was reviewed by experts from the Region, and thenew version will be disseminate to all Member States by the end of 2018. Thegoal is that this list will serve as a model for national lists in the Region,c ontributing for a more rational use of those health technologies.
247	Standard list of medical supplies for WHO emergency response
	Laura Alejandra Velez Ruiz Gaitan, Mr Antoine Delaitre, Dr Ian Norton
	The WHO - Operations, Supply and Logistics department is in the process to build the standard list of medical commodities that are needed for WHO Emergency Response. It is part of the efforts to streamline the supply chain in WHO Emergency Operations. It would help to build WHO Catalogue with identified products and minimum specifications that ensure good quality, safety and effectiveness. Also, in the future some of those items will be stockpiled to improve response capacity and ease the needs of expression at the time of placing request.

PD3S	IVDs and laboratory services
2	Assessing optimal infectious diarrhea PoC diagnostic tests
	Vince Salazar Thomas
	PROBLEM: Infectious diarrhea remains a disease of stubbornly high mortality and morbidity, particularly among infants and children. Improvement in the range and availability of diagnostics for acute diarrhea has been identified as an important unmet need. METHOD: In light of the need for accessible and inexpensive diagnostics for implementation in LMIC contexts, a development planning exercise was undertaken to determine extant test availability, optimal enhancements in test and platform technology as well as feasibility. RESULTS: A portfolio of tests is suggested to guide disease management, applicable to remote as well as outbreak situations.
43	Point-of-care diagnostics for primary care
	Mohammad Ameel, Dr Rajani Ved, Mr SB SInha, Mr Ajai Basil, Mr Anjaney Shahi, Dr Madhur Gupta, Dr Yogita Kumar
	The Government of India announced that 1,50,000 Health & Wellness Centers (HWCs) would be created by transforming existing Sub centers and Primary Health centers to deliver Comprehensive Primary Health care under Ayushmaan Bharat. The credibility of a HWCs rests on the availability of essential medicines and diagnostics for a wide range of services provided by the HWC. The primary objective is to minimize the movement of the patient and improve the timeliness of reporting. This can be achieved by providing Point of Care Diagnostics and following the hub and spoke model, with context specific protocols for peripheral collection of samples.
55	National road-map on utilization of multi-disease point-of-care testing platform for HIV, TB and HPV testing in Kenya
	Dorcus Awuor Abuya, Ms Nancy Bowen, Ms Bintiomar Tsala, Dr George Githuka, Dr Richard Njoroge
	Background: PoC testing has demonstrated that it can greatly complement the conventionalsystem in Kenya. Part of the PoCT platforms have the potential to analysemultiple diseases. MOH-Kenya jointly developed the multi-disease policy document. Method: Development of key thematic areas and road map necessary for implementation Result:Successful development of an all-inclusive national document in Kenya that nowallows for use of multi-disease PoC Conclusion: Developed policy document will pave way for universal access to diagnostic services but in addition, aims at improving health systems tosupport the linkage to care, improved treatment outcomes and cost save atcounty level.
120	Development of the Essential Diagnostics List (EDL) for India
	Madhur Gupta, Dr Vandana Kumar, Dr Sonam Vijay, Dr Sandhya Kabra, Dr Kamini Walia
	In a path breaking development, 40 years after publishing the first Essential Medicines List, the World Health Organization (WHO) published the first Essential Diagnostics List (EDL) in 2018. India is the first country to ever begin the process of developing a National diagnostic list and this is a huge step for in the direction of improving Indian Healthcare system. In March 2018, India began the process of developing a National List of Essential Diagnostics, to complement the National List of Essential Medicines. Implementation of EDL will enable improved health care delivery through evidence-based care, improved patient outcomes and reduction in out of pocket expenses for patients.

209 Building consensus for creating a national essential diagnostics list: Indian experience

Sonam Vijay, Madhur Gupta, Sandhya Kabra, Kamini Walia

India's health care system is undergoing through immense churning at this stage and Government of India is taking serious steps to strengthen availability of diagnostics at various health care levels. Indian Council of Medical Research started the process for compilation of National Essential Diagnostics list (NEDL) in March 2018 by holding a first consultation with all the stakeholders and experts. NEDL along with the National Essential Medicine List, will form the basis of providing essential primary care services across the country, and greatly improve quality of care. The World Health Organisation (WHO)'s first Essential Diagnostics List (May 2018) has further provided direction to this process.
This poster/talk will present the process followed for development of National Essential Diagnostics List for India.

Annex 4: Posters

Posters: Title and author(s)

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	Diagnostics
24	3- Dimensional vasculography: non-invasive solution for cardiovascular disease
	Shikha Agarwal, Rajah Kumar
30	Healthdevicesdata.org - device data from across the globe
	Sandeep Kunkunuru, Sudheer Kunkunuru, Pradeep Kandru
31	Medical device safety: India's perspective
	Ritu Jain, Vivekanandan Kalaiselvan, Adusumilli Kumar
34	Fluorescent nanoparticle based sandwich immunoassays: a promise for ultrasensitive, affordable, rapid, robust and early detection of HIV infection
	L. A. Avinash Chunduri, Aditya Kurdekar, Mohan Kumar Haleyurgirisetty, Indira Hewlwtt, Venkataramaniah Kamisetti
61	Innovations in medical technology design and delivery
	Nita Sachan, Medha Hazari
84	Performance of a new portable, affordable diagnostic test to detect malaria parasites in India
	Poornima Arun Kumar, Praveen Bharti, Priya Thota, Tyler Witte
87	Role modeling for the healthcare delivery through genetic testing services: a public sector initiative
	Akshay Anand, Rahul Tyagi
89	Retinal lesions screening
	Mahalakshmi. S, Sudhesna Kar, Santi Maity
94	A non-contact system for early detection of Surgical site infection in postoperative patients
	Punit Ratnakar Fulzele, Syed Quazi, Abhay Gadhane
95	Quality control evaluation of qualitative and quantitative molecular diagnostic kits
	Manjula Kiran, Anoop Kumar, Ranjan Satapathy, Richa Baranwal, Reba Chhabra, Surinder Singh
96	Quality control testing of immunodiagnostic kits
	Chandranand PS, Reba Chhabra, Richa Barnawal, Surinder Singh, Gaby Vercauteren, Madhur Gupta
97	Inclination towards High throughput advanced technique over conventional method of diagnosis
	Rajeev Kumar, N. Gopal, Rajesh Sharma, Richa Barnawal, Reba Chhabra, Surinder Singh
98	Artificial intelligence in cervical cancer prediction
	Chandranand PS, Surinder Singh, Shalini Tewari, Dhruv Srivastava, Yasha Singh
100	Implementation of foldscope for the diagnosis of infectious diseases in rural areas
	Nishant Rajendra Burnase, Zahiruddin Syed, Abhay Gaidhane, Punit Fulzele

105	Comparison of visual and cytology cervical cancer screening in Maharashtra, India
	Renuka Matti, Dior D'Sa, Vibhav Gupta, Ariel Beery, David Levitz, Cathy Sebag
150	Budget impact analysis for ASHA+ (multi parameter monitor) in Indian sub-centres
	Devarshi Bhattacharyya, Tanushree Pavithran, Jitendar Sharma
156	Lightweight clinical chemistry analyzer connected to remote health monitoring platform
	Partha Pvt Chakraborty, Sumalya Sen, Santanu Bannerjee
158	Evaluation of pulmonary nodules using artificial intelligence
	Cai Long, Dawei Yang, Charles Powell, Tillie Hackett, Xiaoju Zhang, Jingfang Wang, Chunxue Bai
166	A novel portable device and thinning reagent for high sensitive TB detection at low resource settings
	Vikas Pandey, Pooja Singh, Saurabh Singh, Nasreeen Ehtesham, Ravikrishnan Elangovan, Seyed Hanain
167	Life- cycle management of drugs in US: a regulatory perspective
	Balamuralidhara Veeranna, Abhishek V, Kaushik D
169	SUGAM, pathway for medical devices: an easy approach
	Balamuralidhara Veeranna, Sidharth Malhotra
181	Design and development of micro sensor array actuating system for needle based biopsy
	Aswani Gera, Rajesh Burra, Rama Koti Reddy DV, Jyothi Vankara, Sowmya Injeti
191	Design of soft flexible cardiac sensor for remote and ambulatory monitoring
	Mahalakshmi Arumugam, Susithra R
227	Rapid pathogen identification and phenotypic antimicrobial susceptibility testing
	Niraj Kumar, Susmita Chaudhuri, Shinjini Bhatnagar

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56	Creating pool of skilled allied healthcare technicians
	Marut Setia, Neha Singh, Akanksha Kapoor
57	Telementoring tool for efficient use of equipment
	Marut Setia, Neha Singh, Akanksha Kapoor
99	Quality control for autoclaves in primary health care
	Renato Garcia Ojeda, Priscila Avelar, Jonas Maciel, Juliano Martins
101	Analysis for electrical system in healthcare methodology
	Renato Garcia Ojeda, Juliano Martins, Priscila Avelar, Pedro Zaniboni, Renato Zaniboni, Reginaldo Dias
103	Health technology ubiquitous management model for primary health care
	Renato Garcia Ojeda, Garcia Pezzolla, Reginaldo Soares Filho, Juliano Martins
164	Quality assurance and effectiveness in hospitals: strategic actions in Peru
	Pilar Rossana Rivas Tarazona, Tobey Clark
174	Software for tracking and prediction of performances of MDs. Planning maintenance
	Almir Badnjevic, Fabiola Martinez, Paolo Lago, Andrea Garcia, Mohammad Ameel, Ajai Basil

194	Design, assessment and maintenance of medical devices resilience to Sub Saharan Africa (SSA) working conditions: the Warwick experience
	Leandro Pecchia, Ashenafi Hussein, Daton Medenou, Roland Houessouvo, Davide Piaggio, Alessia Maccaro
223	Mobile application based wearable FHR contraction monitoring device for low resource healthcare settings
	Arun Agarwal
230	Medical devices for treatment
	GV Venkata Subrahmanhyam
231	Imaging Segmentation of Mandible to find the extent of Mandibular Invasion through CT Imaging
	Nagendra Pratap Singh, Vinay Singh, Balendra Singh, Vijay Kumar, Wishwas Gupta
236	Virtual NICUs for resource constrained settings
	Natarajan Sriraam, S. Tejaswini, G.C.M. Pradeep
237	Wearable cardiac monitoring device
	Natarajan Sriraam,V.S. Prkash, Abdul Wasim

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	Assistive devices
4	Teaching numeral concepts using technology supported traditional methods for children with multiple disability
	Prabakar Srinivasan, Ramanan Srinivasan, Cheranmadevi Karikalan
40	IOT based upper limb rehabilitation system
	Sekar Chander, Naveen Sharma, Sudesh Yadav
46	Thermal imaging as surrogate to compartment syndrome in orthopedic trauma patients
	Naveen Sharma, Vikas Bachhal, Dinesh Pankaj, Surjit Kaman, Anup Chander
133	Analysis of electromyography for the paralysis patient's recovery using CPM
	Bhavani S
206	Interactive interface based integrated hearing assessment and management system
	Sahidul Arefin, Fazle Kibria
214	Low cost medical device for measurement and low pressure generation
	Elena Salazar, Mauricio Andrade, Felipe Arboleda, Diego Duque
	E-health
152	Evaluation of e-subcenter of the ITDA parvatipuram area, vizianagaram district
	Ameya Vaze, Devarshi Bhattacharyya, Tanushree Pavithran, Jitendar Sharma
198	Artificial Intelligence
	Amitabh Dutta, Shyama Nagarajan
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39	A novel system to prevent ventilator associated pneumonia
	Nitesh Kumar Jangir, VImal Kakani, Nachiket Deval, Sujay Shetty, Abu Tauheed, Gopikrishna Babu, Raj Agrawal
51	An epidermal suspension spray device-skin spray gun
	Saiprasad Sanjay Poyarekar, Sandip Anasane, Bharatkumar Ahuja
58	Neonatal CPAP device for low-resource settings

	Nitesh Jangir, Nachiket Deval, Basava Kumar, Kristian Olson, Data Santorino, VImal Kakani
73	Artificial Breathing Capability Device (ABCD): a novel life-saving device for resource-limited settings
	Joseph Mathew, Manu Sharma, Sukesha , Navin Kumar
137	An effective way to truncate the formation of IV catheter clots and reduce the pain during flushing
	Navya Devireddy, Omsai NIdubrolu, Rama Rao N.V, Prashanti N.L, Maneesh Kumar Maddirevula, Rama Rao Nadendla
157	Development of ceramide loaded chitosan composite (ChiCeC) for biomedical applications universally
	Ashrafuzzaman, Afsana Mimi, Faiza Ahmed, Sabrina Shetu
179	FDTD simulation of preoperative treatment plan for liver cancer ablation with nanosecond electrical pulse
	Yanan Hu, Jinjun Zhu, Jiali Bao,Chaoyang Zhu
195	Development of a low-cost anesthetic gas analyzer to improve global surgical safety
	John Langell, Patrick Kolbay, Joseph Orr, Kai Kvock
196	Indigenous "555 Manish retractor" (patent pending) for innovative Optiview totally extra-peritoneal repair of inguinal hernia repair by 5mm ports
	Shyama Nagarajan, Manish Gupta
197	Customized 3D printed orthoses device: a rehabilitation solution for congenital hemiplegic children
	Harpreet Singh, Aarti Chauhan, Neelesh Kumar, Rishab Agarwal
	Regulation
233	Medical device Vigilance systems in USA and EU
	M.P.Venkatesh, N. Shashank, T.M. Pramod, V. Balamuralidhara
234	Drug - device combination product in USA and EU:regulatory perspective
	M.P.Venkatesh, Soorya Thaikadan, T.M. Pramod, V. Balamuralidhara

Posters: Title, author(s) and abstract

	Poster session - Thursday 13 December 2018
	Diagnostics
24	3- Dimensional vasculography: non-invasive solution for cardiovascular disease
	Shikha Agarwal, Rajah Kumar
	Objectives: A device for fast and cost-effective assessment of cardiovascular health in rural settings. Technique: By superimposing the measured haemodynamic data obtained from an individual on a multi-variable mathematical model, a pattern, called 3D-Cardiovasculography (CVG), is generated. The alterations in CVG are carefully analyzed using artificial intelligence and back propagation neural networks and the exact status of the coronary insufficiency can be reconstructed. Conclusion: It's now feasible to use 3D-Vasculographic techniques to detect the primary presence of CAD and to assess its severity, other cardiovascular abnormalities, pulmonary pathology etc., in mass screening of patients among the rural population.
30	Healthdevicesdata.org - device data from across the globe
	Mr Sandeep Kunkunuru, Dr Sudheer Kunkunuru,Mr Pradeep Kandru
	Introduction: Medical devices are manufactured and used across the globe. Regulatory bodies like FDA and CDSCO approve such devices and list them publicly. healthdevicesdata.org, a global web/cloud platform, aims to make all such device lists/databases available at one place. Such platforms don't exist until now creating information barriers on availability, safety and usage patterns of devices. Objectives: Provide: - access to databases. - full text search. - analysis results. - enable learning. Methods: Bulk download, web scraping and big-data techniques are employed using AWS. Results: healthdevicesdata.org currently covers FDA with 1,829,304 devices. It aims to cover CDSCO soon.
31	Medical device safety: India's perspective
	Ritu Jain, Vivekanandan Kalaiselvan, Adusumilli Kumar
	Medical Device Safety: India's Perspective Medical devices are an important part of health care, yet they are an extraordinarily heterogeneous class of products. Perhaps there are some unique challenges like safetyconcerns and diversity of products coupled with the sheer number of differentdevices in market that makes the development of an effective and efficientregulatory scheme a unique challenge for domestic as well as internationalregulatory bodies. Ministry of Health and Family Welfare, Government of India, has approved the commencement of "Materiovigilance Programme of India (MvPI)" (dated 10/2/2015) with Indian Pharmacopoeia Commission, Ghaziabad. MvPI programme helps in creating a nation-wide system for patient safety monitoring, analyze the benefit-risk ratio of medical devices, generateevidence-based information on safety of medical devices and supports CDSCO in the decision-making process on use of medical devices along with communicating the safety information on use of medical devices to various stakeholders to minimise the risk.
34	Fluorescent nanoparticle-based sandwich immunoassays: a promise for ultrasensitive, affordable, rapid, robust and early detection of HIV infection
	L. A. Avinash Chunduri, Aditya Kurdekar, Mohan Kumar Haleyurgirisetty, Indira Hewlwtt, Venkataramaniah Kamisetti

Exploiting the unique properties like higher quantum yields, greater stability, strong ability toresist photo bleaching, SiO2, ZnO, Silver nanoparticles, Goldnanoclusters, Copper nanoclusters, Europium nanoparticles and carbon quantumdots have been synthesized employing the appropriate cost effective synthesisroutes and engineered for the purpose of conjugating with streptavidin and functionalized withstreptavidin (SA) for detection of p24 antigens using the detection methods based on well-established non-covalent interaction between streptavidin andbiotin thus developing FNPIAs: SNIA, ZNPIA, FSNIA, GNCIA, CNCIA, EUNIA andCDNIA for the detection of infectiousdisease causing agents like HIV (Human Immunodeficiency virus) by Time ResolvedFluorescence (TRF) and fluorescence immuno assays.The analytical sensitivities have been evaluatedthrough clinical HIV+, HIV- blood serum samples and Thespecificity of the assays was further evaluated to test the interference ofother viruses in the detection of HIV-1 p24 by testing HIV-ve/HBV+ve HIV-ve/HCV+ve and HIV-ve/Dengue+ve plasmasamples. The protocol can be tested for blood samplesafter standardizing the protocol in lab. The findings of this study might helpin the developing a point-of-care detection kit which can be affordable, sensitive, specific, user-friendly, rapid, robust and equipment-free, and delivery to those who need it , a point-of-care detection kit for low -resource settings to enhance theoverall quality of life of global population.

61 Innovations in medical technology design and delivery

Nita Sachan, Medha Hazari

Cyient is working on an innovative ophthalmological device for detecting and assessing pupil related disorders by removing subjectivity around the traditional method of swinging flashlight test. This work is in collaboration with LV Prasad Eye Institute. The device intended use is to detect early stages of glaucoma and neurological issues. Cyient is also running a pilot at two PHCs in Mokshagundam village in Andhra Pradesh to demonstrate and test last mile delivery of cardiac care. Cyient in collaboration with Cardiac Design Labs (CDL) has deployed, MIRCaM, a portable ECG device designed to detect 48 types of cardiac conditions for three months.

84 Performance of a new portable, affordable diagnostic test to detect malaria parasites in India

Poornima Arun Kumar, Praveen Bharti, Priya Thota, Tyler Witte

Malaria is one of the most severe public health problems worldwide and is prevalent in tropical and subtropical regions. The mainstay of malaria diagnosis has been microscopic examination of blood and more recently rapid diagnostic tests (RDTs). Although inexpensive, microscopy is labor intensive, requires skilled personnel and has poor sensitivity and specificity, especially following parasitemia. Testing times for RDTs (~15-20 minutes) are shorter than microscopy (~30-60minutes) but accuracy concerns remain. RDTs cannot reliably detect parasitemia lower than 100-200 parasites/ÂµL and sensitivity varies across malaria species and variants. There is an acute need for imprtics that are not ooved malaria diagnosnly cost-effective but also rapid, highly accurate and detect species and strains that other diagnostics may miss, such as low-density infection, and P. falciparum with HRP2 deletion.

87 Role modeling for the healthcare delivery through genetic testing services: a public sector initiative

Akshay Anand, Rahul Tyagi

Background: Population explosion in India, is also leading to increased number of cases with aberrant genetic diseases. The bulk of genetic testing is taken by private sectors with limited participation of public sector leading to costly diagnostics. Growing need of timely and affordable diagnosis requires benchmarked Genetic testing services. MLPA is a potential tool of genetic diagnosis which detect the range of variations in DNA and suitable to be developed for resource limited settings.

89 Retinal lesions screening

Mahalakshmi. S, Sudhesna Kar, Santi Maity

Abstract Objective: Diabetic Retinopathy (DR) is character-ized by the progressive deterioration of retina with the appear-ance of different types of lesions that include microaneurysms, hemorrhages, exudates etc. Detection of these lesions playssignificant role for early diagnosis of DR.

94 A non-contact system for early detection of Surgical site infection in postoperative patients

Punit Ratnakar Fulzele, Syed Quazi, Abhay Gadhane

Introduction: Surgicalsite infection (SSI) is an infection that develops within 30 days after a surgery. SSIs remain a major cause ofmorbidity and death among the operated patients. The incidence of SSI rangefrom 5% to 50% across literature. Patients who develop SSI require significantly more medical care andincreased hospital stay. SSI are detected by clinical signs and symptoms, theinfection is at advanced stage.

95 Quality control evaluation of qualitative and quantitative molecular diagnostic kits

Manjula Kiran, Anoop Kumar, Ranjan Satapathy, Richa Baranwal, Reba Chhabra, Surinder Singh

The Immunodiagnostic Kit & Molecular Diagnostic Laboratory, National Institute of Biologicals (NIB), NOIDA, is involved in the quality control testing of serology and molecular based diagnostic kits for HIV, Hepatitis, Syphilis, to name a few. For the quality control evaluation of the molecular diagnostic kits, the plasma samples negative and positive for HIV/HBV/HCV are collected from various blood banks and hospitals from Delhi/NCR region. All the samples are then characterized individually at the molecular level for the true status. The plasma samples are designated as the panel member namely: Negative, HIV, HBV & HCV panels, which are then used for the quality evaluation of the kits forwarded to NIB by the Central Drugs Standard Control Organization (CDSCO).

96 Quality control testing of immunodiagnostic kits

Chandranand PS, Reba Chhabra, Richa Barnawal, Surinder Singh, Gaby Vercauteren, Madhur Gupta

National Institute of Biologicals (NIB) was set up in the year 1992 as an apex autonomous Institute under the administrative control of the Ministry of Health & Family Welfare, Government of India for promoting and protecting human health through various activities assigned to it. The mandate of the Institute includes ensuring provision of quality biological drugs i.e. In-vitro diagnostics, Vaccines and Bio-therapeutics, including therapeutic monoclonal antibodies used by patients suffering from cancer and autoimmune diseases by undertaking high end science-based testing with R&D interface for application of science. The Immunodiagnostic Kits & Molecular Diagnostic Laboratory has been declared as a Central Drugs Laboratory for Immunodiagnostic Kits since the year 2002 and re-notified in the year 2014. In addition, the Laboratory has acquired Central Medical Device Testing Laboratory (CMDTL) status in June 2018.

97 Inclination towards High throughput advanced technique over conventional method of diagnosis

Rajeev Kumar, N. Gopal, Rajesh Sharma, Richa Barnawal, Reba Chhabra, Surinder Singh

Immunoassays are valuable tools for the detection of blood borne diseases and per se are widely used for detection of specific antigen and / or antibodies present in the sample of interest in all over world. In the past three decades so many new principle-based immunoassays for screening of blood borne diseases like Hepatitis B Virus (HBV), Hepatitis C Virus (HCV) and Human Immunodeficiency Virus (HIV) have come in the Indian market viz Rapid, Enzyme Linked Immunosorbent Assay (ELISA), Enzyme Linked Fluorescent Assay (ELFA) and Chemiluminescence Immuno Assay (CLIA). Hence, quality of these kits needs to be evaluated before release in the market for population use. Based on the Quality Evaluation of these kits in our laboratory, it is observed that CLIA is a better alternative method over conventional or traditional assays particularly ELISA for detection of antigen and/or antibodies of these blood borne viruses.

98 Artificial intelligence in cervical cancer prediction

Chandranand PS, Surinder Singh, Shalini Tewari, Dhruv Srivastava, Yasha Singh

Machine learning aided by computer vision is one of the most advanced aspects of AI, and many algorithms are able to surpass the human ability to distinguish extremely fine details in clinical images, with tremendous promise of accuracy for diagnostic, pathology. Here, we project such methodologies in cervical cancer therapeutics, primarily focusing on detection of malignant cells. Cancer of cervix is the situation in which the cervix, which in normal situation is covered by a thin layer of tissue consisting of normal cells changes into malignant cells which have a tendency to grow and divide more rapidly than usual, thus developing into a tumor. By medical image processing and tissue texture analysis methods, cervical cancer screening at early stage becomes feasible and cancer can be controlled in the dysplasia itself, before it steps into chronic stage. The intelligent system approach for analysis of malignant cells is cost-effective and found to have an edge over the routine detection methods like Pap smear and Liquid cytology based (LCB) test or Colonoscopy or Cervicography etc in terms of accuracy and time.

100 Implementation of foldscope for the diagnosis of infectious diseases in rural areas

Nishant Rajendra Burnase, Zahiruddin Syed, Abhay Gaidhane, Punit Fulzele

Foldscope is a portable microscope and thus, it could be used as alternative for the conventional microscopy in the rapid diagnosis of infectious diseases. We are succeeded to identify fungal morphological structures by using foldscope and hence, parasitic helminth could be diagnosed by performing the foldscope-based stool microscopy, especially needed for the remote, impoverished areas lacking basic medical facilities. In addition to this, we are planning to develop a smart phone-based app which can identify the parasitic agents by the processing the images captured by the smart phone attached to foldscope thus minimizing the need of skilled technicians.

105 Comparison of visual and cytology cervical cancer screening in Maharashtra, India

Renuka Matti, Dior D'Sa, Vibhav Gupta, Ariel Beery, David Levitz, Cathy Sebag

India has the most deaths from cervical cancer in theworld. When available, cytology is the primary method of screening for cervicalcancer. Because cytology requires a laboratory infrastructure, visual screening- digital cervicography using a smartphone-based colposcope (Enhanced VisualAssessment (EVA) System) - was proposed. In this study, visual screening usingthe EVA System is compared to cytology. N=327 women, 20-50 years old from the Mumbai region of India were enrolled in the study. Positive with either methodwere referred to colposcopy with biopsy, following the standard of care. Of theN=327 patients, 304 patients were EVA-/Pap-, 19 patients were EVA+/Pap-, 0 Patients were EVA-/Pap+, and 4 patients were EVA+/Pap+. These results suggestthat cytology screening results had false negatives, some of which were caughtby the EVA System.

150 Budget impact analysis for ASHA+ (multi parameter monitor) in Indian sub-centres

Devarshi Bhattacharyya, Tanushree Pavithran, Jitendar Sharma

Introduction: ASHA + device is a multiparameter device for temperature, oxygen saturation, pulse rate, blood pressure, ECG, blood glucose and auscultation. The device being compact and easy to handle can be made available for the rural population. Objective: To quantify the cost of introducing ASHA+ device in Indian public health settings at the sub-centre level. Method: Budget impact analysis over a short time horizon of one year was done using secondary data. Outcomes were measured in Budget Impact, Budget Impact per sub-centre and Budget Impact per patient. Conclusion: ASHA+ device is an economically viable option to be introduced to the sub-centres.

156 Lightweight clinical chemistry analyzer connected to remote health monitoring platform

Partha Pvt Chakraborty, Sumalya Sen, Santanu Bannerjee

One of the significant costs of primary healthcare isrelated to the travel to a distant facility. Our cloud based remote healthmonitoring platform and lightweight connected 25 parameters clinical chemistry analyzerbrings care to the doorsteps of rural India by- bringing the physicians and the patients from differentplaces together- making the required diagnostics available to the caregiver, while monitoring progress of the treatment.12000+ patients are served in remote area of West Bengalusing the platform. Aftersatisfactory conduct of Investigator initiated trials, discussion with CDSCO iscurrently ongoing for regulatory approval of the analyzer.

158 Evaluation of pulmonary nodules using artificial intelligence

Cai Long, Dawei Yang, Charles Powell, Tillie Hackett, Xiaoju Zhang, Jingfang Wang, Chunxue Bai

Objective: Deep Convolutional Neural Network(DCNN) is a widely used artificial intelligence tool in medical imaginingstudies to aid clinical decision making. This study aimed to study the efficacyof applying DCNN on detection of pulmonary nodules and early diagnosis of lungcancer on a local CT image database and a public CT database. Methods: 375 CT scans of patients withpulmonary nodules in Zhongshan Hospital, China are obtained study, along with1018 cases from an open LIDC database. The DCNN system was constructed with twomodules: nodule automatic detection module and nodule automatic diagnosismodule. Both systems were trained and evaluated using LIDC and ZhongshanHospital dataset. In auto-detection module, the AI was trained to identifynodules from normal tissues.

166 A novel portable device and thinning reagent for high sensitive TB detection at low resource settings

Vikas Pandey, Pooja Singh, Saurabh Singh, Nasreeen Ehtesham, Ravikrishnan Elangovan, Seyed Hanain

Background Tuberculosis (TB) is a major global health burden with 10 million suspected patients causing 1.6million deaths in 2017. TB continues to remain a burden, as there are three million TB patientswho are left undiagnosed and each undiagnosed TB patient continues to spread the infection. Bringing all the TB patients under the treatment has been major focus as part of END-TBstrategy across the world. Definitive diagnostics of pulmonary TB is done with confirmation ofpresence of Mycobacterium tuberculosis (MTB) in sputum samples. Microscopy based TBdiagnosis i.e. Ziehl-Neelsen (ZN) screening still remains the primary diagnostic method in highTB burden countries, however this method has poor sensitivity (~60%). Recent developments inrapid molecular tests have changed the dynamics of TB diagnostics and treatment. Although itis recommended to screen all the suspected patients using these molecular tests but cost ofimplementation is a hurdle in the low and middle-income countries.

167 Life- cycle management of drugs in US: a regulatory perspective

Balamuralidhara Veeranna, Abhishek V, Kaushik D

Developingan innovative healthcare product from proof-of-concept stage to marketing stageis an expensive and complex process. It involves many years of research and development work. To save time and money in bringing products to market, productdevelopment activities should be conducted in accordance with the regulatoryrequirements. Tofacilitate the regulatory understanding that governs product development&ensure regulatory compliance. Now-a-days Quality Accreditations have become anintrinsic part in the regulatory submission package to gain the confidence fromRegulatory Authority. Quality Accreditations like GMP, GLP are applicable andto compile the procedure and the documents required for obtaining theseAccreditations from their respective Accreditation bodies. The eventual aim isto understand the impact of quality accreditations in the regulatory approvalsof pharmaceutical products.

169 SUGAM, pathway for medical devices: an easy approach

Balamuralidhara Veeranna, Sidharth Malhotra

SUGAMis the online portal for submission of the various applications related to manufacturingand import of medical devices and their clinical investigation to CDSCO inIndia. The objective of the SUGAM is to enable paperless grant of variousclearances by CDSCO, consolidate the Indian Drug Regulatory Framework bystreamlining the CDSCO processes, permit higher level of transparency in drugregulatory processes. SUGAM is launched by the Ministry of Health & FamilyWelfare.cThe various applications that are submitted through this portal arepermission to import drugs, medical devices, cosmetics and biologicalPermission to conduct clinical trials and BA-BE studies etc. SUGAM plays amajor role in Pharmaceutical regulatory sector by making submission more simpleand easy. The intentions of current study is to apprehend the software & online portal requirements and registration process of Medical devices in India.

181 Design and development of micro sensor array actuating system for needle based biopsy

Aswani Gera, Rajesh Burra, Rama Koti Reddy DV, Jyothi Vankara, Sowmya Injeti

When inadequate tissue sampling or marked artifactual alterations preclude a definitive diagnosis, it isappropriate for the pathologist to recommend that the surgeon repeat the biopsy. Repeating these invasive biopsy procedures increases the potential complicationsfor the patient. Needletract seeding refers to implantation of tumor cells by contamination wheninstruments like biopsy needles are used to examine, excise or ablate a tumor. Here, we propose a design and to develop a clinical micro-system which can beclambered up the biopsy needle to distinguish the healthy tissue with abnormaltissue during the biopsy procedures, thereby mitigating the need for repetitivetissue sampling. The system developed will aid in tissue characterization bydistinguishing the modulus.

191 Design of soft flexible cardiac sensor for remote and ambulatory monitoring

Mahalakshmi Arumugam, Susithra R

Contemporary cardiac and heart rate monitoring devices capture physiological signals usingoptical and electrode-based sensors. However, these devices generally lack the formfactor and mechanical flexibility necessary for use in ambulatory and homeenvironments. In our proposed work, the WiSP device will be a highlyminiaturized and low-power bio sensing platform, which can be readily appliedfor remote cardiac monitoring of endurance athletes and heart disease patientsand for soldiers. By exploiting advances in flexible electronics and softpackaging technologies, a new class of ultrathin, highly flexible wearable cardiac sensor (WiSP) designed to be minimal in cost (disposable), light weight, water resistant and capable of wireless energy harvesting.

227 Rapid pathogen identification and phenotypic antimicrobial susceptibility testing

Niraj Kumar, Susmita Chaudhuri, Shinjini Bhatnagar

Unavailabilityof rapid diagnostics for pathogen identification andantimicrobial-susceptibility-testing has been the significant factorcontributing towards unnecessary/inappropriate use of antibiotics resultinginto emergence/spread of antimicrobial-resistance (AMR) among pathogens. We aimto develop syringe compatible, single-use, affordable and user-friendlycombination of device that can isolate bacteria from whole-blood/urine samples, enrich, culture, identify and establish their antimicrobial susceptibility profile(s) for multiple drugs simultaneously within 90-minutes. The proposed solution would help in guided clinical-decision making and minimize empiricaluse of antibiotics resulting into reduced emergence/spread of AMR.

	Poster session - Friday 14 December 2018
	HTM
56	Creating pool of skilled allied healthcare technicians
	Marut Setia, Neha Singh, Akanksha Kapoor
	Objectives: Address the skill gapamong allied HCPs in IndiaMethod: Skilling program totrain 10,000 underprivileged youth as X-Ray, OT/AT, Radiology and CC technicians.1-year program, soft loans from Tata Trusts. Results: 42 centers across 17 state >2500 students enrolled, 95% pass percentage, ~80% placements Social impact: 42% women candidates, 96% families reported increased hygiene and health-seeking behavior·Economic impact: Rs 20k per monthhighest salary, 70% women feel financially empowered, 92% students contributingto household income, Relevance to industry: HSSC-approvedcontent, 100% course-job match as per employersLessons learnt: Focus on setting up centersin rural areas
57	Telementoring tool for efficient use of equipment
	Marut Setia, Neha Singh, Akanksha Kapoor
	Objectives: A real-timetelementoring solution for techniciansMethod: Digital Expert is aremote support tool for technicians who are guided through advanced scans, thereby reducing wastage of time/materials and preventing iterations. It helpsimprove image quality for better patient diagnosis. It makes imaging expertise aclick away and provides a self-paced learning platform to increase technician knowledgeand confidence. Results: Pilotedin 12 locations pan-India. 85 trainings conducted on CT & MRI. Lessons learnt: This tool has the potentialto be a real-time, global peer training solution in remote areas so there isa need for localization of content and trainers.
99	Quality control for autoclaves in primary health care
	Renato Garcia Ojeda, Priscila Avelar, Jonas Maciel, Juliano Martins
	Sterilization is a critical process, which if notperformed effectively can cause to infection through the use of contaminated healthproducts. The Clinical Engineering (CE) has contributed to the adherence to bestpractices in the processing of health products in the sterilization phase ofarticles in the SterileServices Department (SSD). Class I SSD control is not effective, monitoring of the sterilization process is performed only by biological indicator. This paper presentsa quality control program for autoclave of 20 to 50 liters. Based on the analysis ofhistorical and failure modes (HFMEA) and Brazilian Technical Standards - NBRfor validation of equipment used in SSD and in the resolution of best practices, aiming at patient and clinical safety.

101 Analysis for electrical system in healthcare methodology

Renato Garcia Ojeda, Juliano Martins, Priscila Avelar, Pedro Zaniboni, Renato Zaniboni, Reginaldo Dias

TheElectrical System infrastructure (ESI) in Healthcare Facilities (HF) must beappropriately evaluated. ESI may be unbalance in the three-phase circuit, peakand voltage drop that are as possible causes of failure in sterilizationequipment and other medical equipment. It causes interruptions in the HFservice and safety loss, reliability reducing of the medical technology. TheClinical Engineering (CE) is not always present in the sector when the faultoccurs, making it difficult to analyze the problem, and it is necessary torecording ESI parameters. This paper presents a methodology for evaluating ESIparameters in HF, based on Brazilian Technical Standards NBR 5410, NBR-13534and National Electric Energy Agency Protocol (ANEEL).

103 Health technology ubiquitous management model for primary health care

Renato Garcia Ojeda, Garcia Pezzolla, Reginaldo Soares Filho, Juliano Martins

A model of Ubiquitous Technology Management that uses sensing of technology inreal time in decentralized primary health care is a tool of support theClinical Engineer. This methodology is based on three categories: theoperational category develops solution and identification of monitoring parameters. The monitoring divided in Layers of: Sensor, Processing, Standardization andManagement. And the Decision category uses Artificial Intelligence for actionsof technology management. A case study was applied to the primary health carecenter more than 3 miles away in dental compressors. The Monitoring responsesbrought important information adds reliability and safety for the performanceof Clinical Engineering.

164 Quality assurance and effectiveness in hospitals: strategic actions in Peru

Pilar Rossana Rivas Tarazona, Tobey Clark

The Ombudsman Offices findings in Peru on 2017 were: 21.7% of hospitalsdo not have an ambulance for emergency units; 44% of the organizations do nothave the required equipment for patient care, etc. MoH-Health Maintenance &Equipment Direction and the Comptroller Office of the Republic of Peru-CORPHealth Control Direction joint efforts to lead the implementation of HealthTechnology Units. Actions will be developed with the Health TechnologyManagement WHO Collaborator Center of the University of Vermonts advisory. Staff physicians, engineers and architects will be trained with internationalstandards. Starting on 2019, a process of training and quality control isplanned; the poster describes the goals, challenges and actions based on HealthTechnology Management, Health Technology Planning and Assessment.

174 Software for tracking and prediction of performances of MDs. Planning maintenance

Almir Badnjevic, Fabiola Martinez, Paolo Lago, Andrea Garcia, Mohammad Ameel, Ajai Basil

Different software solutions in healthcare are extremely necessary especially because of big data issues. Management of Medical Devices (MD) is one of themost important challenges too. eVerlab software solution, for tracking inspection processes is an easy accessible and reliable online program updatedon Verlab Inspection Laboratory's website and comprises imported records ofperformance statuses based on inspection processes of MDs in all countryhealthcare institutions. This database is allowing application of MachineLearning techniques on existing data for prediction of performances of MDs and also for planning the maintenance.

203	Redefining neighborhood networking in palliative care (NNPC) in heterogeneous society a case study
	Jaseela Majeed, Hamza K. V., Suresh T. P.
	Homogenous society of Kerala has developed astructure for palliative care labelled as Neighborhood Networks inPalliative Care (NNPC). Based on the same structure, DNipCare, Delhiites National Initiative in Palliative Care, a voluntary initiative was formed for rural/Urban poor.
213	Integration of maintenance activities of biomedical equipment: maintenance model applied in the entities of San Vicente Fundacion
	Francia Elena Salazar, Olga Tobon, Michel Gomez, Maximiliano Trujillo
	San Vicente de Pal hospital is an health services provider institution with an emphasis on high complexity patient care.A research leader that recognizes biomedical devices as elements that directlyimpact the well being and life expectancy of people; This policy is reflectedin the management of a properly structured maintenance plan, which is executedhand in hand with the implementation of performance and safety inspection procedures developed under local and international recommendations that ensure the safeuse of the technology. This has allowed us to prolong the lifetime of our equipment and decrease substantially the report of corrective maintenance.
218	Promoting good practices in clinical engineering in Colombia
	Elena Salazar, Leonardo Garcia, Andrea Garcia, Mr Paula Berrio, Maximiano Trujillo, Javier Garcia
	With the aim of promoting good practices in Clinical Engineering in Colombia and bringing the knowledge to all professionals working in hospitals and clinics in the country, the Colombian College of Clinical Engineering (COLCINC) has been created. The foundation of COLCINC was carried out in 2017 by 10 leading clinical engineers in Colombia. As initial results we can highlight the academic forums with topics related to clinical engineering, the creation of the WEB page through which constant interaction is promoted through news publication, answering of questions, academic events, among others.
243	In Search of Harmonized Nomenclature for Medical Devices
	Adriana Velazquez Berumen, Umberto Vitale, Rebecca Lee Baker, Laura Alejandra Velez Ruiz Gaitan, Maurice Page, Karen Kulp, Daniel Diethei
	The Health Sector is aware of the need of a harmonized nomenclature/coding system for medical devices, encompassing their entire lifespan.From development through testing, approval, manufacture, procurement, use, maintenance and finally disposal or recycling, WHO envisions unique nomenclature and device identification codes, freely and entirely available for all.WHO launched a survey in 2018, whose results confirmed the global intention of progressing in this direction.A pilot project has been undertaken to create a nomenclature system inspired by current systems, based on ICD-11 ontological database platform.Stakeholders are encouraged to join this initiative on the freely available medical devices nomenclature.
	Innovation
1	Social and economic implications of technology transfer
	Luca Passaggio

The technology transfer of medical devices involves complex economic and social aspects, which contribute to the development of the recipient country.When a recipient country or organization is adopting and replicating the technology, skills and knowledge from another country or organization, with the ambition to improve and expand further, then the whole country receives social and economic benefits from the technology transfer.These benefits are 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 transfer of manufacturing technology within the domain of medical devices involves different channels, concepts and algorithms, but the human factor and the standard of living are a priority if we want to start the whole process of social and economic development in a society.

22 Clinicaltrialsdata.org - trial data from across the globe

Sandeep Kunkunuru, Sudheer Kunkunuru, Anil Pattabhi

Introduction: Clinical trials are executed across the globe and several trial registries, including 16 primary registries (as designated by WHO), exist today. This poster aims to introduce clinicaltrialsdata.org - a web platform built to make data from all trial registries available. Objectives: Clinicaltrialsdata.org aims to collect data from all trial registries near real-time and on-demand across the globe to provide below features. - access: to all trials registered anywhere. - full text search: on all registry records. - discover: additional information about a trial - compare trials - analysis of trials Methods:Clinicaltrialsdata.org collects data using bulk download, web scraping and applies various data transformation techniques using APIs and cloud-native technologiesResults:Clinicaltrialsdata.org currently covers 14 registries 493,447 trials across 4 continents and more than 20 countries.Lessons:Discovering links across registry records is important and helps cross-validate and enrich information.

32 Global medical innovation through an integrated approach

Tomasz Petelenz, John Langell, Joel Bagley

Objectives: 5-Billion people lack access to safe surgical care, partially due to a lack of high-quality, low-cost surgical equipment. Our objective was to use our innovative Design Box process to create a solution to this problem.

68 International technology bazaar

Aynampudi Subbarao

Last mile for Researchers is connecting them to market and that market can be faraway, unknown, uncertain. International Technology Bazaar operated by Indian Innovators Association connects innovators with buyers. It is online portal, where information on innovators participating in major International Fairs, China, Korea, Germany etc is uploaded. With network partners in various countries, the leads generated will be converted into deals.

74 Completing the cycle from innovative idea to invention implementation in India: challenges and solutions

Joseph Mathew

In developing countries, a very small fraction of medical deviceinnovations reaches the stage of implementation in clinical practice. The majorreasons for this are: (1) Failure to consider the end-user (healthcareprofessional/consumer) perspective during innovation. (2) Failure to complete thefull cycle from Idea to Innovation to Invention to Testing (Laboratory &Clinical), Regulatory approval, Commercialization, Implementation, & Post-implementationsurveillance. (3) Focus on efficacy without due emphasis on patient safety. Recognizingthese challenges, a novel programme has been initiated in Chandigarh (India)wherein partners from healthcare and technology institutions collaborate totranslate innovative ideas from real-world clinical scenarios to innovativemedical devices through the full cycle described above.

77 Ptosis crutches: an experience on making an open-source medical technology

Sudesh Sivarasu, Saberi Marais

Ocular Myasthenia Gravis (MG) affects eye muscles, resultingin the patients struggling to control and raise their eyelids. The resultingdrooping eyelids can impact their line of sight, general vision and quality of life. The Ptosis Crutch, developed bythe UCT Biomedical Engineering group is an adjustable crutch that can be fittedto spectacles to support one or both eyelids. after receiving approval from theNational Intellectual Property Management Office (NIPMO), UCT providesprototypes of the device under open source license. The abstract discusses the experiencesof making a medical technology and how this has increased availability of the Ptosis Crutch device to public.

80 Design thinking workshop - reimagining healthcare with device innovation and digital

Surinder Rangi, Divesh Sisodia, Navjit Brar, Odd Sandbekkhaug

Healthcareindustry has been very slow in adoption of technology to improve the wayhealthcare is accessed and delivered for decades. There is a need to find newways to approach healthcare in general to become more consumer/patient centric. Design Thinking is ahuman-centric approach to problem solving. It starts with the human user, createsmore solution choices and then refines the solution through rapid prototyping. In this participativeworkshop we practice design thinking to reimagine a "home healthcare"based patient journey and design a future state journey using a combination ofmedical device innovation and digital technologies

81 Medical device development: prototypes, stakeholders, and settings

Marianna Coulentianos, Ilka Rodriguez-Calero, Jocelyn Burridge, Shanna Daly, Kathleen Sienko

This study aimed to characterize prototypetypes, diversity of stakeholders engaged, and engagement settings leveraged bypractitioners during the front-end phases of a medical device design process. Semi-structured interviews were conducted with 24 design practitioners from 17companies. Distinct stakeholder groups, prototype types and engagement settingswere identified. Prototypes were classified as physical or virtual, and as conveying information about form and/or functional goals. These outcomes demonstrate the depth and breadth of stakeholderengagement with prototypes in the design front-end and can inform future design practices.

82 Characterizing stakeholder input as prototype quantities are varied

Marianna Coulentianos, Jocelyn Burridge, Shanna Daly, Achyuta Adhvaryu, Kathleen Sienko

This study aimed to explore thedifferences in types of information gathered from stakeholders as the number ofprototypes presented during Requirements Elicitation (RE) interviews varied. Structured RE interviews were conducted with 36 medical professionals in Ghana.Participants were presented with three, one or no prototypes of a medicaldevice concept solution. Preliminary findings suggest that the presentation ofthree prototypes resulted in the solicitation of a greater proportion of product quality requirements compared to the other conditions. Additionally, the lackof a prototype during a RE interview led to the generation of more contextualrequirements compared to the other conditions.

116 Prematurity or Intrauterine Malnutrition: an international multicenter clinical trial protocol to validate a new medical device, the Preemie-Test

Zilma Reis, Sergio Taunde, Gabriela Vitral, Carolina de-Silvo-Josev, Roberta Romanelli, Rodney Guimarves

Background: We previously reported the newborn's skin reflectance analysis to assess gestational-age (GA), facing the high costs of current approaches. Objective: To validate the Preemie-Test for GA estimation at birth and its accuracy to detect prematurity and small-for-GA newborn, through the mathematical processing of optical properties of the skin.

180 Internal resource re-organization to match external regulating factors and to improve utilization of equipment in a tertiary care teaching hospital and its satellite center in north India

Dumpala Venkata ravi Kiran, Ashok Kumar, Anil Gupta, Navin Pandey, Narendra Kumar, P. Sharma

Resource constraints is a major hurdle in providing quality health care services in developing countries. Recruitment of manpower falls on the top of them and is been governed by many external factors. Aim of the study is to emphasize the need of an internal re organization of the human resources within the regulations to deliver services effectively. study is conducted by analyzing the recruitment rules and adjusting the manpower according to the need of the time which concluded that reshuffling and re organizing the human services helped in providing better services.

190 Alternative birthing positions

Nichodemus Kafui Gebe, Cecilia Ampadu, Emmanuel Srofenyo, Adusei

The child delivery policy of Ghana prescribes that all mothers should deliver in health facilities whereskilled deliveries can be assured. The main challenge inhibiting theimplementation of the policy is the thriving services of Traditional BirthAttendants, who offer preferred birthing positions to clients, not in government facilities. This led to the development of a simplestainless steel delivery chair in Ghana, now being piloted. It has been used successfully in delayed second stage; intra-uterine foetal death with hydrocephalus (IUFD); shoulder dystocia. The chair was adopted as one of West African Health Organization (WAHO) Good Practices for Maternal Health in 2016.

194 Design, assessment and maintenance of medical devices resilience to Sub Saharan Africa (SSA) working conditions: the Warwick experience

Leandro Pecchia, Ashenafi Hussein, Daton Medenou, Roland Houessouvo, Davide Piaggio, Alessia Maccaro

Global population is mainly diagnosed and treated in low-resourcesettings. Yet medical devices are designed, assessed, donated or maintainedreflecting high-resource country needs, knowledge, protocols and regulations.This hinders the diffusion of safe and effective medicine in SSA.The Applied Biomedical Signal Processing and Intelligent eHealth(ABSPIE) lab, University of Warwick, is collaborating with Scholars in Beninand Ethiopia, IFMBE and other international experts, demonstrating how innovativeengineering paradigms and tools (e.g., circular economy, local manufacturing,3D printing, artificial intelligence, cloud computing, smart phones) canincrease resilience of medical devices in SSA.This talk will present ABSPIE results and vision.

223 Mobile application based wearable FHR contraction monitoring device for low resource healthcare settings

Arun Agarwal

Every year, an estimated 1.02 million intrapartum stillbirths, 904000 intrapartum neonatal deaths & 250000 maternal deaths occur globally.
During intra-partum period, fetal heart rate and uterine contraction monitoring is really important to know the status of themother and fetus, but monitored inaccurately and ignored more than 85% of thetime. This leads to mortality/morbidity in case of any anomaly. Existing devicecardiotocography is high cost (200000 INR), non-portable (5 Kg) and requiredskilled healthcare worker for continuous monitoring of FHR & uterinecontraction displays both the parameters in a graphical format

230 Medical devices for treatment

GV Venkata Subrahmanhyam

TheUN Political Declaration on noncommunicable diseases (NCD) states that NCDs"constitute one of the major challenges for development in the twenty-firstcentury." Hence noncommunicable diseases (NCDs), has significantly underminedthe social and economic development of LMI countries. Among the NCD's a broaderresponse is required for cancer. Globally, for most common cancers Radiotherapyis an integral part of treatment delivery.

231 Imaging Segmentation of Mandible to find the extent of Mandibular Invasion through CT Imaging

Nagendra Pratap Singh, Vinay Singh, Balendra Singh, Vijay Kumar, Wishwas Gupta

Oral cancer or Oropharyngeal cancer is the third most prevalent type of cancer in India. It comprises 30 percent of all cases of cancer. In all the cases of oral cancers squamous cell cancers are the major percentage of the cancers seen in India. It comprises 9 out of 10 cases of oral cancer. Doctors use CT scan images the extent of mandibular invasion which help them to remove the infected bone during the surgery. In the current scenario, there are specific segmentation algorithms for lung, abdominal, spine cancers but none for oral cavity. Because of absence of specific algorithm doctors remove 2cm more bone as detected in the images.

236 Virtual NICUs for resource constrained settings

Natarajan Sriraam, S. Tejaswini, G.C.M. Pradeep

In Today's Scenario, neonatal healthcare needs special attention towards controlling the mortality rate with continuous monitoring facilities. For Biomedical Engineering Community, Design and developing a framework for neonatal intensive care is quite challenging. This proposed framework comprises of automated monitoring of physiological vital parameters along with the pathological parameters to assess the pain level of neonates admitted to the NICUs.

237 Wearable cardiac monitoring device

Natarajan Sriraam, V.S. Prkash, Abdul Wasim

Wearable Cardiac monitoring has created a huge impact on the society with sophisticated technology connectivity. For Developing and underdeveloped nations, there is a huge need to develop such technologies with low cost device design without sacrificing the required clinical diagnosis. A wearable cardiac framework is proposed which makes use of textiles material as sensing medium to acquire the cardiac signals continuously. The selection of textile materials ensures the required bio-compatibility and adequate skin impedance for signal recordings.

	Poster session - Saturday 15 December 2018
	Assistive devices
4	Teaching numeral concepts using technology supported traditional methods for children with multiple disability
	Prabakar Srinivasan, Ramanan Srinivasan, Cheranmadevi Karikalan
	Across the globe, children with disabilities have attended the school with an emphasis on learning functional living skills. In mathematics teaching process student response is comparatively very less especially children with Multiple Disabilities (MD). The aim of this proposed study is to utilize simple Traditional(games) Approaches with Technology Support (TATS) for effectively Teaching Numeral Concepts through which enhance the cognitive, affective and psychomotor skills.Individualized Education Program models are articulated with essential strategies for every student in learning mathematics through TATS.
40	IOT based upper limb rehabilitation system
	Sekar Chander, Naveen Sharma, Sudesh Yadav
	Objective: Development of a feedback integrated rehabilitation station for upper limb functional training. Method: Physical objects for upper limb hand functional training activity are identified and integrated with a feedback system. The system is embedded with sensors to measure force applied, position, and acceleration. Processed data is then displayed on a user (healthcare providers, patients) oriented display system.
46	Thermal imaging as surrogate to compartment syndrome in orthopedic trauma patients
	Naveen Sharma, Vikas Bachhal, Dinesh Pankaj, Surjit Kaman, Anup Chander
	Objectives:1. Design and development of computer aided diagnosis (CAD) system for thecompartment syndrome affected patients using thermal imaging. 2. Availability of captured data to healthcare providers and patients for progress assessment.
133	Analysis of electromyography for the paralysis patient's recovery using CPM
	Bhavani S
	Abstract: More than 15 million people suffer paralysis every year according to WHO. OfÂ these, 5 million do not survive and another 5 million remain disabled permanently. Another problem is that Human elbow joint gets fractured or dislocated due to accidents. Paralysis or elbow dislocated patients will be suffered from muscle stiffness and joint stiffness. There are nearly 1 in 50 people are affected by paralysis which restrains the free movements of human body parts. Such people rely on support systems that can aid motion and force enhancement to body parts affect by paralysis.
206	Interactive interface based integrated hearing assessment and management system
	Sahidul Arefin, Fazle Kibria

At present hearing loss is the 3rd most common health issue after arthritis andhypertension. Hearing clinics are available only in tier 1 cities. Clinics are few in no, not easy toaccess and also unaffordable. In India there is only 1 audiologist to serve apopulation of 9.5 lakhs. Polymerbased sensor with software assembled operating system make the device portable advanced and low cost. This homemade venture is easy and convenient to use, time efficient, can create huge employment opportunities and increase accessibility.

214 Low cost medical device for measurement and low pressure generation

Elena Salazar, Mauricio Andrade, Felipe Arboleda, Diego Duque

Endotracheal intubation isa technique frequently used in medical interventions; effective for assistancewith mechanical ventilation in adults and children. However, it is linked totracheal damage with potential complications associated mainly with pressurevalues that are handled in the endotracheal tube balloon.

E-health

152 Evaluation of e-subcenter of the ITDA parvatipuram area, vizianagaram district

Ameya Vaze, Devarshi Bhattacharyya, Tanushree Pavithran, Jitendar Sharma

Introduction- With a shortage of Doctors at theprimary level of healthcare, and the growing burden of chronic degenerativediseases, subcentres with video consultations and drug dispensing facilitybrings primary healthcare at the doorstep of the beneficiary. Cost evaluation& Patient satisfaction is considered an important parameter in assessingthe quality and success of any healthcare initiative

198 Artificial Intelligence

Amitabh Dutta, Shyama Nagarajan

Human beings have complex genetic and constitutional makeup with host of inter/ intra racial variability. The symptomatology due to a disease process affecting bodily integrity is also therefore hyper-variable; influenced by circumstantial, nutritional, and ageing process of the select patient. Also, as the training, knowledge, motivation to serve patients interest differs with different experts, the decision-making is impacted differently. Current practice guidelines/standards notwithstanding, the variability quotient of experience in application of principles of medicine, the translatability and two-way outcome tracking suffers, which more often than not leads to inadequate treatment and sub-optimal handling of the disease through its natural course.

Treatment

39 A novel system to prevent ventilator associated pneumonia

Nitesh Kumar Jangir, VImal Kakani, Nachiket Deval, Sujay Shetty, Abu Tauheed, Gopikrishna Babu, Raj Agrawal

Background: Ventilator associated pneumonia is one of the most common and the most critical hospital-acquired infection across the globe. Objective: Clinical evaluation of first in the world an intelligent secretions and oral hygiene management system to prevent VAP.

51 An epidermal suspension spray device-skin spray gun

Saiprasad Sanjay Poyarekar, Sandip Anasane, Bharatkumar Ahuja

An injury due to burning is a critical problem in India, around 1.4 lakhs people die every year due to burning. World Health Organization (WHO) has observed that a burning injury is the seventh leading cause of death in the world. Classic skin grafting process is the current standard medical process used in the treatment of burning injury. The pneumatic system has been developed which spray skin pieces (skin graft) on the wound enabling to cover large wound area and faster healing. Experimentation with the cadaver skin developed system has been achieved skin expansion of 1:25 in the simulated environment.

58	Neonatal CPAP device for low-resource settings
	Nitesh Jangir, Nachiket Deval, Basava Kumar, Kristian Olson, Data Santorino, VImal Kakani
	Background: CPAP therapy, a key intervention to reduce neonatal mortality, is not available in secondary care settings or during transport to a NICU. This leads to avoidable mortality and morbidity. Saans is the first device to address this specific need gap. Objective: Clinical evaluation of safety and efficacy of Saans.
73	Artificial Breathing Capability Device (ABCD): a novel life-saving device for resource-limited settings
	Joseph Mathew, Manu Sharma, Sukesha , Navin Kumar
	Each year, thousands of patients require mechanicalventilation/ artificial respiratory support, but this is not readily availabledue to resource constraints. Many end up receiving manual ventilation performedby untrained personnel including family members. This uncontrolled procedureresults in considerable morbidity and mortality. Recognizing these challenges, we developed a smart electro-mechanical device which replaces manualcompression of a self-inflating silicon bag by a motor-driven set of plates
137	An effective way to truncate the formation of IV catheter clots and reduce the pain during flushing
	Navya Devireddy, Omsai NIdubrolu, Rama Rao N.V, Prashanti N.L, Maneesh Kumar Maddirevula, Rama Rao Nadendla
	Formation of clots in cannula due to stasis of blood and moderate tosevere pain during flushing the cannula clots in the patient who is already illstill remains a good challenge. Antithrombotic and antibacterial lock solutionsmay improve patency, reduce Catheter Related Bacteremia but may be cost-prohibitive, routineuse of Antimicrobial lock solutions may increase systemic toxicity and resultin resistant organisms. Overcoming these cons, inserting an economicallyinert device into the lumen of the cannula can put a check. This device willact by preventing the back flow of blood into the cannula and thereby prevent clot formation.
157	Development of ceramide loaded chitosan composite (ChiCeC) for biomedical applications universally
	Ashrafuzzaman, Afsana Mimi, Faiza Ahmed, Sabrina Shetu
	Yearly several hundred thousandsof patients died from accident and hemorrhage and infectious complicationsafter surgery. Chitosan uses in wound management and ceramides contribute toform protective layer stratum corneum of skin. This research objective is to developceramide loaded chitosan composite (ChiCeC), presenting the antimicrobial and wound-healing effects on damaged tissues. PreparedChiCeC exhibits significant anit-bactericidal activity in vitro and pointedlyreduced mortality in burned mice model. ChiCeC application as hemostaticadjuvant having antimicrobial properties on burned patients is completely new product. Colossal clinical uses of ChiCeC can be investigated further for its potential biomedicalapplications in near future.
179	FDTD simulation of preoperative treatment plan for liver cancer ablation with nanosecond electrical pulse
	Yanan Hu, Jinjun Zhu, Jiali Bao,Chaoyang Zhu
	Aim: Irreversibleelectroporation (IRE) caused by nanosecond electrical pulse (nsEP) can be used toablate cancers. But as an electric field, the thermal effects are inevitable. It is necessary to predict the electric field, specific absorption rate (SAR)and temperature distribution of organs and tissues before surgery to optimizethe treatment program. Finite-Difference Time-Domain (FDTD) can be used topredict the safety and effectiveness of nsEP.
195	Development of a low-cost anesthetic gas analyzer to improve global surgical safety

John Langell, Patrick Kolbay, Joseph Orr, Kai Kvock

Approximately 28% of the global burden of disease is treatable through surgical intervention and, by affiliation, general anesthesia. Consequentially general anesthesia is, out of necessity, administered in austere conditions with limited support. High-cost sidestream gas analyzers are used in more developed areas to measure the concentrations of volatile anesthetic agents, and consequently determine the depth of anesthesia. To bring similar safety monitoring to low-resource areas, we have created a low-cost alternative by combining a simple tachometer and orifice-plate flow sensor. Using the tachometer to account for the flow of the respiratory limbs, the orifice-plate flow sensor was used as a proxy density sensor to determine the binary gas mixture density, and thereby the volatile anesthetic gas concentration. The resulting measurements had near equivalent accuracy and precision to sidestream monitors, but at a fraction of the cost.

196 Indigenous "555 Manish retractor" (patent pending) for innovative Optiview totally extra-peritoneal repair of inguinal hernia repair by 5mm ports

Shyama Nagarajan, Manish Gupta

Current Hasson trocar TEP repair is high cost, painful, prone to injury, infection and pneumoperitoneum. Dr. Gupta, has innovated an Optiview '555 Manish Device" (patent filled in India, USA, UK). "Manish Retractor" is used for inserting a 5mm Optiview trocar to peritoneal space between anterior and posterior rectus sheath. It can track the path of trocar up to PPS. A "Tail Pull" technique is used to insert synthetic mesh to cover the hernial orifices. The 5mm incision precision with 162/164 successful cases, is a less invasive, less morbid, time saving, cost effective technique; which is reproducible with this device.

197 Customized 3D printed orthoses device: a rehabilitation solution for congenital hemiplegic children

Harpreet Singh, Aarti Chauhan, Neelesh Kumar, Rishab Agarwal

Recovery of functional movements of hand in Congenital hemiplegic childrenis directly linked to rehabilitation duration and intensity of therapies and effectiveness of orthotic device. For such cases, children require customized orthoses which make them capable of doing their tasks.
The approach proposes an effective solution for the development of customized orthoses using additive manufacturing technique. The solution comprises of 3D scan of the affected hand, modelling and customization of the scanned data in CAD software and then fabrication using 3D printer. The proposed prototype gives desired finger travel with stable wrist position through controlled variable resistance motion mechanism.

Regulation

233 Medical device Vigilance systems in USA and EU

M.P. Venkatesh, N. Shashank, T.M. Pramod, V. Balamuralidhara

Medical device vigilance isconcerned about device problems (incidents); their analysis and mitigation toensure the device performance is good and patient safety are maintained. The main objective of the Medical DeviceVigilance System is to assess risk by FTA orFEMA. Evaluate the potential harm, subject, and minimize it by implementing therisk control measures. The severity of subject, risk assessment should beconducted by manufacturer before marketing.

234 Drug - device combination product in USA and EU:regulatory perspective

M.P. Venkatesh, Soorya Thaikadan, T.M. Pramod, V. Balamuralidhara

Annex 5: Evaluation

This annex presents participants' feedback from three groups of surveys.

The first survey was an immediate feedback form administered upon the conclusion of each of the workshop, plenary and parallel oral sessions, via the phone application. This provided instant insight into the participants' opinions of the presentation of each topic.

The second survey was collected at the end of the Forum. Attendees were invited to access the phone application and provide their general comments.

The final evaluation survey was sent to all participants via email a month after completion of the Forum. This survey was more general in nature and surveyed opinions on logistical issues of the Forum as well as soliciting general feedback.

Some of the comments received have been selected for presentation below.

5.1 Immediate feedback

Immediate feedback was collected at the end of each of the workshop, plenary and parallel oral sessions. The opinions were compiled graphically and are displayed in the figures below from Fig. A5.1 to Fig. A5.15 . Some of the many submitted comments are also shown below.

5.1.1 Workshops

Survey feedback results

Fig. A5.1 Percentage of attendees that liked the workshop

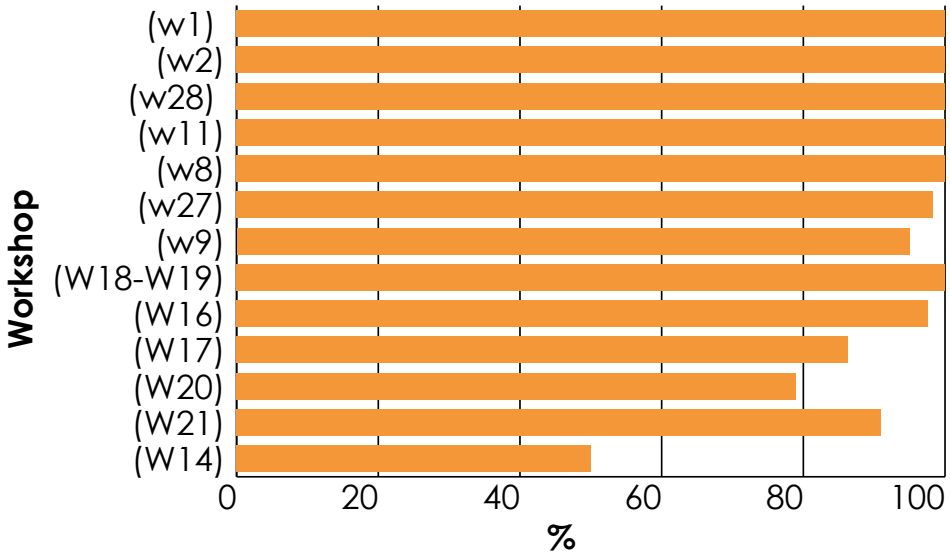


Fig. A5.2 Percentage of attendees that would like WHO to advance on this topic

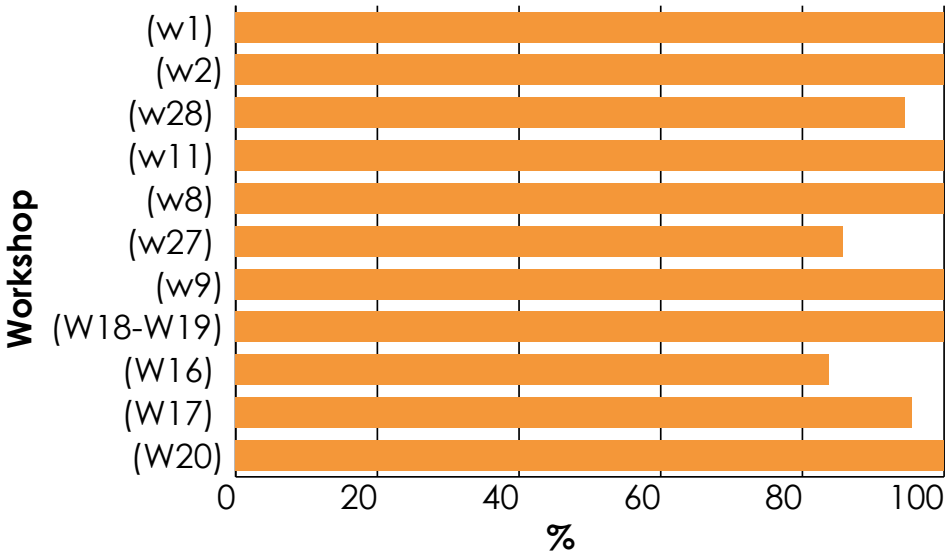


Fig. A5.3 Percentage of attendees that thought this topic supports access to medical devices

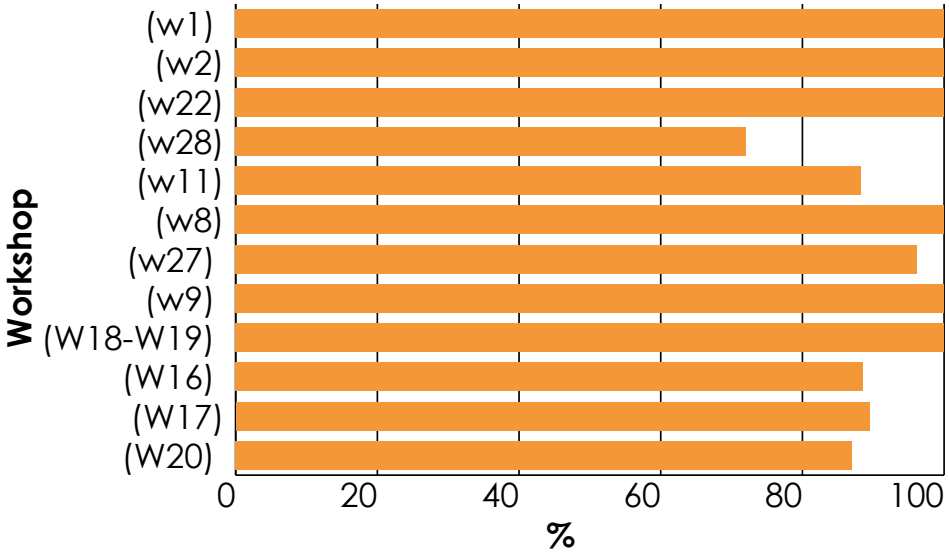


Fig. A5.4 Percentage of attendees who thought this topic was useful for their work

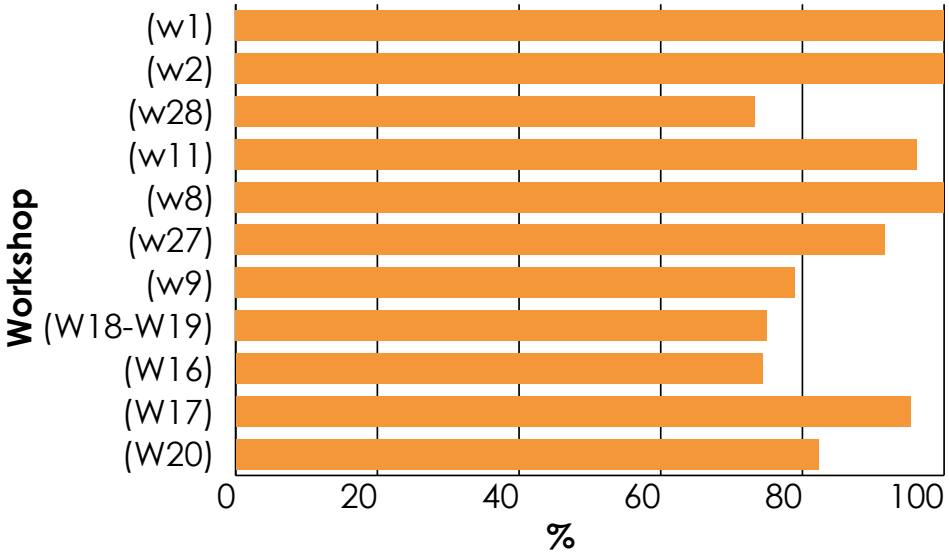
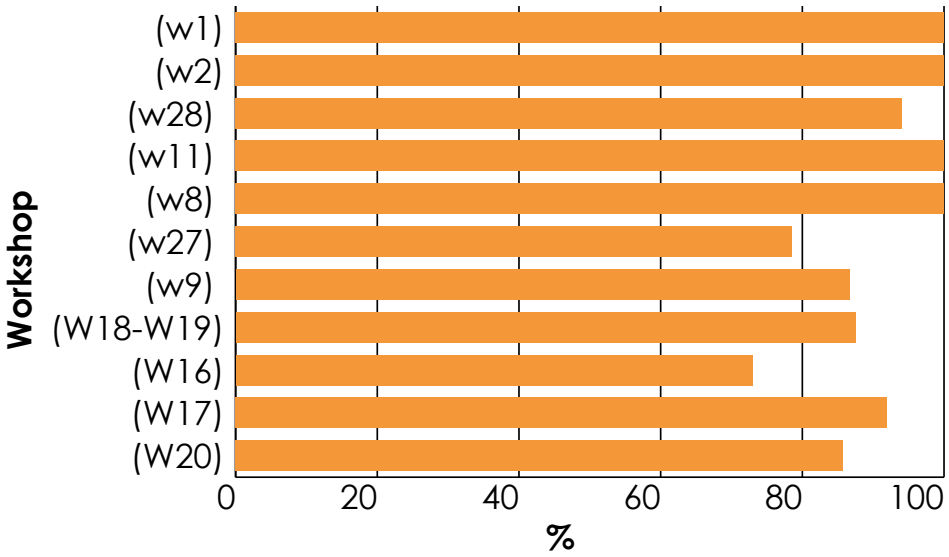


Fig. A5.5 Percentage of attendees who would like to engage/contribute with WHO on this topic



Open ended suggestions

Open ended suggestions were received at the end of each workshop session. Selected comments on the respective workshop topic are shown below.

Session	Comments
(CM1) Medical devices in African francophone countries	This session is very helpful
(CM1) Medical devices in African francophone countries	In future it should be nice to see a real case of migration, from one system to the harmonized one
(CM1) Medical devices in African francophone countries	Well done especially for complex program
(CM1) Medical devices in African francophone countries	Would have liked more information on the timing for 2 sessions at the same venue. Also in general would have been nice to have the details of the speakers in the programme.
(CM2) Technical specifications for cervical cancer	Please kindly share all of the presentations for the 3- day workshop for our reference. Thank you for the great organization.
(CM3) Oxygen supply systems	Excellent
(CM3) Oxygen supply systems	Increase access to oxygen remains high priority. Affordable and good quality oxygen is required at all levels healthcare. Good to know WHO, PATH, CHAI, UNICEF work together. Urgent to implement
(W1) Vigilance of medical devices in hospitals	Good
(W1) Vigilance of medical devices in hospitals	Definition of severity of injury to report to the regulatory authority?
(W1) Vigilance of medical devices in hospitals	kindly share all the presentation in this app

Session	Comments
(W14) Technologies for cervical cancer	I would like to contribute to this. In vast countries like India, we may need smart imaging devices for screening of cervical cancer. In remote parts of India, the availability of trained medical staff is limited. So the device should be more user friendly, easy to operate and data interpretation without effecting the efficiency of the system. Continuous awareness programs and camps should be organised to create the awareness in the public.
(W15) Clinical Engineering and information technology best practices	Excellent session
(W16) The role of biomedical engineers in HTA	It was very enlightening
(W16) The role of biomedical engineers in HTA	Helpful
(W17) 3D printing, AI and design of medical devices for low resource settings	Need more information on 3D and 4D printing and how to choose the material. whether open source materials are ok as they are cheap
(W17) 3D printing, AI and design of medical devices for low resource settings	Perfect
(W17) 3D printing, AI and design of medical devices for low resource settings	Excellent session
(W22) Biomedical engineering	Very interesting topics, speakers could have done more justice to the subject if there was more time allocated to them
(W22) Biomedical engineering	Very informative sessions. Got to know about the new development in laparoscopic instruments and also about the m health apps development.
(W22) Biomedical engineering	Useful session
(W24) Regulation of medical devices	1.How EU regulate post market surveillance 2.How you ensure sufficient action taken on alert /recall notice issued 3.How control the regulation related issues? which may change with in EU countries or only with union level if by both any union list, country list & concurrent list based on classification
(W24) Regulation of medical devices	Highlight major changes of ER of new MDR in comparison to Old MDD/93/42/EEC.
(W24) Regulation of medical devices	The session was useful, please share the presentations in the app
(W25) BME global capacity building	Excellent MD presentation by CDSCO. 1.Mapping matrix requested for IMR Vs US FDA & UK MDD. Many are using. these much before IMR came into force. 2.Whom to be communicated for IMR interpretation / doubts. email id please. 3. Request IMR Assessing should not be from scratch for clients who were already in compliance to Eurpean MDD / US FDA etc.

Session	Comments
(W26) Metrology of medical devices	Excellent
(W26) Metrology of medical devices	Recalibration / Recertification should be based on factors like brand / original quality if the instrument, usage environment, user handling skill, last calibration results, area where it's being used etc. while planning calibration frequency it should be justified.
(W27) Regulation of medical devices	Regulations in South East Asian countries should be harmonised so that there is no need for product registration in each country. This is similar to CE or USFDA certification
(W27) Regulation of medical devices	Informative, I had a global perspective
(W28) Nomenclature and classification of medical devices	Should not be made mandatory as currently GMDN is followed by regulators n industry
(W28) Nomenclature and classification of medical devices	A good concept for coming generations but involve lots of finance and time to implement.
(W28) Nomenclature and classification of medical devices	fantastic session
(W28) Nomenclature and classification of medical devices	Please make available the website to access the pilot
(W28) Nomenclature and classification of medical devices	Good informative session. would have liked to have focus on IVD too
(W6) WHO methodology for the selection of priority medical devices for NCDs	Liked the session
(W6) WHO methodology for the selection of priority medical devices for NCDs	Is there any guidelines to select priority of medical devices?
(W6) WHO methodology for the selection of priority medical devices for NCDs	I would like to be engaged with WHO. Elder Care/ Geriatric and stroke rehabilitation
(W6) WHO methodology for the selection of priority medical devices for NCDs	I would like to volunteer and contribute towards WHO
(W8) Management of medical equipment	Excellent session
(W8) Management of medical equipment	Thank you, it was perfect!!!
(W8) Management of medical equipment	Thank you for the nice forum gathering with many delegations from several countries

5.1.2 Regional (PR1 to 6) and industry (IN) sessions - Friday 14 December morning

Survey feedback results

Fig. A5.6 Percentage of attendees that liked the regional session

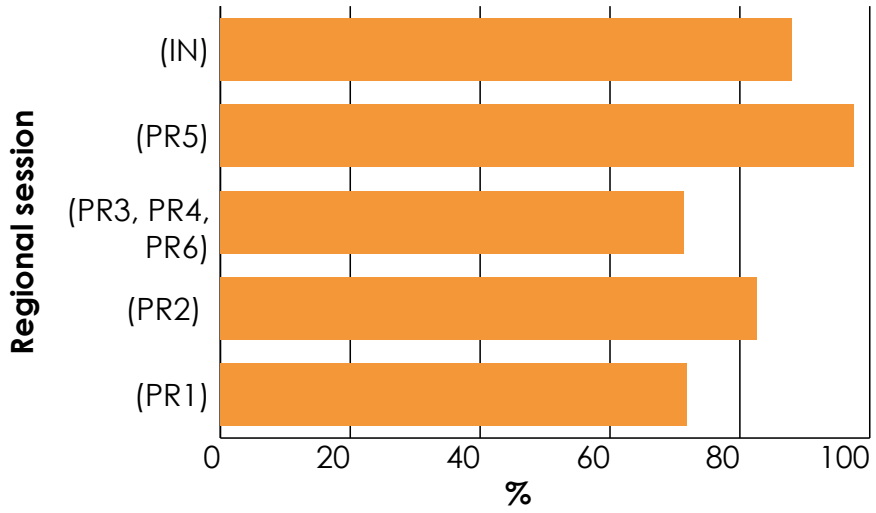


Fig. A5.7 Percentage of attendees that would like WHO to advance on this topic

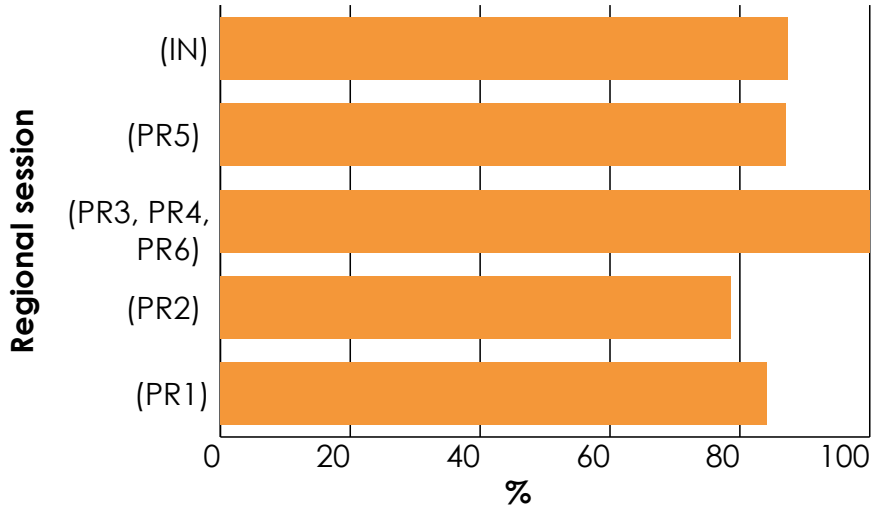


Fig. A5.8 Percentage of attendees that thought this topic supports access to medical devices

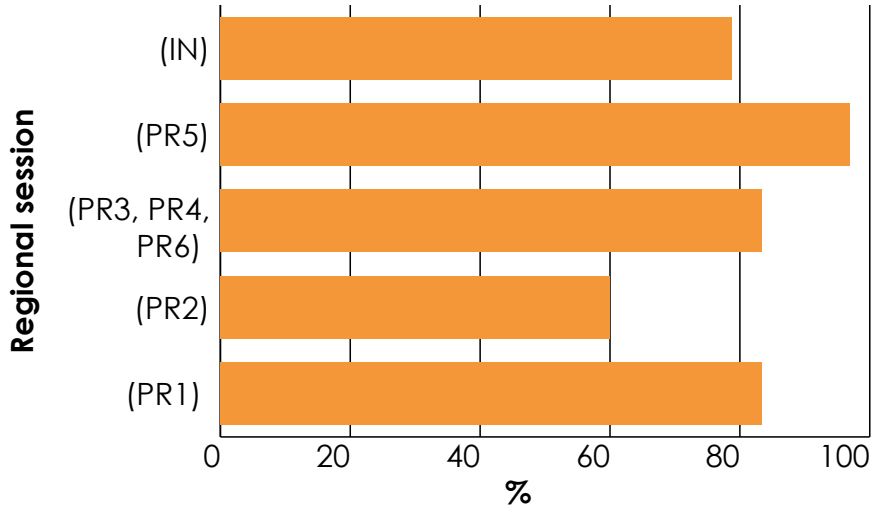


Fig. A5.9 Percentage of attendees who thought this topic was useful for their work

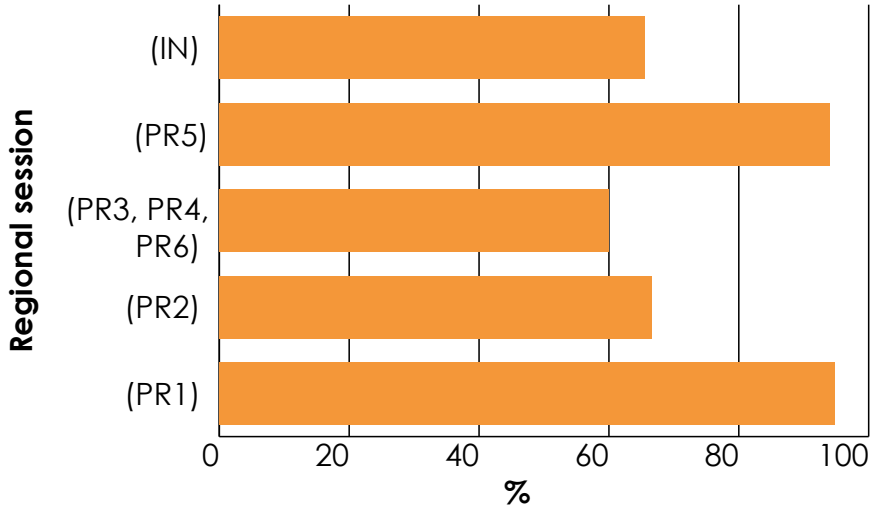
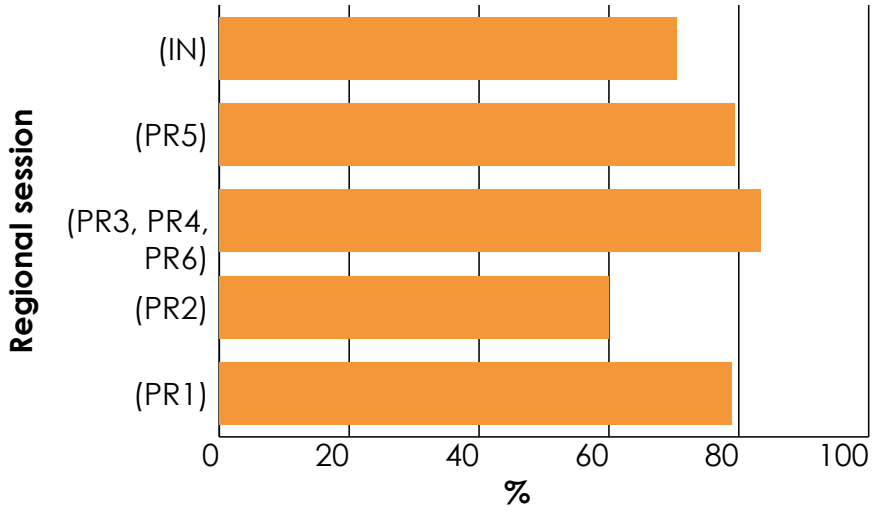


Fig. A5.10 Percentage of attendees who would like to engage/contribute with WHO on this topic



Comments of plenary panel sessions

Open ended suggestions were received at the end of each plenary session. Some have been chosen for display along with the respective plenary topic.

Session	Comments
(CS) Proposal for 5th Global Forum in 2020 and Closing Ceremony	Important establish a limit of political session.
(OS) Inaugural session of the 4th WHO Global Forum on Medical Devices	English words have showing in the screen to the speech
(PP1) Donations of medical devices: consequences to patients and health workers.	Thank you facilitating a conversion on this important issue.
(PP1) Donations of medical devices: consequences to patients and health workers.	This is a very important topic to be addressed with much ethics, equity and justice. At this stage, most of Africans countries including my country the Comoros are experiencing medical equipment donations and less or non-medical devices donations. There is here a need of capacity building in terms of regulations and medical engineering before everything. everything, otherwise those countries
(PP1) Donations of medical devices: consequences to patients and health workers.	Equipment donations are still a challenge in Malawi. WHO should continue with the work on this topic. We need to define a donation as a package.
(PP1) Donations of medical devices: consequences to patients and health workers.	Local medical equipment manufacturer could be helpful if they get the donated products and refurbish they and they supply it to the respective hospitals. In this way the problems with the donated equipment could be reduced as well as local manufacturers can also be beneficial with it.
(PP1) Donations of medical devices: consequences to patients and health workers.	Awesome panel and content. Enlightening discussion... I would like who to advance on NCDs
(PP1) Donations of medical devices: consequences to patients and health workers.	Donations would need to be approved by regulatory agencies to ensure products are of good quality
(PP2) Priority medical devices for non-communicable diseases towards Universal Health coverage	Need of top 10 challenges, in specific area like geriatrics, Maternal & child healthcare.
(PP4) Oxygen supply systems, needs and challenges	Provided an insight about the importance of oxygen
(PP5) Classification, coding and Nomenclature of medical devices, challenges and opportunities	Will the nomenclature also look at medical terminology for example we talk of radiology equipment which is also classified as X-ray equipment or imaging equipment?
(PP9) Conclusions and action plan	The meeting was a great success- Maybe in the future program schedule could ensure wider balance between content-based vs institutional plenaries. Overall congratulations to the organizers!
(WS) Welcome session of the Fourth WHO Global Forum on Medical Devices	The speeches and video were interesting but it ran long and the next sessions are delayed.

5.1.3 Parallel oral sessions

Survey feedback results

Fig. A5.11 Percentage of attendees that liked the parallel session

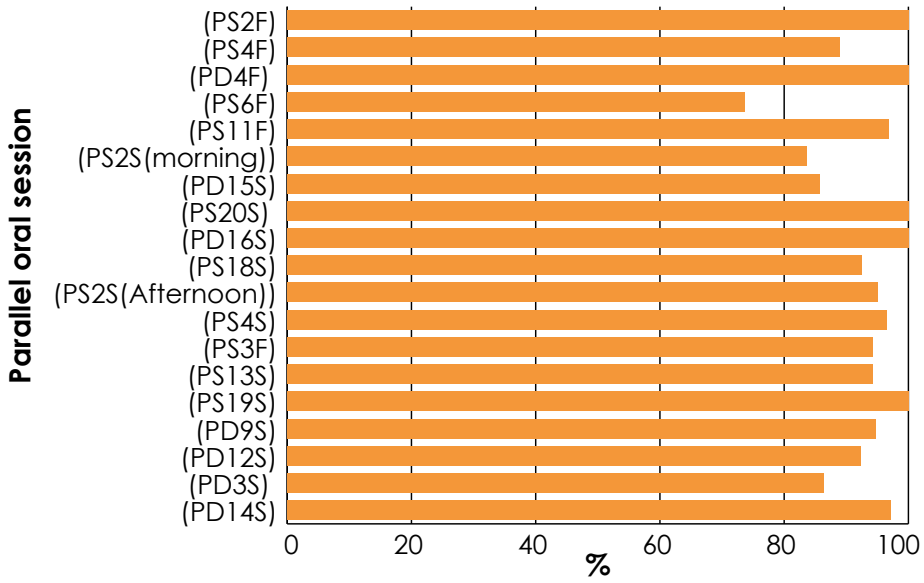


Fig. A5.12 Percentage of attendees that would like WHO to advance on this topic

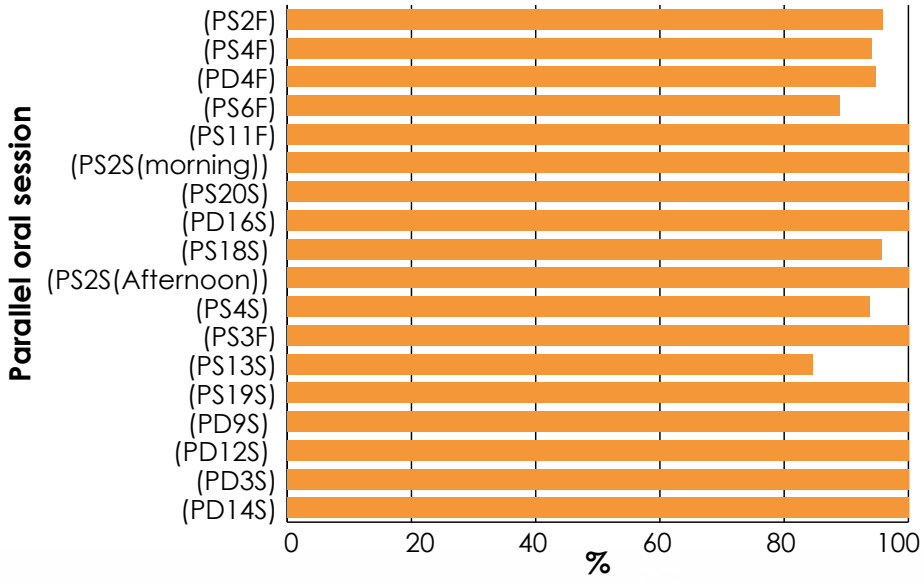


Fig. A5.13 Percentage of attendees that thought this topic supports access to medical devices

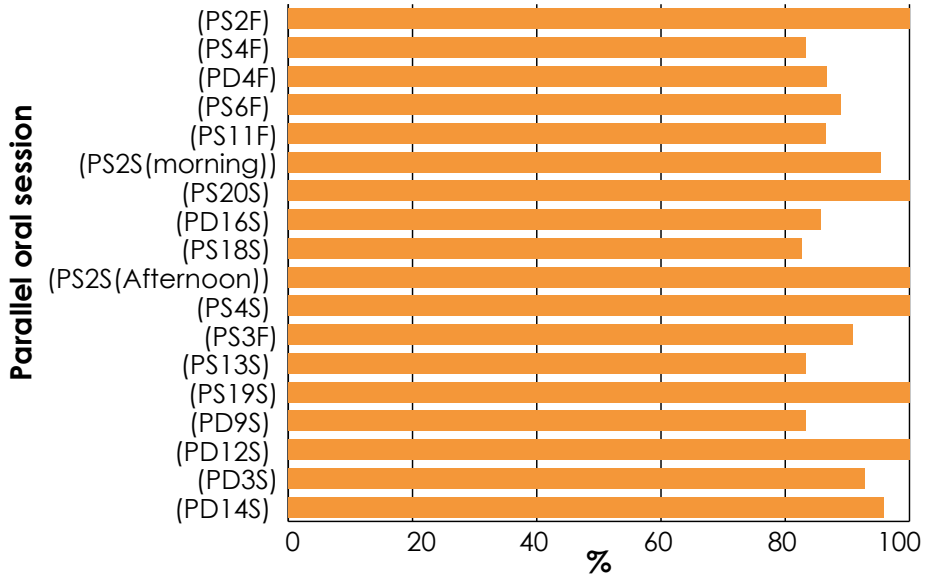


Fig. A5.14 Percentage of attendees who thought this topic was useful for their work

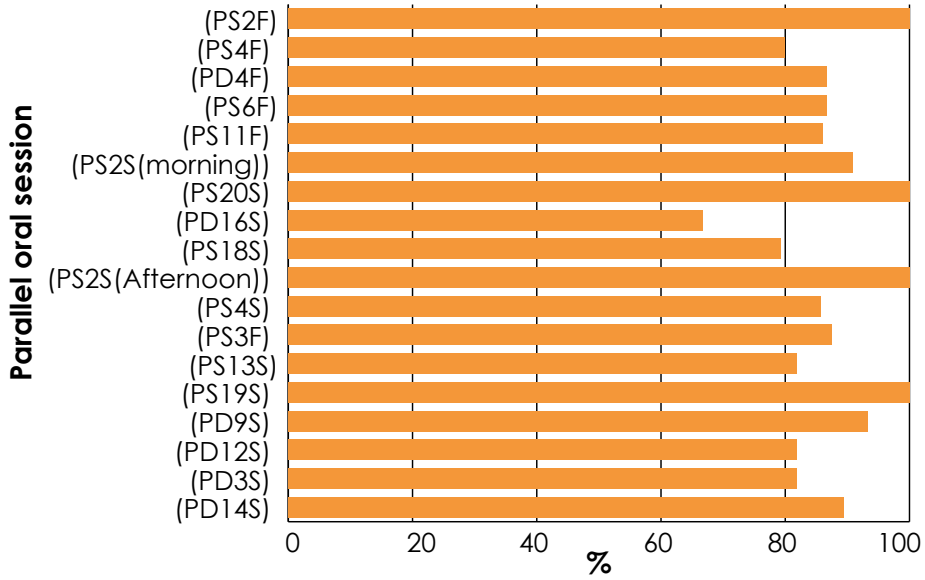
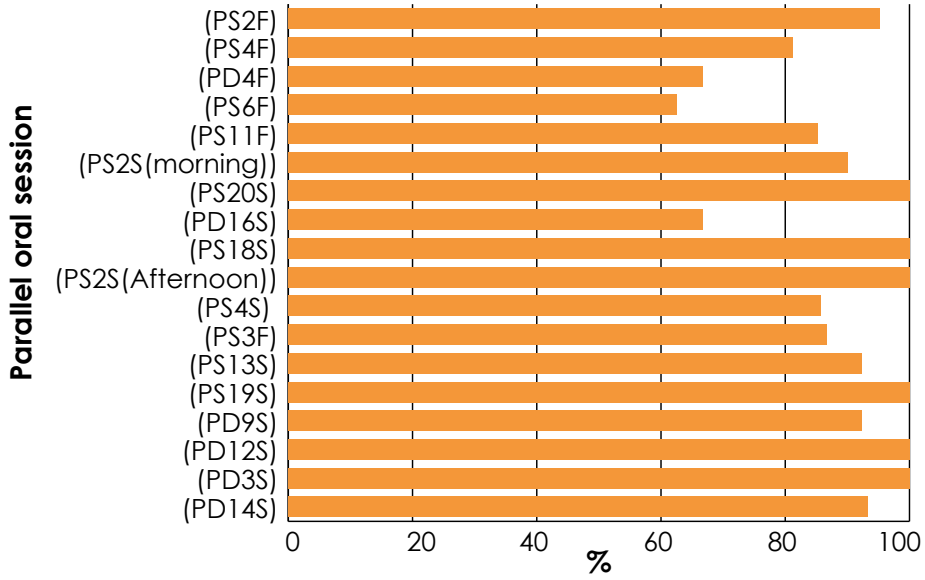


Fig. A5.15 Percentage of attendees who would like to engage/contribute with WHO on this topic



Open ended suggestions

Open ended suggestions were received at the end of each parallel oral session. Some have been chosen for display along with the respective parallel session topic.

Session	Comments
(PD12S) Medical devices for non-communicable diseases	Good...few speakers didn't turn up
(PD12S) Medical devices for non-communicable diseases	I was expecting more focus on the medical device aspect of NCDs; the session spent about 2/3rd time on policy and analysis frameworks.
(PD14S) Packages for primary health-care and emergencies	Priority other than epidemics should be included ASAP.
(PD14S) Packages for primary health-care and emergencies	Good work
(PD17S) Single-use devices	beneficial
(PD4F) ehealth	Special support small islands development states to implement their national eHealth strategies
(PD9S) Medical imaging for diagnostic and interventional procedures	Great session. Only suggestion to enlarge the number of speaker and covered continents. Same challenges in different contexts
(PD9S) Medical imaging for diagnostic and interventional procedures	Great sessions!
(PD9S) Medical imaging for diagnostic and interventional procedures	I really had a good session and insights of innovation
(PR1) Africa	WHO to support ESA countries to harmonize regulations within regional and sub regional bodies, SADC, COMESA, COI, etc
(PR1) Africa	Should have been opportune to share a specific objective for the session and more guidance like a simple sentence or question to introduce the debate
(PR1) Africa	This was not an informative session. It is not enough to share website information as that is common knowledge now. You can just refer. The discussion could have been enriched by round table discussion on a key topic such as donations and regulations.
(PR2) Americas	Unhappy with the content and talk.
(PR3) Eastern Mediterranean	Thanks
(PR3) Eastern Mediterranean	Thanks
(PR3) Eastern Mediterranean	Good
(PR4) Europe	Thanks
(PR5) South East Asia	Good
(PS11F) Regulation in South-East Asia	Excellent session
(PS13S) Health technology management	Excellent session

Session	Comments
(PS13S) Health technology management	Well conducted program, very useful deliberations, it's a good platform to share the experiences, studies, results from all over the world on health care and medical devices to suggest further standards and policies. I felt very useful. Just as a suggestion...delegate badges are extremely good quality. The font used for printing delegate name and other deltas are not very clear one. One has to hold up the card to read the name of the delegate and Country name. Example font used to print name "World Health Organisation" in the badge is very clear and readable. Just it's a suggestion for the purpose of future planning. Overall very successful event and thank you for considering me part of this event. My Best wishes for WHO initiatives and future programmes
(PS16S) Pricing of medical devices	Only one session with limited knowledge sharing. Request to accommodate more sessions on this so various countries pricing strategy, SWOT analysis.
(PS17S) Regulation of medical devices	Was useful
(PS18S) Regulation post market	Good
(PS19S) Challenges in donations	1. Would have liked to know more about the details of the programme such as the multiple different sessions and the people taking those sessions as well 2. It would be more convenient if the venue of the conference was a little closer to the city
(PS1S) Policies on medical devices	The presentations was very helpful. Thank you for organizing such conferences.
(PS1S) Policies on medical devices	This was my first time to participate to WHO Global forum on Medical devices and I am very satisfied. All the presentations was very helpful. As a clinician and biomedical engineer, I know the challenge with the use of medical devices especially in Africa where there is a lack qualified biomedical engineers to help. I thank the organizers for their commitment and my wish is to continue participating actively to the next forums. Once again thank you for everything.
(PS2S) Innovation	Excellent session - the best one I attended. would request more time devoted to the sharing of emerging innovations.
(PS2S) Innovation	The innovation has always to be linked to VALUE.
(	
(PS2S) Paths to health technology innovation	Very important and expect more on innovative technology from who
(PS3F) Human resources to manage medical devices	WHO/CDSO (India) should come out with common portal where MD trainings can be log onto for common data base both for statistics & for upgradation.
(PS4F) Assessment of medical devices for LMIC	Excellent leadership and commentary
(PS4F) Assessment of medical devices for LMIC	More time is needed. The regional networks are important

Session	Comments
(PS4F) Assessment of medical devices for LMIC	Please provide translation when the speaker use different languages other than English or French.
(PS4F) Assessment of medical devices for LMIC	I would like to volunteer and contribute towards WHO
(PS4S) Assessment of medical devices	Good
(PS6F) Procurement and supply	WHO challenge to do Ministries S M Es
(PS7F) Nomenclature and classification of medical devices	I would like to volunteer and contribute towards WHO
(PS7F) Nomenclature and classification of medical devices	Excellent initiative, global nomenclature will go a long way in providing access to affordable, quality medical devices especially to the vulnerable
(PS7F) Nomenclature and classification of medical devices	WHO to share this new nomenclature system and receive support and collaboration from MOH And agencies, so that it can become available for all stakeholders 2020.

5.2 Feedback received during the conclusion of the Forum

At the conclusion Forum, the following comments and insights were received from attendees:

"The event was well organized and well executed. The topics discussed were pertinent to current issues related to medical devices across the global."

"There is a need for similar forum focused on In vitro diagnostic. More IVD sessions may be included. Information sharing Web portal among all regional regulatory bodies need to be sped up."

"Forum was very useful. The purpose of my visit is fulfilled. I understand the necessity of inventing or creating new technologies for providing access to health care at the grassroot level and the challenges in doing it so. Thank you WHO."

"Themes, topics and subjects developed very important and useful for changing and improving the use of medical devices and equipment in West Africa. Just suggest integration for future forum or assembly the question about maintaining these biomedical equipment and devices."

"Very helpful and useful forum which should include other UN agencies if not all UN agencies for their participation. A formal invitation to these agencies will be good."

"The conference was good, but I feel the program was too cramped. Day 1 I would say was the best day- the sessions flowed well and accommodated the Chief Minister and his team very well. Things seemed to flow well. Overall, some sessions had very good content while others lacked order. There was some repetition too. Next time, be strategic about the conference theme and how to keep delegates engaged."

"Excellent, worth attending"

5.3 Final Evaluation feedback

The Final Evaluation feedback survey was sent to participants a month after the completion of the forum. 210 participants answered the survey questions and provided open ended feedback.

5.3.1 Final survey results

Figures A5.16 through A5.26 below describe the general feedback of the Forum, for each of the questions in the online survey received a few weeks after the completion of the Forum.

Fig. A5.16 Overall quality of workshop sessions

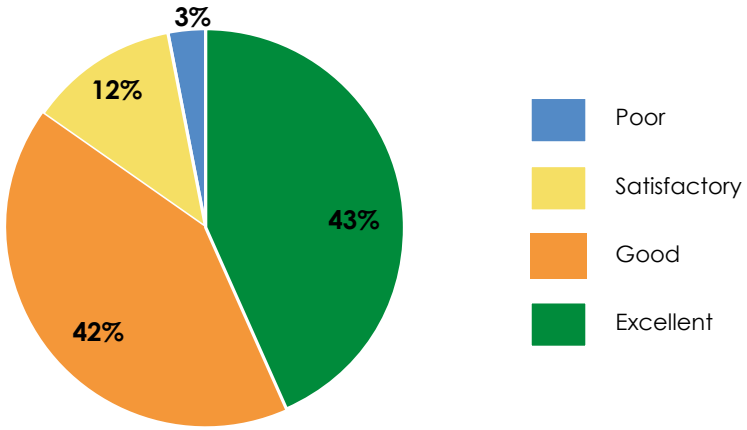


Fig. A5.17 Overall quality of plenary sessions

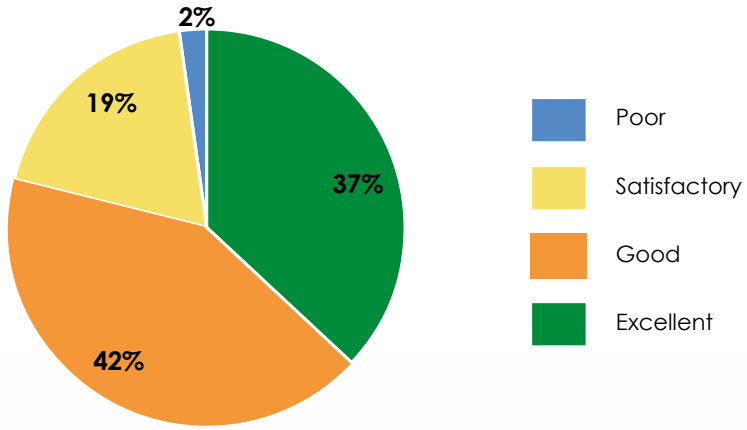


Fig. A5.18 Overall quality of parallel oral sessions

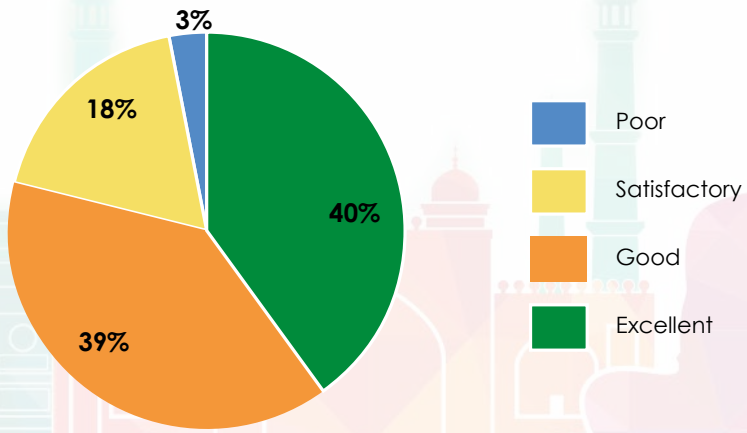


Fig. A5.19 Website of the Forum

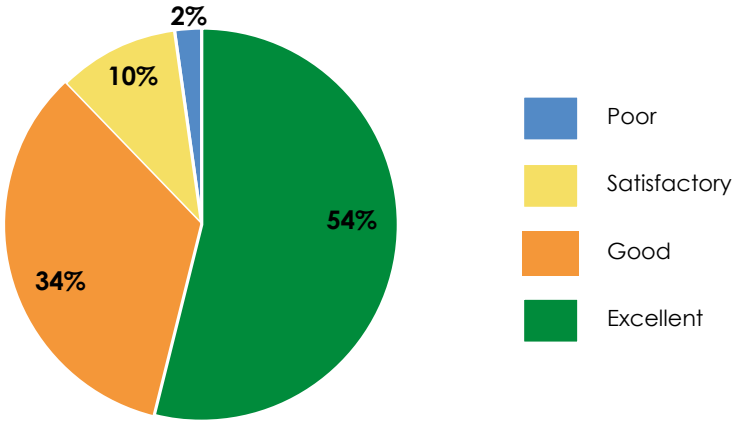


Fig. A5.20 Abstract submission process

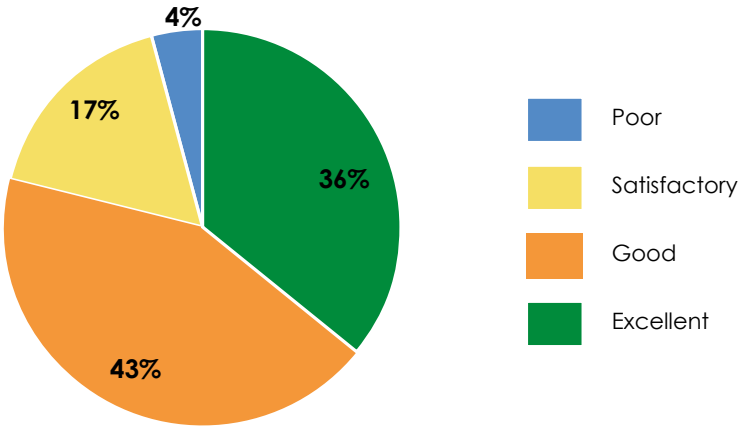


Fig. A5.21 Plenary welcome and ministerial sessions

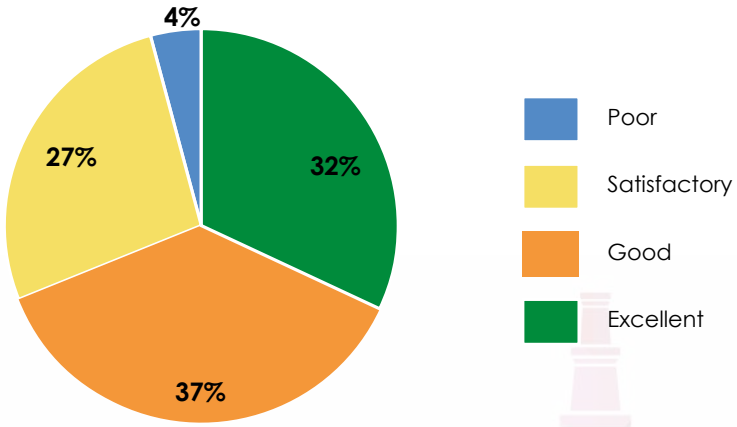


Fig. A5.22 Transportation to and from the hotel/airport

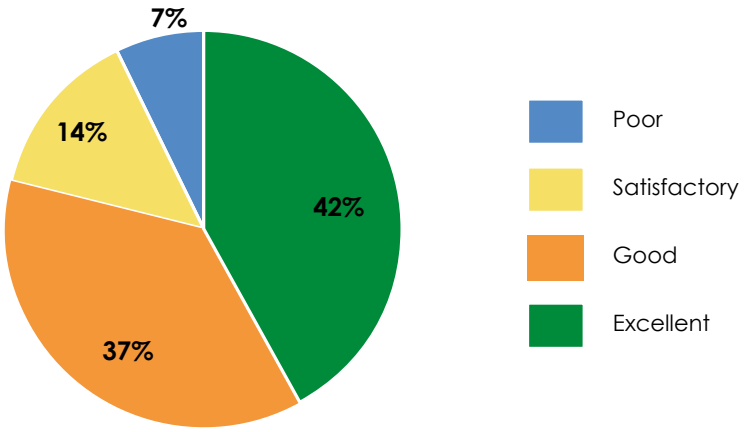


Fig. A5.23 Convention center facilities

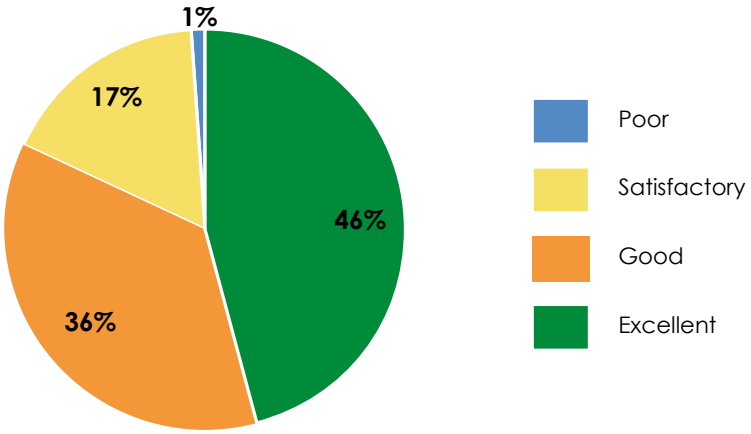


Fig. A5.24 Beverages and food at the venue

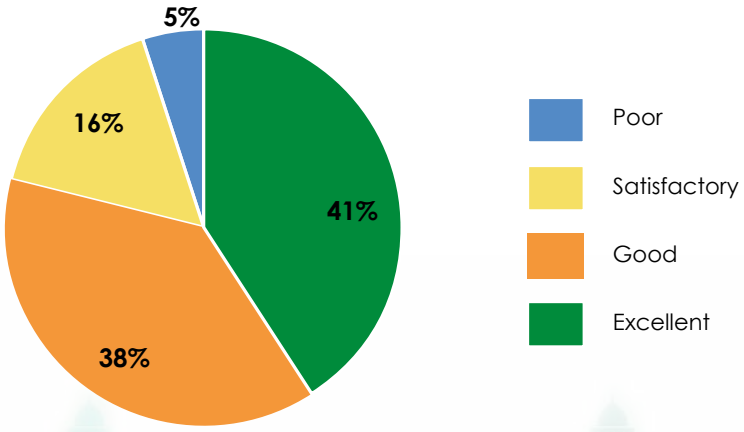


Fig. A5.25 Forum phone application

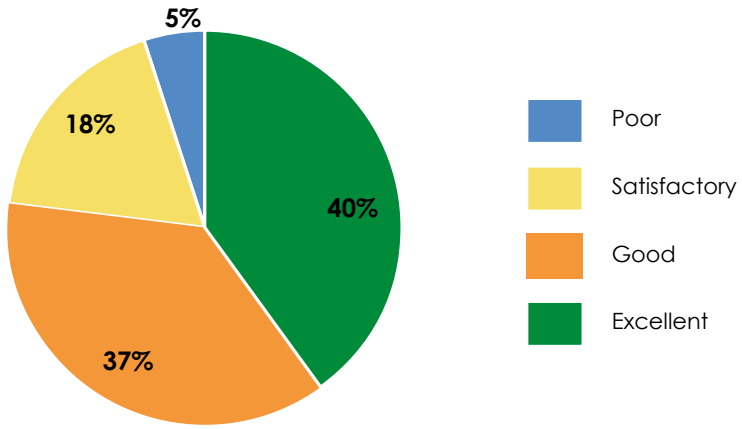
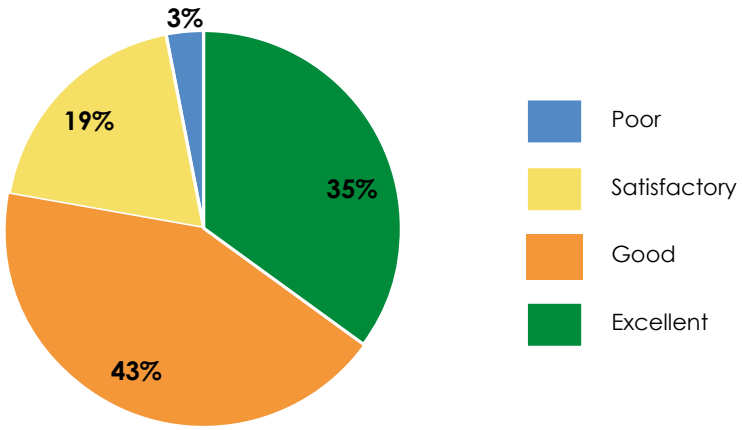


Fig. A5.26 Webcast application



5.3.2 Participants' final comments

This part of Annex 5 presents some of the comments received from the Final evaluation survey. Feedback was solicited on issues to be addressed and suggestions for improvement at the subsequent Forum; as well as general positive comments on the Fourth Global Forum on Medical Devices

Issues to address at the subsequent Forum

"Diagnostics for rural healthcare"

"Advances in Biomedical waste management"

"Software security and software malfunction investigation in Medical devices"

"In the next forum, it will be necessary to concern much program from African and prioritize the problem of maintaining devices and equipment."

"Health technology assessments for medical devices"

"1. Classification of medical devices 2 - How to manage medical devices. 3. How to obtain information from ICD-11"

"Innovation in medical devices to increase the quality of life of geriatric and other patients"

"Ensuring long term funding and management of devices and accessories used in donor-sponsored health programs"

"1. New researches related to medical devices 2. How to make medical devices cost effective and efficient 3. How to make accessible to the people"

"Standards for quality control in medical devices"

"1. Developments in 2nd EDL & path forward 2. Nomenclature, especially with reference to IVDs 3. WHO PQ plans with reference to EDL list"

"Private-public partnerships for scalability of medical devices"

"Affordable radiotherapy technologies and management of cancer. Innovations in radiological imaging technology"

"How to make Low cost, portable medical devices, so that it can reach the masses"

"1. How to come up with good technical specifications that can lead to procurement of quality medical devices. 2.Evaluation of medical devices tenders to procure quality medical devices. 3.Global link"

"Regulation of medical devices and regional regulators network"

"Medical devices regulations, medical devices classification according to risk basis"

"1. Other methods of acquisition of medical device (leasing, pool or sharing or clustering, refurbishing, innovation, technology transfer, local production...) 2. Ownership shifting on HTM...Like PP"

"(i) Promoting access through rational use (ii) A whole-of-health system approach to improving access to and rational use of medical devices (iii) Preparing the health workforce to promote rational use"

"Regulatory affairs for the innovative products (specific to in-vitro diagnostics/point-of-care device)"

"It would be better to conduct one session to discuss problems faced by the regulators in evaluating safety and efficacy of medical devices and how to overcome the same."

"Eco-friendly design and decommissioning."

"Health economics outcome research on medical devices"

"Elaborate sessions on regulatory pathways and classification of medical devices with special focus on the recommendations of WHO"

"Standardization and certification of medical devices"

"Harmonization of listing and classification of medical devices including diagnostics"

"Reuse of single use devices, digital health, CMMS using international nomenclature, protective equipment, combination products, global benchmarking tool for medical devices, medical devices for emerging states"

"Adverse event reporting, stability studies for biologicals (discussion on designing accelerated stability studies of molecular diagnostics IVD kits), acceptance of a uniform regulatory approval across"

"Just talk about how to improve national politics on medical devices in West African french speaking countries. Large part on problems of maintaining devices"

"Maintenance of medical devices"

"Global harmonization of medical device regulation"

"WHO Pre-qualification and WHO Collaborating center - Optimization and application in resource limited settings (Reduction of evaluation timelines and testing fee, supply of global reference standard)"

"Topics in devices medical for surgery specialist and hospital specialist"

"Good practices of med device procurement"

"Pricing in medical devices"

"Oxygen delivery devices, regulation of donated medical devices. Essential diagnostics list."

"Innovation in Medical devices"

"More presentations on health technology management"

Suggestions for improvement for the Fifth Global Forum on Medical Devices

"Le forum mondiale a été réussi en général mais beaucoup des cessions parallèles intéressant étaient organisé à la même heure alors qu'on aurait aimé participé à certains qui étaient bénéfique sur mon"

"Some parallel sessions were very interesting, however impossible to attend all. If some alternative methods can be arranged to access the information discussed in parallel sessions. It will be a great."

"Well organized. Would prefer less bureaucratic involvement in future forums"

"Too much of ministerial talk diverted the forum"

"The venue is too far from the hotel"

"Some addresses delivered in Hindi should have been translated into English."

"The distance between the venue and the hotel was too long. This affected the starting time and closing time which was a major setback. The initiative by the India Government was excellent."

"Greater planning ahead please, rather than last-minute preparations would greatly enhance the impact of the forum and convene vital stakeholders who could not participate because of the hasty preparation"

"It was an enlightening experience; however, I feel that too many parallel sessions made it difficult to choose and we missed out some interesting sessions."

"1. Critical to share list of confirmed attendees (and contact information) at least a week or two before event. This allows presenters to modify their presentations to suit audience as well as suitable"

"Please make sure to transport delegates from airport to hotel and take them back when they are departing after the forum."

"1. Important need to have programme committee and appoint chair and co-chair of sessions as the first step in the organization of the next Global Forum, who will follow up with speakers."

"One humble request, please give your feedback to the author of submitted abstract or presentation about their acceptance or rejection, so that the presenter can further decide to participate or not."

"WHO must give the opportunity to have more large discussing about item chosen for parallel sessions"

"If possible, translate to French in more sessions"

"Prefer to have insights from a more evenly distributed range of countries"

General positive comments on the Fourth Global Forum on Medical Devices

"Well organized forum with discussion on relevant topics. I am willing to contribute more to this area. I will be happy to be a part of the next forum. Thanks to the organizers for the great hospitality"

"The medical devices content of the forum was excellent, diverse, very interesting, and tremendously important to improve healthcare provision and outcomes for all. We have a long way to go."

"Congratulations to the organizers. Job well done."

"Thanks for providing an opportunity to participate."

"The development of Global Forum on Medical Devices is apt; and will go a long way in promoting total quality of healthcare service globally."

"Great meeting with amazing opportunities to discuss relevant topics on technologies to improve health care"

"The conference was successful and an eye opener. I personally benefitted a lot as I learnt a lot of things which when applied in my country (Malawi) will lead to quality health service delivery."

"With the help of few staff you have done excellent work. I am lucky to participate that kind of work and I learn so many things from this forum. Thank you, Adriana and WHO staff. Wish you all the best"

"Thank you for the opportunity. I hope the suggestions and comments that are being given will be looked a critically to improve the next forum. Especially about providing funding for students."

"All of the Plenary, Parallel, and Workshop activities were extremely well done along with the submission process and the venue - sincere congratulations! Improvements could be made in the poster place"

"The Forum was a great opportunity both from a professional and networking point of view. I hope contacts will be maintained in time. Thanks also to your reminders."

"Fantastic exposure to the issues challenging member states today! Excellent facilitation of the discussion of how they may be solved and what WHO is doing to support this process globally."

"Had a great opportunity to gain exposure to a lot of new things. Hospitality is unforgettable"

"We spent a good forum in Visakhapatnam in India and would like to assist in the next global forum in 2020 with WHO. I thank WHO for inviting me to the global forum in India."

"Good job . . . Congratulations to the organizers"

Annex 6: List of registered participants

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