REPORT

Clinical Engineering (CE) and Health Technology Management (HTM) 2017 Summit for Latin America and the Caribbean (LA&C)

September 20, *São Paolo, Brazil, prior to the 2nd International CE-HTM Congress (ICEHTMC 2017)*

Methodology

This report contains a summary of the invited presentations done by representatives of 11 countries at the Latin American & Caribbean Summit on Clinical Engineering (CE) & Health Technology Management (HTM) on September 20, 2017. The event took place at the Sirio Libanes teaching and research facilities in São Paulo, Brazil. PAHO/WHO, the Ministry of Health of Brazil, and The American College of Clinical Engineering (ACCE) promoted this meeting.

Executive Summary

Eleven countries were represented at this venue. Each of the representatives addressed priority topics relevant to device regulations, training, challenges, number practicing Clinical engineering and HTM professionals, and organizations active in their country and their goals. In addition, the World Health Organization and The Pan American Health Organization reported their work plans and goals related to Clinical Engineering (CE)/ Biomedical Engineering (BE).

Individual Reports

WHO reported its focus to contributing to the fulfillment of the third development objective "sustainable development goals." In this framework, there is an invitation to work towards achieving universal sustainable coverage, with medical devices that meet the 5 "As" (Affordable, Appropriate, Accessible, Available, Acceptable).

Furthermore, there was a promotion for the participation of CE and BE professionals in the emergencies and disasters preparedness and response programs. And in this frame of reference, the progress is already showing up in the publications of the Organization.

WHO set priorities on the following points:

1. Information of Biomedical Engineers and Bioengineers in the world. At least 300,000 are required to be recognized by the International Labor Organization as a unique profession.
2. Decommissioning.
3. Nomenclature.
4. Technical Specifications
5. Biomedical equipment lists.
6. Prices.
7. Hospital website.
8. Translation of the website in Portuguese.

PAHO reported the implementation of networks on healthcare technologies, with the goal of effectively addressing the following issues in the Americas and The Caribbean:

1. Regulation: risk management, reprocessing, virtual training, indicators -- currently in Ottawa meeting with International Medical Device Regulation Forum (IMDRF).

2. Evaluation: Regional Network of Health Technology Assessments for the Americas (RedETSA). Network launched in 2011. Thirty-two institutions representing 15 countries, started with drugs and have been including medical devices (MD) gradually. They have promoted virtual courses, HTA guides for MD, and webinars.

3. Management: Invites to participate to collect information on this topic.

The summary of the presentations delivered by representatives from each of the countries is as follows:

ARGENTINA:

- The Argentinian college of engineers supported the drafting of national medical equipment management regulations, and the Argentinian society of Bioengineering (SABI) is supporting the implementation of this laws.
- One of the society goals is create a clinical engineering chapter and sustain and expand the creation and implementation of regulation and standards.
- SABI is proposing and will advocate for a funded program for Clinical engineering residencies at provincial hospitals. Additionally, the society is seeking accreditation of their calibration laboratory
- Argentina has one main Clinical Engineering related society, the “Sociedad Argentina de Bioingeniería SABI.”

BRASIL:

- The Secretariat of Science, Technology and Strategic at the MoH, provides resources for innovation.
- The challenge is to align innovation with the need and trends of the medical demand
- The industry needs a sustainable development, the improvement of medical devices availability, strengthen logistics chains and logistics.
- There are advancements in policies formulation and inventory mapping of medical devices. It is required the promotion of commercial policies to articulate intellectual property processes.
- Research is understood as a relevant support for technology development.
- MoH’s strategy focuses on Technology Planning and the promotion of Training for Human Resources Education. Relevant challenges are around the Control and Management of Technology Costs, and the alignment of Human Resources.
- One of the goals is to increase the articulation with the private sector in order to accelerate the processes of transfer and development of health technology.

CANADA:

- Implementation of health care regulations in Canada is managed by the provinces.
- There is a Health Technology Management certification process. Clinical Engineers have the opportunity to enroll in practicums and internships.
- Objectives include collecting and documenting data to support their initiatives, seeking alliances with the private sector, and having the CE certification validated by the employers with additional salary for certified clinical engineers.
- Canada has a professional Clinical Engineering and HTM society, the Canadian Medical and Biological Engineering Society (CMBES).

CHILE:

- There is no specific law that mandates that hospitals require to hire Clinical Engineers.
- Adverse events may be underreported because according to the regulation adverse events are considered medical negligence.
- University of Valparaiso teaches courses in hospital safety and design and fabrication of analyzers and simulators for calibration of medical equipment.
- There is an emphasis on bringing technology for the support of senior's well-being. this includes the sustained fabrication of medical equipment for this community.
- The university goals include the development of curriculum to teach emergencies and disaster preparedness.

COLOMBIA:

- The standards are established by MoH, working from a board of experts (clinical engineers of accredited hospitals) to define mandatory technology management standards in all Colombian healthcare facilities. This board of experts also leads the regional nodes of biomedical teams, work groups generating innovative solutions based on communication.
- The country has 11 undergraduate programs, several graduate programs, and some technical training. There is a group of universities in the department of Antioquia working in a coordinated way to organize events (congresses and webinars) with integration of government, hospitals and industry in order to strengthen and boost clinical engineering.
- There are implemented basic regulations and HTM standards.
- There are neither public nor private reference institutions for CE and HMT, and technology evaluation agencies promoting strategies and tools to generate and share knowledge.
- There are no mechanisms, tools, or institutions responsible for certification of technologists and engineers
- One of the challenges is include more institutions to boost clinical engineering, work from the Institute of technology assessment in healthcare management areas.
- Supporting the Colombian HTA Institute (IETS) in HTM projects. Strengthening of Formal Network. Next step: The activation of The Colombian College of Clinical Engineering

(COLCINC). Establishing formal collaboration with ACCE. New projects include Webinar Series, and sustained educational activities.
- There are several associations of biomedical engineering.
- The goal is to improve of Clinical Engineering demand, positioning, and the recognition and to improve of Clinical Engineering education and training.

COSTA RICA:

- Costa Rica has implemented legislation requiring EHR for the country. Requirements for RIS, PACS and other imaging connectivity technologies are also included in the law.
- There is an electromedical engineering degree that began in 1998. This degree is similar to a biomedical engineering degree.
- Goals include enhancing technical education to increase the number biomedical engineer available to work in hospitals, and in the national department that provides health care auditing. In addition, there is an initiative to design and provide in-house metrology services.
- They have a professional society "El Colegio Federado de Ingenieros y Arquitectos," within this organization there is an electromedical division. For biomedical engineers to legally work, they are required to be members and pay a monthly fee. There is also an (inactive) chapter of IEEE-EMB and the "Asociación de Ingenieros Electromédicos (ACOBEN)".

ECUADOR:

- Currently there are no undergraduate biomedical engineering or clinical engineering programs.
- The "Honorable Junta de Beneficencia of Guayaquil" is promoting the implementation of a Master degree in Biomedical Engineering with the support of ACCE.
- One of the goals is to provide opportunities for people to obtain a clinical engineering education and therefore promote and bring visibility to the profession.

MÉXICO:

- There is a validated database of functional high technology medical equipment to support better resource allocation. This include all levels (micro, meso and macro)
- There was no reliable high technology medical equipment database, "Equipo Médico de Alta Tecnología (EMAT)." This was a challenge to effective and efficient management of equipment for the Mexican national health system.
- There was a definition of twelve different types of high technology equipment. subsequently, there was an analysis and classification of healthcare public and private facilities with high technology equipment to be surveyed.
- The goal to have a national unified database of functional medical equipment including the private and public sector.

PARAGUAY:

- The challenges in this country include the lack of resources to provide healthcare and further to acquire medical devices, as the demand for health services increases.
- With the support of ACCE education and training programs, the clinical engineers were motivated to propose solutions to these problems. A telemedicine solution was the most appropriate approach suggested to solve these challenges.
- Telemedicine technology was designed, developed and implemented in rural regions. This project was very successful and changed the paradigm of having face to face doctor-patient patient consultation as the only way of providing care.

PERÚ:

- Ministry of Health-MoH and Social Security System (EsSalud), have created and strengthened departments of infrastructure, technology assessment, and regulation.
- the Comptroller office of the Republic (CGR), will initiate a process of evaluation of hospital technology.
- The CE and HTM cluster (CENGETS) is working with organizations of the MoH, EsSalud and the CGR to respond to their needs.
- The challenges and opportunities are related to the misuse, access and availability of health technology. Additionally, there is a need for training and education in clinical engineering, technology assessment, technology management, and technology planning.
- In this regard, a priority is primary health care level
- CENGETS with the supporting of College of Physicians, the College of Engineers and the College of Chemistry & Pharmaceutical are advocating for the hiring of Clinical and Biomedical Engineers in Hospitals

REPÚBLICA DOMINICANA:

A project of medical gases was presented. This included the adaptation and subsequent implementation of international standards. The outcome promotes safe pipelines in the hospitals and thereby increases patient safety.

Observations

In terms of regulation 6 countries reported that initiatives have been developed from the Ministries associated with Health Technology Management. They are all aligned in different phases of the Technology Life Cycle. In addition, there are gaps primarily in security, surveillance, acquisition, maintenance, and replacement that should be covered. Some countries reported they are developing innovative health technology projects not related to regulation.

Regarding training, most countries have undergraduate and some postgraduate engineering programs which are associated with health technology;

Currently in Latin America, there are engineers from related disciplines working in Clinical Engineering.

Canada and Brazil reported that they have a Clinical Engineering certification processes in place.

All the countries shared challenges and opportunities that may be better addressed under a collaborative framework.

Most countries have engineering associations, they also recognized the importance of a regional network for achieving their respective goals.

Finally, there is a CE community working together, who is focused on patient centered care, and who is taking action to educate themselves and solve problems.

Respectfully,

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