All About
CLINICAL ENGINEERING (CE)

IFMBE
Clinical Engineering Division

IFMBE CED 2020 CE Competency & Leadership Webinars:

CEs & HT Regulation: Addressing Health Technology Regulation Challenges

September 16, 2020

Moderators: Peter Grainger, Chair, IFMBE CED Regulation Project, CED Collaborator **(Ireland)**
and **Ashenafi Hussein,** Chair, IFMBE Working Group on Africa Activities, CED Collaborator **(Ethiopia)**
Stefano Bergamasco, MS CE, Owner & Director, MedTech Projects Srl, & Board Secretary, IFMBE CED (Italy)
Lorena Garza, BS BME, Executive Deputy Director of Health Services and Medical Devices, COFEPRIS (Mexico)
Jim Keller, MS BME, Business Development Director, Emergo by UL; Former: VP, ECRI & President ACCE (USA)

Agenda (pictures clockwise)

- Introduction to *CEs & HT Regulation* – Peter & Ashenafi
- *CE Perspectives on HT Regulation in Europe – Stefano*
- *CE Perspectives on HT Regulation in Mexico – Lorena*
- *Harmonization of Global HT Regulation - Jim*

Introduction to *CEs & HT Regulation*: Definitions

- **Health Technology[1]:** Defined by the World Health Organization (WHO) as the "application of organized knowledge and skills in the form of (medical) devices, medicines, vaccines, procedures, and systems developed to solve a health problem and improve quality of lives". [CED focuses on devices and related clinical procedures & systems.] See WHO/WHA 60.29 (2007).
- **Clinical Engineer[2]:** The WHO noted in 2018 that it is critical that "trained and qualified medical engineering professionals are required to design, evaluate, regulate, maintain and manage medical devices, and train on their safe use in health systems around the world. **This role is referred to as clinical engineering (CE),** biomedical engineering (BE), and/or health-care technology management (HTM) dependent on regional terminology."
- **Health Technologies and Medical Device Regulation[3]:**
  - **Regulation** is primarily concerned with enabling patient access to high quality, safe and effective medical devices, and avoiding access to products that are unsafe. When appropriately implemented, regulation ensures public health benefit and the safety of patients, health care workers and the community.
  - WHO has a mandate, as outlined in the World Health Assembly (WHA) Resolution **Health Technologies** 60.29 "to encourage member states to draw up national or regional guidelines for good manufacturing and regulatory practices, to establish surveillance systems and other measures to ensure the quality, safety and efficacy of medical devices and, where appropriate, to participate in international harmonization".
- **IMDRF[4]:**
  - **WHO** is an official observer in the management committee of the "International Medical Devices Regulators Forum" (IMDRF).
  - **IMDRF** was conceived in February 2011 as a forum to discuss future directions in medical device regulatory harmonization. It is a voluntary group of medical device regulators from around the world who have come together to build on the strong foundational work of the Global Harmonization Task Force on Medical Devices (GHTF), and to accelerate international medical device regulatory harmonization and convergence.

[1]https://www.who.int/medical_devices/definitions/en/
[2]https://www.who.int/medical_devices/support/en/
[3]https://www.who.int/medical_devices/safety/en/
[4]http://www.imdrf.org/

Introduction to *CEs & HT Regulation*: Resources

1. **The Survey of 3 Departments in Guangdong Province Under New Regulations**, Yang Shaozhou, China
2. **Necessity of Clinical Engineering to Regulate the Medical Devices in Middle Income Countries**, Anwar Hossain, Bangladesh
3. **International Standards for Medical Device and The U.S. FDA**, R.G. Fernandes, Brazil
4. **FDA Internationalization Under the Aspect of Medical Device Standards**, R.G. Fernandes, S.J. Calil, Brazil
5. **HT Regulation, Policy, Management**, 2015, Andrea García Ibarra, Rojas Morales, (part2), Colombia
6. **The Regulation of medical devices in the European Union**, Carlo Pettinelli, Italy
7. **The AHWP Playbook for Implementation of a Health Technology Regulatory Framework, An Overview**, Ms. Joanna Koh et al
8. **The role of HTM in WHO, to support access to medical devices for Universal Health Coverage and achievement of SDGs**, Adriana Velazquez, (part2, part3)
9. **HTA, HT Regulation, HTM to improve care delivery**, Cardenas, de Alba, Orencio, Moreno, (part2), Mexico
10. **BME/Clinical Engineering (CE) Role for Policy Implementation of Medical Equipment regarding Post-Market Surveillance in Health Systems**, KP Lin, (part2), Taiwan
11. **Accreditation of BME/CE in Taiwan**, KP Lin, (part2), Taiwan
12. **MoH HT Unit product tracking/surveillance/pricing & Country-wide HTM Data**, Ugur Cunedioglu, Bilal Beceren, Turkey
13. **WHO & International Labor Organization discussions 2015-2017**, Adriana Velazquez
14. **Strengthening Medical Devices Regulation in the Eastern Mediterranean Region of WHO**, Adham R Ismail
15. **Medical devices proactive surveillance – trends and impact from field and enforcement actions in Brazil**, MG Vincente, Brazil, 2017
16. **Preventable Adverse Events: How to?** Yadin David, USA, 2017
17. **Medical Devices Vigilance and the European Union Regulations**, Nicolas Pallikarakis, Greece
18. **Medical Device Post Market Surveillance** by A. Badnjevic, 2019
19. **Effecive CE Health Policy Innovation, Leadership, Strategy, and Action Plan to Overcome Global Health Disparities** by Elliot Sloane, 2019, USA
20. **When an Unintended or Unwanted Event Happens,** by Yadin David, 2019, USA
21. **CED Health Technology Regulation Project** by Peter Grainger, 2019, Ireland
22. **III ICEHTMC Presentation YouTubes**, Rome 2019*:*
https://www.youtube.com/watch?v=sdV47c3PNWY&list=PLhnffEvoohI3_qu18oWPlERd_Rv_KIpAG

23. **WHO 4GFMD, Workshop: Vigilance: HT Regulation Issues,** 2018
https://www.who.int/medical_devices/global_forum/4th_gfmd_Workshops/en/index13.html
   (a) Peter Grainger, Ireland/BEAI, CED Health Technology Regulation project Overview; http://cedglobal.org/peter-grainger/
   (b) Mohammad Ameel, India/MOHFW, Developing HT Policy: India's Perspective
   (c) Nicolas Pallikarakis, Greece/EU, MD Vigilance: Need for a global approach
   (d) Almir Badnjević, Bosnia & Herzegovina, MD Post-market surveillance experiences
   (e) Tobey Clark, USA/ WHO CC, Adverse event notification, investigation/reporting

24. **WHO 4GFMD, Workshop: Nomenclature, 2018:**
https://www.who.int/medical_devices/global_forum/4th_gfmd_parallel_session_presentations/en/index13.html
   (a) Murilo Conto et al, Brazil, Main Priorities and a Global Standard on MD Nomenclature
   (b) Stefano Bergamasco, Italy, Auto transcoding across different MD coding and nomenclature systems
   © Leandro Pecchia, Nicolas Pallikarakis UK, Greece, Harmonising MD and medical location policies among Africa and Europe

25. ***Making a Difference: Global HT Success Stories*: Overview of 400 from 125 Countries,** Global CE Journal, 2018: Yadin David, Thomas Judd, USA, https://globalce.org/index.php/GlobalCE/article/view/43

26. **WHO-IFMBE CED COVID19 Critical Topic May Townhall Webinars and Resource Center,** July 2020, Global: https://ced.ifmbe.org/blog/who-ced-covid19-townhalls.html and https://ced.ifmbe.org/blog/covid19-resources.html

27. ***IMDRF Principles & Practices for Med Dev Cybersecurity***: 2019, http://www.imdrf.org/consultations/cons-ppmdc.asp

28. **MDCG European Commission Guidance on Cybersecurity for Med Devices**: EURO, 2020:
https://ec.europa.eu/docsroom/documents/38941

29 (a) **IMDRF Working Groups** earlier:
   i. NCAR: http://www.imdrf.org/workitems/wi-ncarsystem.asp facilitating the exchange of relevant post market safety information on medical devices with global distribution; Nancy Pressly, USa FDA, member

29 (b) **IMDRF Working Groups** where CED could best contribute/collaborate, eg, to be the 'voice of CE'; 2020
   (1) Adverse Events;
   (2) Linkage of Standards & Regulations; and
   (3) Cybersecurity.

30. ***Telehealth (Regulatory) Law Comparison Chart: Latin America 2020*:** *Peru, Colombia, Paraguay, Mexico, Venezuela*, by Rossana Rivas, Pedro Galvin, Andrea Garcia, Roberto Ayala, Ricardo Silva for CED Telehealth, 2020

31. ***Reengineering the Medical Equipment Management system: The Provider- Regulator-Purchaser Aspect***, Ashenafi Hussein, Ethiopia, 2014

32. ***Towards improving access to medical devices through local production,*** WHO 2013, A. Hussein et al.
https://apps.who.int/iris/bitstream/handle/10665/206545/9789241510141_eng.pdf;jsessionid=C983A6FDF2A948F83ABC8D0D5F6D6428?sequence=1

33. ***Spin-off use of adverse events data: why and how. The case of FDA's MAUDE***, Global CE Journal 2018, Panagiotis Malataras, Nicolas Pallikarakis

CE-HTM Leadership Principles

These principles need to be learned by all CE-HTM practitioners to advance their careers.

1. **Innovation culture,** eg, create an Innovation culture in all we do; encourage and practice lifelong learning
2. **People-centric,** eg, selfless service to team & others, empathetic, compassionate; priority of patient safety & personalized care
3. **Teamwork & goals driven,** eg, direct teams collaboratively toward shared goals
4. **Adaptive decision-making,** eg, timely analysis and prioritization to resolve challenges
5. **Evidence-based,** eg, scientific use of data, collected systematically, multi-centric, producing unbiased high-quality information
6. **Clinical use of technology,** eg, understand HT applications from both perspectives
7. **'Systems of Systems'-focused,** eg, using our unique SoS perspective to improve healthcare delivery
8. **Communication skills,** eg, understand, articulate clearly, and address various stakeholder needs in a timely manner
9. **Humble,** eg, people value humility and appreciate the respect a leader shows by asking for their input; willing to admit our errors
10. **Integrity & ethics-driven,** eg, observing a code of ethics such as that published by ACCE, which includes recognizing and avoiding activities that create conflicts of interest; see Appendix for ACCE Code of Ethics
11. **Soft Skills,** In our health worker and patient interactions, demonstrate the following: (1) positive greeting, (2) respectful listening, (3) obtain clarity, (4) manage expectations, (5) initiate collaboration, (6) solution driven, and (7) express gratitude
12. **Investing Deeply,** in one another's lives; strong lasting friendships among colleagues where we pray for and encourage one another through good times and bad. The impact of these investments on each other's professional outcomes cannot ever be well understood or measured.

References: 1-10 from CED leaders; 11 from AAMI, see https://www.aami.org/productspublications/articledetail.aspx?ItemNumber=10501); 12 from Dr. Sharma

So What is the CED Regulation Project?

Regulation

1. Aim :

To Get involved in Regulation and the Regulatory Process.

IMDRF International Medical Device Regulators Forum

IMDRF is a **voluntary group** of medical device regulators from around the world who have come together to build on the strong foundational work of the global harmonised task force on medical devices (GHTF).

It **aims to accelerate** international medical device regulatory harmonisation and convergence.

This– Coordinator – Captain Scott A Colburn, USA

Standards - Improving the quality of international medical device standards for regulatory use

Purpose: To identify and explore possibilities "**to improve the process of developing international standards**" used for regulatory purpose in the medical technology domain.

Development of “Standards”

2. Aim : To Get involved in the Development of “Standards” and Standards Processes.

ISO/TC 210 Quality Management and Corresponding General Aspects for Medical Devices

A

IEC TC 62/ ISO TC 210 Joint Advisory Group
“Life Cycle Aspects for Medical Devices”

Dr Peter Linders
Netherlands

Scope

All aspects of the medical device life cycle, including

- development, manufacturing, installation, maintenance, repair, on-site testing, refurbishment, upgrade, remanufacturing of medical devices
- repair with used parts, possibly after refurbishment or remanufacturing
- reuse of parts for new medical devices
- reuse of medical devices intended for single use or short-term use
- end-of-life aspects such as (final) decommissioning and recycling
- decommissioning to a next user (change of ownership of the device), including cross-border donation to other facilities or users
- environmental aspects
- security aspects, including handling and removal of stored data

B

TC 210 Working Group 7 “Medical Device Maintenance Engineering”.

Convenor: Mrs Salbiah Yaakop, Malaysia

Conduct a Survey, & Draft a White Paper

3. Aim :

To Collate the existing body of references to regulation from around the globe pertaining to the “Role of the Clinical Engineer”.

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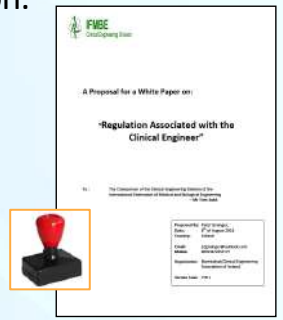
- Develop a questionnaire suitable to collate regulation information.
- Develop network and linkages with key regulation organisations or bodies.
- Catalogue regulation organisations and bodies that develop regulation that relate to the clinical engineer.
- Catalogue Clinical Engineer experts who already contribute to regulation and Standards development.
- This will allow for an initial baseline of such Regulation to be known and understood by the Profession.

4. Aim :

To Draft a White Paper on Regulation detailing analysis and recommendations inclusive of strategic ways forward and present to the CED of the IFMBE for consideration.



2019 - 2021

Health Technology Regulation in Africa

(Pre - COVID and During COVID)

Ashenafi Hussein

Chair, WGAA

HT Regulation in Africa

Pre -COVID-19

Most Regulatory Organization accept What is approved in Stringent Regulatory Authorities (EU, FDA, etc.)

Very Long Process: Pre-Market Surveillance and Post-Market Surveillance are not strong

No Enough Laboratories and personnel

During COVID-19

More challenging many products are not passing through Regulatory Scheme

Many PPE were used without being approved properly

- Studies showing negative impacts on Quality & Safety to be provided

Proposed Solution

Strengthening Local Regulatory Capacity

Fast Track Regulatory Scheme for Emergency

CEs & HT Regulation Success Stories

Today we tell 3 stories from among many that illustrate the best of *CEs & HT Regulation approaches* and **describe the most significant Leadership principles necessary to achieve these results:**

- ***CE Perspectives on HT Regulation in Europe – Stefano***
- ***CE Perspectives on HT Regulation in Mexico – Lorena***
- ***Harmonization of Global HT Regulation – Jim***

[1] **Stefano Bergamasco:** https://www.linkedin.com/in/stefanobergamasco/; ***Role of CE in a changing healthcare: Perspectives of Mediterranean countries; WHO 4GFMD 2018 -*** https://www.who.int/medical_devices/global_forum/4th_gfmd/en/
[2] **Lorena Garza:** https://www.linkedin.com/in/lorena-garza-a3712725/; and http://www.imdrf.org/docs/imdrf/final/meetings/imdrf-meet-180321-china-beijing-presentation-stakeholder-mexico.pdf
[3] **Jim Keller:** https://www.linkedin.com/in/jamespkellerjr/; and https://www.emergobyul.com/services/covid-19