



DITTA Activities

Third WHO Global Forum on Medical Devices

10-12 May, Geneva, Switzerland



Table of Contents

DITTA Presence	2
Medical Device Regulations For Regulators, Manufacture, And Users	3
Medical imaging equipment: global plan for improvement.....	5
Digital transformation of healthcare in LMICs	4
Good practice in Ultrasound probe cleaning	6
Diagnostic Imaging: Health Information Systems and Healthcare Technology Management	7
Ensuring Radiological Security in the Context of Cancer Treatment	8

¹ Image: WHO http://www.who.int/medical_devices/global_forum/3rd_gfmd/en/



DITTA Presence

Date	Time	Ref ID	Workshop Session	speakers
Wednesday 10 May 2017 DITTA	09:15 - 10:45	A111 Salle 16	Medical Device Regulations For Regulators, Manufacture, And Users	Chair: Mary Overland (DITTA/GE Healthcare) Speakers: Josee Hansen (Senior Advisor, Department of Essential Medicines and Health Products, World Health Organization) Robert E. Geertsma (Centre for Health Protection, RIVM - National Institute for Public Health and the Environment)
Wednesday 10 May 2017 - DITTA	09:15 - 10:45	A110-3 Salle 15	Digital Transformation of Healthcare in LMICs	Chair : Jan-Willem Scheijgrond, DITTA Global Health Working Group Vice-Chair Speakers : Prof. Guy Frija, ISR, United States Emmanuel Akpakwu, Associate Director, WEF Phil Leonard, Partner and Vice President, Nicole Denjoy, COCIR Secretary General
Wednesday 10 May 2017 ISR	11:45 - 12:30	A158 Salle 7	Medical imaging equipment: global plan for improvement	Chair: Prof. Guy Frija, ISR, United States Speakers: M. Stoeva, IOMP S. Whitley, ISRRT Nicole Denjoy, DITTA, Belgium
Wednesday 10 May 2017 ISR	13:30 - 14:15	R446 Salle 17	Good Practice In Ultrasound Probe Cleaning	Prof. Guy Frija, International Society of Radiology, United States WFUMB Nicole Denjoy, DITTA, Belgium
Wednesday 10 May 2017 RAD AID	14:15 - 15:00	A101 Salle 7	Diagnostic Imaging: Health Information Systems and Healthcare Technology Management	RAD-AID, WHO, ISRRT, IMP, DITTA. And statements from WFUMB and UICC
Friday 12 May 2017 DITTA	9:30 - 10:30	Plenary Panel Session 4 Salle 1	Priority medical devices for Cancer care and other non- communicable diseases. The role of the medical industry to develop appropriate technologies	Gisela Abbam, DITTA Global Health Working Group Chair
Friday 12 May 2017 DITTA	13:30- 15:00	A110 Salle 6	Ensuring Radiological Security in the Context of Cancer Treatment	Kristina Hatcher - Deputy International Program Director, Office of Radiological Security, National Nuclear Security Administration, U.S. Department of Energy



Medical Device Regulations For Regulators, Manufacture, And Users



Wednesday, 10 May, 9:15 – 10:45, Salle 16

Abstract:

The important of a medical device regulatory framework from a regulator's perspective will be explained, as well as a description of how regulators can put in place a regulatory framework.

Throughout life cycle of a medical device, manufactures comply with regulations to bring products to market of consistent quality and safety. Life cycle phases of the medical devices including R&D, production, marketing authorization, distribution, use, post-market, and disposal will be discussed. Insight as to where in the life cycle of the medical device important data is generated, where the data is used, and by whom will be discussed.

The importance of implementing a continuous cycle of improvement for medical devices. Roles for various stakeholders.

Chair: Mary Overland, DITTA Board of Director Member and GE Healthcare

Speakers:

- Josee Hansen (Senior Advisor, Department of Essential Medicines and Health Products, World Health Organization) - The important of a medical device regulatory framework from a regulator's perspective will be explained, as well as a description of how regulators can put in place a regulatory framework.
- Mary Overland (DITTA Board of Director Member and Director of Regulatory Intelligence and External Affairs, GE Healthcare) - Insight as to where in the life cycle of the medical device important data is generated, where the data is used, and by whom will be discussed
- Robert E. Geertsma (Centre for Health Protection, RIVM - National Institute for Public Health and the Environment) - The importance of implementing a continuous cycle of improvement for medical devices. Roles for various stakeholders.



DITTA GLOBAL DIAGNOSTIC IMAGING,
HEALTHCARE IT & RADIATION THERAPY
TRADE ASSOCIATION



Digital transformation of healthcare in LMICs **Wednesday 10 May, 9:15 – 10:45, Salle 15**

Abstract:

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

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

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

Chair: Jan-Willem Scheijgrond, DITTA Global Health Working Group Vice-Chair

Speakers:

- Prof. Guy Frija, ISR, United States – Information on Clinical Decision Support
- Emmanuel Akpakwu, Associate Director, WEF – Digitization and the transformation towards value based healthcare
- Nicole Denjoy, COCIR Secretary General - Importance of Interoperability and latest updates on developments in Europe
- Phil Leonard, Partner and Vice President, Healthcare Transformation Services, Philips - Strategies for digitally transforming the hospital environment



Medical imaging equipment: global plan for improvement
Wednesday 10 May, 11:45 - 12:30, Workshop in Salle 7

Jointly organized by the International Society of Radiology (ISR), the International Organization for Medical Physics (IOMP), and the International Society of Radiographers and Radiological Technologists (ISRRT)

Abstract

Increasing availability of medical imaging equipment has led to an increase in the number of imaging procedures and thus an increase in medical radiation exposure globally. As the purchase and maintenance of imaging equipment is very cost-intensive, renewal practices vary greatly and are often neglected at the cost of patient and staff safety. In addition, shortage of skilled personnel is still a major factor in poor medical equipment management practice globally.

The ISR, IOMP and ISRRT will in this joint workshop outline the need for access to up-to-date imaging equipment, including dose reduction software and dose reconstruction systems to ensure improved patient and staff safety globally. We will highlight the importance of global workforce development plans for radiologists, medical physicists and radiographers in order to ensure safe use and proper use and maintenance of imaging equipment. Developing and underdeveloped countries need support not only in improving the medical imaging equipment base, but also for developing sustainable training programs for health professionals to establish a safety culture based on teamwork, including quality control and risk management procedures.

Chair: G. Frija, ISR

Speakers:

- Setting the scene – RP regulation as a guidance by G. Frija, ISR (8min)
- Workforce issues
 - Medical physicists' aspects M. Stoeva, IOMP (8min)
 - Radiographers' aspects S. Whitley, ISRRT (8min)
- Equipment-related aspects (DITTA) (8min)
- Discussion (8min)
- Recommendations, G. Frija (5min)



Good practice in Ultrasound probe cleaning
Wednesday 10 May, 13.30-14:15, Salle 17

Jointly organized by the International Society of Radiology (ISR), the Global Diagnostic Imaging, Healthcare ICT, and Radiation Therapy Trade Association (DITTA) and the World Federation for Ultrasound in Medicine and Biology (WFUMB)

Abstract

Ultrasound is considered one of the safest and most affordable imaging modalities at the point of care and thus widely used in global healthcare. However, the International Society of Radiology is concerned by recent publications and a European study that show that good practices during cleaning of the probes after cutaneous or endocavitary examinations are seldom followed and thus lead to the potential development of cross-infection. The goal of this workshop is to present the European study, which showed a large diversity in protocols and practice, and to present the guidelines recently established by the World Federation of Ultrasound in Medicine and Biology to promote the safe use of ultrasound in particular in underserved areas of the world. DITTA as global industry association will present its perspectives and will introduce devices aimed at facilitating probe cleaning in order to achieve a high level of disinfection. Measures to establish and increase the use of infection control processes in ultrasound will be discussed and the importance of good medical practice in this area highlighted, following a multi-stakeholder approach based on training and awareness raising to improve patient safety.

Chairs: Guy Frija (ISR)

Speakers:

- Setting the scene – G. Frija (5min)
- Results of the European survey on infection prevention and ultrasound probe decontamination practices in Europe, Guy Frija (10min)
- WFUMB recommendations on ultrasound safety, tbc (10min)
- Update on probe cleaning technologies, DITTA (10min)
- Discussion (5min)
- Recommendations (5min)



Diagnostic Imaging: Health Information Systems and Healthcare Technology Management

Wednesday May 10th, 14:15 - 15:00 in Salle 7



Abstract

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

Speakers:

- Melissa Culp, MEd, RT(R)(MR), RAD-AID International, Maryland, USA
- Miriam Mikhail, MD, RAD-AID International, diagnostic radiologist, consultant based in Geneva, Switzerland

Programme

- a) Very brief intro./setting the scene by moderator
- b) WHO Radiation Protection presentation
- c) RAD-AID presentation
- d) ISRRT presentation
- e) IOMP presentation
- f) DITTA presentation
- g) WFUMB presentation (to be delivered by moderator: slides contributed, WFUMB unable to attend)
- h) UICC Statement (to be delivered by moderator: UICC unable to attend)
- i) Then "roundtable" discussion of panelists and audience.



DITTA GLOBAL DIAGNOSTIC IMAGING,
HEALTHCARE IT & RADIATION THERAPY
TRADE ASSOCIATION



Ensuring Radiological Security in the Context of Cancer Treatment

Friday 12 May, 13:30-15:00, Session on Medical imaging



Presentation to the WHO Global Forum on Medical Devices

Ensuring Radiological Security in the Context of Cancer Treatment



Kristina Hatcher

U.S. Department of Energy

National Nuclear Security Administration

Office of Radiological Security

12 May 2017



Global
Material
Security



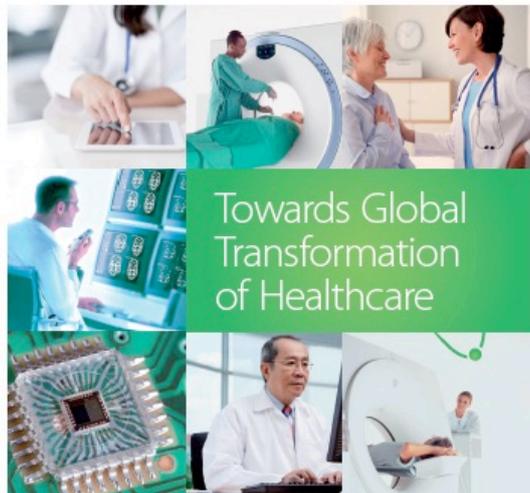


DITTA GLOBAL **D**IAGNOSTIC IMAGING,
HEALTHCARE **I**T & RADIATION **T**HERAPY
TRADE **A**SSOCIATION



DITTA GLOBAL **D**IAGNOSTIC IMAGING,
HEALTHCARE **I**T & RADIATION **T**HERAPY
TRADE **A**SSOCIATION

The global voice of the
medical technology industry



- Providing highly innovative solutions to advance healthcare
- Leading the digital transformation
- Optimizing patient care pathway
- Supporting global regulatory convergence
- Fostering international standards
- Driving circular economy
- Sharing competencies and best practices
- Advancing smart procurement of medical technologies



Medical Technologies
essential towards sustainable
Continuum of Care

www.globalditta.org