Global Clinical Engineering Journal

Special Issue 5

GlobalCE

Publisher International Medical Sciences Group, LLC

5 ICEHTMC
International Clinical Engineering & Health Technology Management Congress
INDIA EXPO CITY, AMTZ CAMPUS, VISAKHAPATNAM, INDIA
NOVEMBER 10-13 | 2023

5th ICEHTMC PROCEEDINGS

www.GlobalCE.org

ISSN: 2578-2762

EVENT WEBSITE:
www.globalcea.org/icehtmc2023

GLOBAL CLINICAL ENGINEERING ALLIANCE | IFMBE Clinical Engineering Division | AMTZ | AAMI

Editor's Corner

5th International Clinical Engineering & Health Technology Management Congress (ICEHTMC)

November 10-13, 2023, Visakhapatnam, India

Dear 5th ICEHTMC Congress Community,

On behalf of the organizers and the organizers and sponsors of the 5th International Clinical Engineering & Health Technology Management Congress (ICEHTMC), it is our honor to offer this publication that contains all of the abstracts accepted for the oral and poster sessions in this Congress. The strict peer review process of the submissions received that was accomplished through the amazing support received from the Scientific Program Committee members and Global Clinical Engineering Journal team, that together have over 100 experienced reviewers from all over the world, resulted in these Proceedings. This made the 5th ICEHTMC Congress an amazing scientific as well as professional networking event. This program exceeds all previous Congress records for quality and quantity.

Major recognition must be given to the unique cooperation between the Global Clinical Engineering Alliance (GCEA), the IFMBE Clinical Engineering Division (IFMBE CED), AAMI, and the local hosts AMTZ.

This is the 3rd time that the Congress's proceedings are published and available in an on-line format (GlobalCE.org). The Global Clinical Engineering Journal's commitment to the promotion and sharing of knowledge is evident through its selected editors community of experts and obligation to timely publication of subjects at the cross between engineering, technology, and patient care outcomes. These proceedings are a great accomplishment that will serve the ongoing and growing Global Clinical Engineering field into the future.

Conducting a hybrid style international Congress presents a different stage and greater opportunity to engage with more members within our field as well as with other healthcare stakeholders interested in professional development, scientific debate, networking, collaboration, strengthening friendships, and learning more about best practices from faraway places. We thank all the participants, exhibitors, local hosts, and are confident that you will find these proceedings useful. We wish you success and hope to meet you at our next Congress.

Together we can make it better!

Yadin David

Editor-in-Chief of GlobalCE Journal
and GCEA President

SCIENTIFIC PROGRAM

	November 9, 2023	10 November 2023		
Time	**KCC Entry Lounge & Central Area**	**KCC Entry Lounge & Central Area**	**KCC Auditorium**	**AMTZ Exhibition Centre**
9:00 am - 9:30 am	Registration	Registration		
9:30 am - 11:00 am			**Global CE Summit**	
11:00am - 11:15 am	Break & Posters			Exhibition
11:15 am - 12:00 pm	Registration		**Welcome Keynote:** Dr. Jitendra Sharma	
12:00 pm - 1:00 pm			**Short Course 1** Traditional Maintenance	
1:00 pm - 2:00 pm			**Short Course 2** Integrated Device Maintenance	
2:00 pm - 3:00pm	Break & Posters			Lunch & Exhibition
3:00 pm - 4:00 pm	Registration		**Short Course 3** Health Technology Assessment and Innovation	
4:00 pm - 5:00 pm			**Short Course 4** Health Technology Quality and Risk	
5:00 pm - 6:30 pm		Hors D'oeurves and snacks	**GCEA Annual Meeting**	Exhibition

	11 November 2023					
Time	**KCC Entry Lounge & Central Area**	**KCC Auditorium**	**KCC Omega Hall**	**KCC Celsius Hall**	**KCC Tesla Hall**	**AMTZ Exhibition Centre**
8:30 am - 9:00 am	Registration					
9:00 am - 10:00 am		**Welcome Keynote:** GCEA, CED & AMTZ and **Opening Keynote** **WHO:** Adriana Velazquez				
10:00 am - 12:00 pm		**Track A1**	**Track A2**	**Track A3**	**Track A4**	
12:00 pm - 12:15 pm	Break & Posters					**Exhibition Hall**
12:15 pm - 2:15 pm		**Track B1**	**Track B2**	**Track B3**	**Track B4**	**Exhibition Hall**
2:15 pm - 3:15 pm						Lunch & Posters
3:15 pm- 5:15 pm		**Track C1**	**Track C2**	**Track C3**	**Track C4**	**Exhibition Hall**

SCIENTIFIC PROGRAM

12 November 2023

Time	KCC Entry Lounge & Central Area	KCC Auditorium	KCC Omega Hall	KCC Celsius Hall	KCC Tesla Hall	AMTZ Exhibition Centre
8:30 am - 9:00 am	Registration					
9:00 am - 10:00 am		Welcome & 2 Keynotes: GCEA and IFMBE CED				
10:00 am - 12:00 pm		Track D1	Track D2	Track D3	Track D4	
12:00 pm - 12:15 pm	Break & Posters					Exhibition Hall Open
12:15 pm - 2:15 pm		Track E1	Track E2	Track E3	Track E4	Exhibition Hall Open
2:15 pm - 3:15 pm						Lunch & Posters
3:15 pm- 5:15 pm		Track F1	Track F2	Track F3	Track F4	Exhibition Hall Open
5:15 pm - 6:00 pm	Congress Closing Ceremony					

13 November 2023

Time	KCC Entry Lounge & Central Area	KCC Auditorium	AMTZ Exhibition Centre
9:00am-1:00pm	AMTZ tours and Vizag local area tours; registration required Bag lunches available for local area tours		
12:00pm-1:00pm			Lunch & Posters in Exhibition Hall
1:00pm-2:30 pm		Joint Congress-Forum Panel 1: ***Ministers of Health teams review of future management of Health Technologies (MOH)***	Exhibition Hall Open
2:30pm-3:00pm	Break		Exhibition Hall Open
3:00pm-4:30pm		Joint Congress-Forum Panel 2: ***Women Global Leadership in Clinical Engineering and Health Technologies (WICE)***	Exhibition Hall Open
4:30pm-4:45pm	Break		Exhibition Hall Open
4:45pm-6:00pm		**Global CE Community and AMTZ: Future directions**	

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POSTERS

On behalf of the Organizers Committee of the 5th ICEHTMC Congress, we would like to thank all who participated for their valuable contribution and support.

A1-Pandemic Response 1

Enhancing Quality Assured Medical Devices (PPE) in Pakistan: Strengthening Local Manufacturing and Testing Capabilities

By Tazeen Bukhari and Syed Khalid Saeed Bukhari

PQM+, Pakistan

The abstract highlights the efforts undertaken by Pakistan to enhance the quality assurance of Personal Protective Equipment (PPE). It focuses on two key initiatives: Facilitation of local manufacturing capabilities including testing for quality-assured PPE and the establishment of the first public sector laboratory for PPE quality testing. The abstract outlines the goals, strategies, and results of these initiatives, showcasing Pakistan's commitment to ensuring the safety and effectiveness of PPE in the face of public health emergencies.The main goals of the project were: 1.Promoting Local Manufacturing: The goal is to establish local manufacturing capabilities for quality-assured PPE in Pakistan, reducing dependence on imports and ensuring a steady supply of reliable protective equipment during public health crises. 2.Strengthening Quality Testing Infrastructure: The aim is to establish a dedicated public sector laboratory equipped with state-of-the-art facilities and qualified personnel to conduct rigorous quality testing of PPE. This will enable comprehensive evaluation and verification of the safety and performance of PPE products. Health workers, Local Manufacturers, Patients, Public Sector Laboratories, Regulatory Authorities, Government official and Policy makers can benefit from the project and ultimately contributes to the overall health and well-being of the population, strengthens healthcare systems, and improves the response to public health emergencies. **Results:** 1.Local Manufacturing Capacity: Pakistan successfully initiated the manufacturing of quality-assured PPE, including masks, gloves, gowns, and face shields. This has led to increased availability of reliable PPE within the country, reducing reliance on imports and ensuring a stable supply during emergencies. 2. Public Sector Laboratory: The facilitation in establishment of the first public sector laboratory dedicated to PPE quality testing has significantly strengthened the quality assurance infrastructure. The laboratory shall be equipped with advanced testing equipment, trained staff, and standardized testing protocols, enabling comprehensive evaluation and certification of PPE products. 3.Enhanced Quality Assurance: Through rigorous testing, leveraging Private sector investment, and incorporating and adopting international standard testing and regulation, and creating awareness, public sector laboratory has played a crucial role in identifying and addressing quality issues in PPE products. This has led to improved product quality, enhanced safety for healthcare workers and the public, and increased confidence in the effectiveness of locally manufactured PPE. 4. Contribution to Public Health: The initiatives have contributed to the overall public health preparedness and response capacity in Pakistan. The availability of quality-assured PPE and robust testing capabilities ensures the protection of healthcare workers, reduces the risk of infection transmission, and supports effective pandemic management.By highlighting these results, this abstract showcases the successful efforts of Pakistan in promoting the quality assurance of PPE through local manufacturing and testing capabilities. These initiatives serve as a model for other countries aiming to enhance their preparedness and response to public health emergencies, emphasizing the importance of ensuring reliable and effective PPE for frontline workers.
Keywords: medical devices, PPE, standards, testing, capacity building, local production, promoting quality, quality assured

A1-Pandemic Response 1

Applying COVID-19 Telemedicine 'Lessons Learned' for LMICs

By Elliot Sloane, Rossana Rivas Tarazona

Villanova University, WHO Collaborating Center for HTM, USA

During the COVID-19 pandemic scientific and medical journals opened all their COVID-related articles for free global distribution. IFMBE CED and GCEA launched a 3-year literature review project, The Hacking COVID Update (HCU). The two authors were part of a team that met daily for the first two years to scan and curate global literature for articles that could help health technology managers and policy makers improve COVID diagnosis and therapy. Approximately 4,000 relevant articles were identified and published in the free daily HCU newsletter set to over 20,000 daily subscribers. The large number of innovative telemedicine and telehealth articles that rapidly emerged from the COVID literature was quite surprising because many unexpected medical applications showed up. For example, successful and novel cardiology, dental, dermatology, pediatric, psychiatry, rehabilitation, and surgical telemedicine applications were described. It is interesting, too, that the deployments were not just in UICs, but also in LMICs. Even infrequent countries like Iran and Saudi Arabia contributed to the body of knowledge. The lines between the two domains of telemedicine and telehealth were also blurred during the pandemic. For example, one common differentiation used in the past was that telemedicine was a clinician-to-clinician activity to support diagnosis or treatment, while telehealth was often an adjunct concept used for patient health guidance

or health maintenance. Instead of direct physician contact, telehealth often involved a healthcare aide or simple automated chatbots supporting patient self-care. During the pandemic, however, direct physician-to-patient diagnosis and therapeutic intervention occurred, and healthcare aides were often empowered to become significant surrogates for physicians or nurses. The UK NHS's innovative Pulse Oximetry @Home and COVID Virtual Ward programs are two excellent and well documented examples. This presentation is aimed at informing HTMs in LMICs about the Hacking COVID archives that are freely available at www.globalcea.org/hcu and pointing them towards the rich repository of telemedicine and telehealth articles. Instead of "reinventing the wheel" for dental or psychiatric telemedicine and telehealth, for example, by searching the HCU repositories LMICs can locate peer-reviewed scientific and medical articles that document successful designs, implementations, and applications. To find relevant articles in HCU archives at www.globalcea.org/hcu, HTMs must remember to search both the HTM articles and the "C-Suite" archives! The telemedicine and telehealth articles that will be found in the C-Suite archives were put there because they related more to policymaking, public/population health, or long-COVID concerns rather than day-to-day COVID patient diagnosis and treatment. It is hoped that using the HCU archives, HTMs in LMICs will be able to leapfrog past prior telemedicine and telehealth obstacles by applying the lessons learned and published in HCU during the COVID-19 pandemic. This literature can also support policy makers who often depend on independent peer-reviewed research and literature to make resource allocation decisions.

Keywords: telemedicine, telehealth, health technology management, innovation, COVID-19, hacking COVID update, clinical engineering, workforce development, digital health, eHealth, mHealth

A1-Pandemic Response 1

Global CE Development and the Coronavirus Hacking Repository

By Thomas Judd

GCEA, USA

The Global Clinical Engineering (CE) "Community" – GCEA and IFMBE CED in partnership with WHO – responded to the global Coronavirus (COVID-19) pandemic in many ways. One of the most important was creation of a weekday e-Newsletter called "Hacking Coronavirus", that began in March 2020 and only concluded nearly 800 issues later in 2nd quarter 2023. https://www.globalcea.org/hcu. It was sent out to 17,000 colleagues daily to deal with the tsunami of COVID related studies and articles and to show those that were judged by experts as most credible. A small team gathered every weekday for over 3 years to judge and publish CE-related studies in WHO segmented topic areas. The team was led by Elliot Sloane, with also Yadin David, Tom Judd, Rossana Rivas, Luis Fernandez, and Kallirroi Stavrianou. It was estimated that by December 2020 alone, over 200,000 COVID-19 related articles and preprints had been published. Not all were scientific and medical peer reviewed so represented a combination of strongly supported articles as well as "gray literature" from all kinds of sources. After an early focus on modeling the spread of the pandemic, researchers - analyzed from PubMed - turned to other topics, such as Controlling the Spread, Public Health, Diagnostics & testing, and Hospital Mortality. Only a smaller percentage of these articles focused on topics relevant to CE. For example, buried in these topics are patient care and patient safety topics, including: HTA, HTM, oxygen, ventilators, pulse oximeters, PPE, home monitoring, virtual COVID care at home, rehabilitation, telehealth, telemedicine, ML/AI, cold chain for vaccines, ECMO, and senior care/nursing homes, etc. This study analyzed the Hacking database (over 5000 citations) for 10 topics related to CE with a particular focus on two highly ranked items, Ventilators (125+ including the EUA subtopic) and Oxygen (161+ including both sources, devices, pulse oximetry and methods of delivery). A separate abstract by Dr. Sloane addresses Telehealth and AI/ML. Why these 2 topics? The 194-member state Ministers of Health at WHO's World Health Assemblies, held virtually in 2020 and 2021 at the height of the pandemic, chose to focus on these two topics and assigned great responsibility to the WHO Medical Device Unit, led by our CE colleague Adriana Velazquez, for addressing these resource needs. 1. Ventilators: The author found 40 sub-topics in the Hacking database links directly relevant to CE practitioners, led by device comparisons, manufacturing & design, EUAs for emergency use, training for use & support including common use errors, repair, clinical appropriateness, strategies for optimal use, and disinfection. 2. Oxygen: The author found at least 25 subtopics in the Hacking database links directly relevant to CE practitioners, led by consumption, use of ECMO, High Flow, delivery, supply, decontamination, CPAP, home use, strategies for optimal use, training, and repair issues. This allowed CEs the world over - along with the Community webinars - to learn global best practices and to give evidence-based responses as able. It also resulted in tremendous growth and influence of the Global CE Community during that time period.

Keywords: clinical engineering, pandemic, global clinical engineering community

A1-Pandemic Response 1

Digital Organizational Transformation and Readiness for the Future of Health Services Through Telemedicine

By Pedro Galvan, Ronald Rivas, Benicio Grossling, Jose Ortellado, Juan Portillo, Julio Borba and Enrique Hilario

Health Sciences Research Institute (Ministry of Public Health), Paraguay

Clinical background: Universal coverage, increased operating costs, efficient use of available resources, labor shortage, understaffing, and improvement of the health care for remote populations are some of the issues identified that are challenging for the healthcare organizations worldwide. In this sense, healthcare organizations must align their priorities and create a strategy to support organizational transformation and future readiness. The challenge for clinical and biomedical engineers is to develop a digital health system to fulfill health services requirements for the future. In this context, telehealth tools should be directed towards offering universal coverage of health services contextualized to scarce human and health financial resources. This study has evaluated the results of telehealth services in remote public hospitals in Paraguay, to show how the digital organizational transformation in form of a telemedicine platform as a first step for the future readiness by providing access to tertiary level diagnostic services by specialists. **Methodology:** Descriptive study, where the results using telediagnosis in remote public hospitals were evaluated as a strategy to support digital organizational transformation and future readiness for health services. For these purposes, the type and frequency of diagnosis performed was determined. **Objective:** To evaluate the utility of telehealth services as a tool to implement digital organizational transformation and future readiness for health services. **Results:** A total of 774,711 telediagnosis were performed in 67 hospitals. The 505,695 ECG diagnosis performed in the 61 hospitals were mainly normal (63.8%), unspecified arrhythmias (11.3%), and sinus bradycardia (10.2%). 252,935 teletomography tests were performed in 12 hospitals, where 57.1% corresponded to head because of accidents (motorcycles) and cerebrovascular diseases, 14.3 % chest, and the rest the other anatomical regions. Regarding the 16,062 EEG tests performed in 19 hospitals, antecedents of seizure (57.5%), evolutionary controls (16.1%), and headache (13.8%) were mainly diagnosed. The 19 ultrasound studies corresponded to prenatal controls. **Conclusion:** Despite the results of the telemedicine tool implemented in the public health to introduce digital organizational transformation and future readiness for health services and consequently offer better equity in the provision of services in remote locations, a widespread use-assessment should be analyzed before this tool is adopted.
Keywords: digital transformation, organizational transformation future readiness, telehealth services, public health, telemedicine, telediagnosis, telehealth

A1-Pandemic Response 1

The Implementation of a CoViD-19 Floating Intensive Care Unit (FICU): A Resilient and Agile Response to ICU Capacity Expansion

By Jean Ngoie, Bill Bartlett and Zhihong Huang

University of Dundee, Scotland

The global expansion of Intensive Care Units (ICU) in response to the CoViD-19 pandemic has posed significant challenges for healthcare organizations. This study examines the implementation of a CoViD-19 Floating Intensive Care Unit (FICU) as an innovative and efficient model for rapidly expanding ICU capacity in NHS Tayside, Scotland, and its potential for addressing future surge scenarios. The FICU model was recommended by Clinical Engineering in NHS Tayside to meet the urgent demand for ICU beds during the pandemic. Where Scottish Government models projected that the existing capacity could be exceeded within weeks and requested that NHS Boards quadruple their ICU bed capacity within their existing infrastructure. Leveraging an integrated patient monitoring system and interoperable medical devices, all ICU devices were connected to a network, enabling data assimilation and mobility across the organization. A radio-frequency identification (RFID) tracking system was also implemented to locate and track equipment assets redeployed post-CoViD-19, facilitating their rapid deployment back to ICU areas within 24 hours when demand increased. This approach provides an agile and resilient response to fluctuations in ICU demand, whether due to subsequent waves of disease during a pandemic or emerging pressures. It optimizes the utilization of assets by allowing their capacity to be applied to patient care throughout the organization during periods of low ICU demand. This model has been successfully implemented in NHS Tayside, enabling a smooth response to the third wave of the pandemic while minimizing disruptions. The system relies on connectivity, interoperability, and RFID asset location technology, which are facilitated by innovations in diagnostic testing and the provision

of a robust and flexible system. By enhancing the value of asset investments and ensuring efficient resource allocation, the FICU model minimizes the revenue cost related to service of new assets and offers a sustainable solution for ICU capacity expansion. In conclusion, this innovative approach, supported by connectivity and asset management technologies, has the potential to address future surge scenarios, improving resource utilization and patient care across healthcare organizations.
Keywords: floating intensive care unit, Covid 19, clinical engineering, patient monitoring system

A1-Pandemic Response 1

How Can Digital Technologies Help Rural Communities in Times of Pandemic?

By Talant Sultanov

Internet Society Kyrgyz Chapter, Kyrgyzstan

COVID-19 demonstrated that during crisis rural communities become the most vulnerable groups of societies with lack of access to government services and social benefits such as health and education. Internet connectivity and digital transformation could narrow the gap and make communities more resilient during such crises.We will discuss the extent to which civil society organizations and individuals can encourage remote and rural communities to deal with challenges posed by the pandemic and to take advantage of digitalization opportunities. Some experiences include delivering educational materials through offline digital libraries and digital skills development for children, teachers, and local communities. Also, another important issue is the availability and promotion of digital educational and health content in local languages. We want to share experience and knowledge in closing the digital divide in times of the pandemic, so that no one will miss out of opportunities due to challenges related to connectivity, devices accessibility, availability of relevant content, and other challenges. Internet Society Kyrgyz Chapter is a non-profit organization that promotes digital development, and Internet since 2015 to empower rural communities through such activities as: 1. Building Internet Infrastructure and Community Networks. We are connecting and improving connectivity in remote and mountainous areas of the Kyrgyz Republic by setting up community internet networks in several villages with the support from the global Internet Society Foundation. 2. Supporting School Connectivity. In partnership with GIGA, a global initiative of UNICEF/ITU, we are working on creating a playbook for sustainable internet connectivity models for schools around the world with the support of UNICEF. 3. Improving Digital Skills. Sanarip Insan (Digital Citizen) is a project on improving digital literacy of youth and women in rural communities; the project is funded by the EU and implemented jointly with European Neighborhood Council. 4. Developing Educational Content. IlimBox or Internet-in-a-Box project brings educational content like Khan Academy videos and Wikipedia in the Kyrgyz language to schools and libraries in rural areas without access to the Internet with the support of the EU and USA; the Ilimbox project was listed among seven worldwide digital education initiatives by Thomson Reuters Foundation. 5. Online educational platform IlimBox.kg. ISOC-KG continues to work on the online educational platform IlimBox.kg by creating educational platform in Kyrgyz language with the support of the US Embassy in the Kyrgyz Republic. 6. Tech4Society – Enhancing Cyber Security of Citizens. We are working on cybersecurity protection and cyber hygiene for civil society organizations and citizens. The project is implemented jointly with partners such as the Nothing2Hide in France with the support of Soros Foundation. 7. Building of the Internet Exchange Point (IXP) in the Fergana Valley, which would help lower the prices for Internet, while improving the speed and the quality for the people in Kyrgyzstan, Tajikistan, and Uzbekistan.8. Protecting Climate through ICTs for Disaster Prevention. Using smart sensors and long-range communications technologies we monitor climate conditions for disaster forecasting and prevention with the support of the ISOC-Foundation jointly with jointly with the International Center for Theoretical Physics in Italy.
Keywords: digital, cybersecurity, alliances

A1-Pandemic Response 1

Pandemic Solutions for Grenada

By Keishauna Baptiste

Grenada General Hospital, Grenada

Description: 2021 was one of the most difficult years for Grenadians as we grappled with the impact of COVID-19. The health sector and non- governmental institutions (NGO) were not totally prepared for such a substantial number of the population to become infected with this virus. Despite the efforts by Government and health officials these numbers were

hard to contain and later resulted in the loss of 200 lives that same year. Learning from our shortcomings encountered in dealing with the COVID surges will help to determine how to reduce the risks of future pandemics. **Goals:** We must first analyze all the strategies used by the different health institutions and NGOs to contain the outbreaks. We will identify seven primary targets for pandemic prevention and preparedness: educate the population about the vaccines available to treat a specific virus; erect proper infrastructures such as fully equipped isolation facilities with a capacity of a minimum of 100 beds and sectioned areas for severe to moderate to mild cases; increase the human resources pool for trained nurses and doctors; collaborate with neighboring countries in order to create a pool of current information on pathogens; implement digital platforms to work remotely; make training courses on the current digital platforms more accessible to everyone so that it can be utilized to work from home; launch a national tracing and warning app which offers the possibility of alerting and warning citizens that they have been in close proximity with an individual who tested positive for a virus such as COVID-19. Finally, we can now create a healthier, safer, more equitable Grenada where; There is a reduction in number of closures of businesses; Educational institutions remain open throughout the year; The numbers of infectious persons are reduced; Points of entry into the Country are kept open. Social activities are quickly restored.In conclusion, the government, the private sector, and other entities need to work together to put more structures in place to improve preparedness and response to future events.
Keywords: pandemic, clinical engineering, digital health

A1-Pandemic Response 1

Preparing Your Hospital for a Natural or Man-made Disaster

By James Wear

GCEA, USA

Disasters that impact a hospital can be internal or external and may be natural or man-made. Natural disasters are earthquakes, hurricanes, tornadoes, or floods that can result in a large patient input. They can also result in the loss of utilities and other resources. Man-made disasters can be the result of industrial accidents, train wrecks, or terrorist's activities. These are most frequently chemical exposures but could be radiation exposure or biological exposure. The hospital engineers, including clinical engineers, should develop an emergency management plan in conjunction with the clinical staff to prepare for these potential disasters. They need to consider not only patients, but staff and the community. The main goal of the plan is to keep the hospital operating to provide care for new patients and continuing care and safety of the existing patients and staff. The plan needs to address power outages, water outages, gas outages, facility structure, communications and keeping the facility from contamination. Contamination of the facility is a real possibility when patients arrive from industrial accidents or terrorist's activities. Potential decontamination of incoming patients must be considered in order not to endanger the staff and existing patients. The engineers and the clinical staff need to work together to develop the plan and conduct drills of the plan.
Keywords: clinical engineering, disaster, hospitals

A2-Capacity Building 1

The Effect of Advanced Medical Device Technology in Africa

By Ashenafi Hussein

WGAA, Ethiopia

Introduction: Healthcare professionals and patients are getting a lot of advantages from the implementation of medical technology in healthcare facilities. It is clear that Advanced Medical device Technology will help in better diagnosis, Therapeutic, and rehabilitation activities of health care services. Billions of Dollars are spent on the procurement of medical devices which includes advanced medical device technologies CT/MRT, PET, laser technology, CAT lab, etc. Medical devices with high level of technology requires intensive training, and trained personnel for maintenance, availing huge amount of running cost of such devices. Advanced medical device Technology entails building capabilities, technical understanding, and an informational base; acquiring new technical skills and managerial practices. Accelerating the use of digital technologies

is key to creating productive Jobs and Boosting Economic Growth in Africa - With the development of mobile technology which is key in Mobile Health, internet connectivity for advanced medical device technology (World Bank MARCH 13, 2023- PRESS RELEASE NO: 2023/052/AFE); However in a study Where Egypt, Ethiopia, Kenya, Nigeria, Rwanda, and South Africa were taken in Harvard business review; the digital advantages and gaps of different countries vary widely; both the IMF and the World Bank have cut their 2019 economic growth projections for sub-Saharan Africa (SSA) to 3.5% and 2.8%, respectively, with growth in 2018 at 2.3%. (Bhaskar Chakravorti and Ravi Shankar Chaturvedi, December 04, 2019) **Conclusion:** Different African countries use the same technology at vastly different levels of efficiency. Technological competitiveness lies in the effectiveness with which countries promote capabilities. Health Facilities in Africa often lack the expertise to determine which new skills, technical knowledge, and organizational techniques are required to make newly imported technologies function at optimal levels. there are five main factors affecting technology development in Africa. These are physical infrastructure, skills, financing, technology, and supply. Despite the importance of Having Advanced medical device technology, poor economy, poor infrastructure, and limited resources available, human resource problems advanced medical device technology may not provide a positive effect on health service delivery in a Short period of time. However long-term solutions and recommendations can be put in strategy to have such medical devices in effective use. Recommendation include: Corrective policies are needed in order to promote national medical device technological use. This is the essence of technology policy: to promote learning and skill development; to improve the supply of information and skills from Africa's medical device Technology Gap; and to coordinate collective learning within and across related industries, carefully crafted technology policies can accelerate competitiveness and promote entry into more complex and higher-level technology activities. Changes in traditional mindsets are required to form interactions and linkages with other firms or institutions and to build technical know-how.

Keywords: Medical Device, Advanced Technology, Technology Policy

A2-Capacity Building 1

Proposal for a Medical Device Management Education System for Asia and Africa that Utilizes the Knowledge of Japanese Clinical Engineers

By Daisuke Inagaki

Kanagawa University of Human Services, Japan

[Purpose] To improve the safety and quality of medical services in Asia and African countries, propose the system to support medical device management and education using Japanese clinical engineering technology. [Methods] Conducted the following surveys in Japan and developing countries.1- A survey on medical device management and maintenance in Japan. 2-A survey on medical device management and maintenance in Asia and Africa. [Result] In the medical field in Japan, medical devices were sometimes used without sufficient maintenance and inspection until around 2000. As a result, medical accidents caused by medical devices occurred. To solve this problem, a medical device management system was developed around 2003.A medical device management system is not only centralized management of medical devices, but also contributes to hospital management through the implementation of maintenance and inspections. However, management, maintenance, and inspection of medical equipment are not adequately performed at the medical facilities in Asia and Africa. There are also challenges in training maintenance and management technicians. [Discussion] It is necessary to improve operational efficiency through medical device management systems even in Asia and Africa. This survey suggests that in those countries, lack of proper education on medical devices leads to inappropriate medical device operation, which in turn leads to medical device failure. Therefore, it is not enough to provide a medical device management system, but online educational contents that allow users to view how to use, maintain, and inspect the medical devices installed in the hospital are necessary. By improving the existing medical device management system and providing the knowledge of Japanese clinical engineers to medical facilities in Asia and Africa as a medical device management education system, it would contribute to the improvement of medical safety and quality in those countries.

Keywords: clinical engineer, medical device management system, medical device education system, medical safety

A2-Capacity Building 1

Criteria to Maintenance of Medical Equipment in Conflict Affected Contexts

By Wisal Alahdab

International Committee of the Red Cross – Regional Biomedical Engineer

Humanitarian organizations donate medical equipment in low-income countries that has been sourced internationally overlooking the aspect of maintenance. The following explains the added value of maintenance of medical equipment for the health facility and accountability to expenditure. Introduction Medical Equipment should receive regular preventive maintenance and when broken, corrective maintenance. Support through maintenance of existing medical equipment helps with having a timely response compared to provision of medical equipment, can be more cost-effective and maintains end-user familiarity with the equipment. Analysis of the Problem Medical Equipment that's in hospitals in conflict affected context mostly don't receive proper preventive maintenance and experience unavailability of spare parts. However, they still receive an influx of patients and the already worn-out medical equipment in these hospitals, thus becoming over-worked and in dire need of maintenance. Few humanitarian organizations are involved in the maintenance of medical equipment, the ICRC is one of them. To make an informed decision and monitor the maintenance that would be performed by third parties (official representative of manufacturers), I have developed the following technical criteria to be followed to process requests. Physical inspection of equipment will be necessary during evaluation and delivery/testing periods. Considerations for the Maintenance of Medical Equipment Life cycle: According to WHO, the typical lifetime of medical equipment varies between 8 years and 15 years depending on the type of equipment. This is associated with the total working hours the equipment has performed. Age: This is one of the most important criteria to decide how much to invest on maintenance vs. replacement. Cost: The Estimated cost of maintenance of a machine should not exceed certain percentage the price of a new machine depending on its age. Maintenance: To be performed by trained/expert technical staff according to the manufacturer's recommendations and as per the service manuals of the equipment. Calibration: After the maintenance is done, certain medical equipment requires testing and calibration before putting it back in service to avoid adverse side effects, it ensures they are performing according to international standards and manufacturer instructions. Testing Period: After maintenance and prior to technical confirmation by ICRC, the equipment will be in service in a testing period to avoid any errors. Warranty: It is vital for both ICRC and MoH to have a warranty from the authorized representative after the maintenance. Results Achieved This approach and tool achieved the following: 1- Timely response to hospitals with interrupted services due to out of service medical equipment. 2- Cost efficiency of the allocated budget. Number of maintained equipment vs. number of new equipment. 3- Patient safety: maintaining equipment familiar by health staff minimizes human error resulting from using new equipment without proper training. 4- Avoiding over-crowing hospitals with medical equipment. Recommendations In the cases of medical equipment maintenances, following detailed criteria that takes into consideration status of the machine, available service providers, history of the machine helps to arrive at the best cost-efficient decision that aims to restore interrupted health services in hospitals in low-income countries.
Keywords: donations, maintenance, criteria

A2-Capacity Building 1

Promoting CE and HTM Education and Training in Central Asia and other Post-Soviet Countries

By Andrei Issakov

Former WHO, HS&T Consulting, Geneva, Switzerland (from Russia)

Modern health care is technology driven, and its appropriate deployment is indispensable in providing quality healthcare services, containing costs, increasing access to services and improving people's health. Clinical engineers play an increasingly important role in healthcare organizations by supporting and advancing patient care through applying engineering and managerial skills to healthcare technology (HT). Their responsibilities have evolved from basically carrying out maintenance and repair activities to becoming HT managers. While biomedical engineering (BME) deals with research, development and design of innovative HT in university labs and device manufacturers, Clinical engineers work at the point of care being responsible for a wide range of activities from technology planning and acquisition to supporting and optimizing its use in day-to-day operation and educating and training clinical staff on the technical aspects of devices. They interact with technology and with clinicians and patients/family members as well as regulators for audits and management for directing procurement. CEs responsible for HTM in hospitals in addition to a thorough knowledge of all the disciplines comprising the BME field should have a number of special management skills as well as a detailed understanding of systems in a hospital

environment, clinical knowledge of patient cohorts, analytical skills, and be good communicators/ teachers. In all post-Soviet countries, except Baltic States that have to ensure that their HTM is adequate to meet European quality standards, the introduction and use of HT is associated with financial losses, low efficiency and poor quality. The main reason is the lack/ absence of CEs competent in internationally understood and recognized HTM. At the same time, BME education (under-/ post-graduate) is paradoxically rather sophisticated in several countries, particularly Kazakhstan, Russia, Ukraine, Uzbekistan and others. What is lacking is the appreciation of modern HTM concepts and best practices, and their application to routine operation of healthcare services. However, a high level of BME education and more than sufficient engineering knowledge and skills create an excellent foundation on which CE educational programs and thus CE/HTM profession could be built. IFMBE, CED and GCEA have gone a long way in supporting CE/HTM capacity building in this group of countries. Many activities were supported by WHO, bilateral donor and technical agencies such as GIZ, SCIH and associations such as ACCE. Several WHO/ACCE Advanced CE Workshops (ACEWs) were held in 1990s-2000s targeting all post-Soviet countries. IFMBE/EAMBES TEMPUS project in 2010s was instrumental in promoting BME education in Armenia, Georgia, Moldova, and Ukraine through creation of joint multidisciplinary BME programs with EU partner universities. In 2000s, WHO was working in Kyrgyzstan building country capacity in HT planning and management as part of the Manas reform program. From 2013, German GIZ supported the establishment of training programs for management of advanced HT in Uzbekistan. Most recently in 2023, GCEA has developed a Memorandum of Understanding with the MOH Uzbekistan on developing CE undergraduate and graduate curricula and programs for enhancing the use and management of HT for improving clinical outcomes. Similar projects are being planned for Kazakhstan, Kyrgyzstan, and Tajikistan.

Keywords: clinical engineering, post-soviet countries, capacity building

A2-Capacity Building 1

The Evolution and Education of Biomedical Engineering in Turkey: A Multidisciplinary Approach to Advancing Healthcare

By Ugur Cunedioglu, Peliin Kaya

Biomedical Engineers Association Türkiye

Biomedical engineering is an interdisciplinary field that combines engineering ideas with medical and biological sciences to advance healthcare. To fulfill the growing demand for qualified individuals in this industry, Turkey established educational programs after realizing the importance of biomedical engineering. Therefore, since its inception, biomedical engineering has grown significantly in Turkey, with several universities now providing specialized courses in this area.The development of biomedical engineering in Turkey dates back to the late 1970s and early 1980s, when a few pioneering institutions realized the necessity of bridging the gap between engineering and medicine. Early in the 1980s, graduate programs at METU and Boğaziçi Universities began offering courses in biomedical engineering. By accepting electrical and electronic engineers as well as graduates of medical faculties into their programs, these programs tried to fill the academic and industrial gap in the field of biomedical engineering. Başkent University Faculty of Engineering has begun offering undergraduate-level biomedical engineering programs since 2000.The department, which generated its first graduates in our country in 2003, currently employs more than 10,000 graduates to provide high-quality healthcare services. Today, 28 universities still admit undergraduate students. These institutions offer a thorough education that gives students a solid grounding in engineering concepts and a grasp of medical sciences. The curriculum is structured to cover a broad range of topics, ensuring that students gain expertise across a variety of fields that are essential to biomedical engineering. In the first two years, the curriculum focuses on essential engineering courses such as calculus, physics, biology, and chemistry. In the following years, anatomy, physiology, biomedical instrumentation, medical imaging, biomaterials, biomechanics, and signal processing are among the core areas covered in the curriculum. Students who complete these courses will have a fundamental understanding of biological systems, medical device design, image analysis, and the processing of biomedical signals. To give them a well-rounded understanding of the ethical and social aspects of their job, students are also exposed to ethics, regulatory affairs, and healthcare policies courses. In summary, biomedical engineers are taught to design, create, develop, operate, manage, maintain, repair, and calibrate medical equipment in accordance with their requirements. They receive education in collaboration with other disciplines. Collaboration between engineers and medical professionals, advances in technology, and the recognition that healthcare challenges require multidisciplinary solutions are all factors that led to the creation of biomedical engineering as an area of expertise. It is an essential discipline for managing the complex health challenges of the modern world due to its constant development and impact on healthcare.

Keywords: biomedical engineering, CE education, health technology management

A2-Capacity Building 1

Assessment of Healthcare Technology Management Practices in Public Hospitals of Honduras

By Alejandro Zavala

Central America Technological University (UNITEC), Honduras

Introduction: Healthcare Technology Management (HTM) practices in the public sector of Honduran hospitals face various challenges related to inadequate maintenance and poor medical device management procedures. The study aims to identify management capabilities, limitations, current strategies, and requirements for HTM in the public sector. A new plan is necessary to support medical device management in Honduras, involving standardized processes, capacity building, and equipping biomedical departments with test equipment tools. **Methodology:**The present study analyzed information from 12 participants who work as managers of biomedical departments (BD) or have related responsibilities in different public hospitals in Honduras. A 14-question survey was designed to collect information related to organizational and hospital characteristics, biomedical department structure, and healthcare technology management procedures. All information collected in this study is treated as confidential, and data anonymization has been ensured. The collected information was analyzed and presented using descriptive statistics. **Results:**Information from 12 public sector hospitals was collected through a survey. Includes hospitals from different regions of Honduras, and the distribution is as follows: 50% Central Region, 25% West Region, 16.7% North Region, and 8.3% East Region. The hospitals included in the study were categorized based on their number of inpatient beds. The survey collected information to identify management strategies in BD and other activities related to HTM. Only half of the departments have an independent structure within the hospital's organizational chart. In most public hospitals (83%), there is a low number of technicians and engineers available for HTM activities, with 0 to 3 individuals responsible for the maintenance, use, and training. Only 50% of the BD have a medical equipment inventory defined by specific inclusion criteria and classification. Four hospitals have service contracts with medical device distributors or independent service organizations, while the other eight request service support as needed or have no contractual relationship with outsourcing companies. During maintenance management, 91.7% of BD provide periodic reports of maintenance activities, 50% provide reports of medical device downtime and only 8.3% provide reports on spare parts control, staff performance, and other key performance indicators. In terms of medical device user training, 41,7% of the hospitals provide training solely during the installation process, 50% provide training upon request and none of the hospitals have a formal education program. Regarding calibration tools, biomedical simulators, and analyzers only 25% of the hospitals report having a few analyzers, and 75% report that don't have medical test equipment. **Conclusion:**The information collected from 12 public hospitals allows us to identify the principal characteristics of HTM in the public healthcare system in Honduras. In general, hospitals have a basic understanding of HTM with their own strategies limited by their resources. We can conclude a need for greater standardization in HTM practices to improve efficiency and quality across hospitals. Honduras requires regulatory support and new health policies to enhance HTM practices. A new plan is necessary to strengthen medical device management, which should include allocating budgetary resources for human resources, spare parts, and medical testing tools.

Keywords: healthcare technology management, public health, maintenance management, clinical engineering

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A2-Capacity Building 1

Global Healthcare Disparities Can Be Eliminated ~ Technology Transfer through Cardiovascular Surgery in Zambia

By Keizo Wauchi, Manabu Hiroura, Yasunori Yamasaki,Tetsuro Nakamura, Takeshi Matsumura and OsamuYoshida

Department of Medical Technology Faculty of Fukuoka Medical Technology Teikyo University, TICO, Sakura Clinic , Japan

Introduction:TICO is a Non-Governmental Organization (NGO) that conducts international cooperation activities such as medical care and rural development mainly in Zambia, Africa. In November 2022, TICO and the National Heart Hospital of Zambia (NHH) signed a Memorandum of Understanding (MOU) for cooperation. The MOU aims to train specialists in various fields so that 50 open heart surgeries can be performed by Zambian members annually by 2025, and to contribute to patients in Zambia, believing that "the global healthcare gap can be closed. We believe that we can eliminate the disparity in

medical care in the world. As clinical engineers, we are involved in the education of 2 perfusionists and 2 cardiac BMEs, and we mainly operate CPB equipment and maintain the operating room environment through surgery. **Objective:**The purpose of this study is to conduct the 8th to 10th activities to transfer technology through case series with a common goal set by TICO and NHH. **Method:**Since there is no such profession as a clinical engineer in Zambia, one nurse will be assigned as a perfusionist and one BME will be assigned as a cardiac BME. The goal was to educate the perfusionist on the operation of CPB equipment, cannula selection, and collaboration with other professions, while the goal was to educate the cardiac BME on the preparation and assembly of peripheral equipment, extracorporeal circulation recording, and other support activities. **Results:**Perfusionist circulation technicians require much time for education due to differences in circuit configurations and operating methods for both children and adults, and repeated education was provided regarding collaboration with cardiac surgeons and anesthesiologists. Cardiac BME was repeatedly educated on the preparation and assembly of peripheral equipment and extracorporeal circulation records. **Results:**Cardiac surgery is performed at NHH using medical supplies from many countries. Therefore, CPB circuits are created by connecting medical supplies, and perfusionist frequently failed to check shunts during priming due to the fact that the manufacturer and configuration of the circuits used differed each time. Therefore, it is necessary to create NHH's own tailor-made circuits to reduce incidents as much as possible. In addition, communication with the anesthesiologist during the operation is improving with each case.Regarding the education of cardiac BME, it was unclear to what extent they could be involved in the surgery due to their lack of specialized medical education. After many discussions with NHH on this matter, it was decided to provide guidance by preparing and assembling peripheral equipment and providing support for extracorporeal circulation recording. **Conclusion:**TICO and NHH were able to achieve a certain level of technology transfer by setting common goals for the 9thto 10th activities. However, since practical skills education was not available during the period when the participants were not traveling to Zambia, it was decided that in order to provide continuing education for perfusionist and cardiac BME in the future, classroom education could be provided even when they were not traveling to Zambia by using Zoom, a teleconferencing system.
Keywords: Zambia, medical support, cardiac surgery

A2-Capacity Building 1

Enhancing Patient Care Outcomes through Competent Biomedical Equipment Technicians of CEAB

By Md. Anwar Hossain, Mohiuddin Ahmad, Nazmul Hasan Mehadi and Yadin David

NEMEMW & TC, Ministry of Health and Family Welfare, Bangladesh

Despite recent advancements in preventive maintenance for medical devices, further progress is required, particularly in developed countries, to ensure high-quality patient care. The key to achieving this lies in the deployment of competent biomedical equipment technicians. However, low-middle-income countries like Bangladesh are still seeking an optimal approach to address this issue, resulting in negative impacts on patients due to medical device-related conditions, which have been on the rise. Investigations emphasize the urgent need to deploy an appropriate number of skilled Biomedical Equipment Technicians (BMETs), yet regulatory authorities overseeing medical equipment maintenance management have yet to establish guidelines for conventional technicians, including those specializing in electrical, air conditioning, electronics, and mechanical aspects. To address these challenges, this study introduces a nationally certified module aimed at producing biomedical equipment technicians who will enhance the quality of preventive maintenance for medical devices in modern hospitals in lower-middle-income countries, using Bangladesh as a case study. The main objective of this study is to develop a national module that trains certified biomedical equipment technicians in a short period of time, with the aim of improving the existing preventive maintenance programs for medical and surgical equipment to ensure safe and accurate outcomes from these devices. The sub-objectives include: (i) reducing the risks associated with medical devices, including patient injuries and even fatalities, (ii) enhancing the lifespan of medical devices according to manufacturer recommendations, (iii) evaluating the performance and training modules of conventional technicians, and (iv) gathering data from modern hospitals concerning technicians, the functional status of medical devices, and the examination of the education and training curriculum for these technicians. In this study, secondary data was collected from various low-middle-income countries such as India, Bhutan, Nepal, Maldives, and Mongolia, as well as from our own country, to assess the current state of BMET modules. A comparative analysis was conducted, revealing significant gaps. Based on these findings and considering our country's perspective, a comprehensive module was developed to produce nationally certified and competent BMETs. Laptops, cameras, inbuilt cell phones, pen drives, and other modern tools were utilized for data collection and analysis. The adoption of the findings from this study, along with the resulting increase in BMET competency, will create a safer environment where patients benefit from the secure outcomes provided by medical devices. Additionally, it will lead to national cost savings, as equipment users receive training on the appropriate use of these devices. The study will also demonstrate the return on investment when medical device performance becomes predictable, enabling healthcare managers to deliver effective

health programs. These outcomes will undoubtedly encourage healthcare stakeholders and policymakers to support and implement the module's program and its findings.
Keywords: Preventive maintenance, Biomedical equipment technicians (BMETs), Medical devices, Low-middle-income countries, National module, Preventive maintenance programs, Patient safety

A3-Impact Measurement 1

MANTO: Clinical Engineering Residency and Internship Program for Latin American Countries

By Franco Simini, Isabel Morales and Horacio Venturino

NIB - Universidad de la República, Facultades de Medicina e Ingeniería, Uruguay

The number and complexity of Biomedical Equipment installed in Hospitals in Latin America is growing and the maintenance is seldom available after the initial warranty. The personnel in charge of the equipment and of the medical installations such as medical gases, electricity, water and TICs, are scarce and lack professional capacity. To make a difference in medical care, Clinical Engineering must be included in an efficient and safe management capacity. In addition to the in-house Clinical Engineering person in charge, the MANTO approach suggests a mix of University Engineer-Residents and Technical Schools as well as undergraduate Student-Interns to be hired for practical training under remote supervision of University Instructors. Each hospital must be outfitted with basic engineering instrumentation. To keep their positions, Residents and Interns are evaluated every 6 months on academic grounds by producing written evidence of their in-service research or specific previously set study. A professional postgraduate title is granted by the University to Residents as Clinical Engineering Specialists after 3 years of productive training. Similar academic recognition is also granted to Students Interns after 6 months of supervised practice. The Hospital personnel in charge of maintenance is therefore strengthened by groups of Residents (R1, R2 & R3 for the three consecutive years of training) and Interns to man appropriate Computerized Maintenance Management Systems (CMMS) and to properly and timely select equipment to be send for repair, to be repaired locally, dismissed or calibrated. Organized by the University along with the State Health authority, the Program MANTO organizes a yearly (virtual + in presence) meeting of Instructors, Residents & Interns to share and compare results, to motivate and to tend to better efficiency in participating Hospitals. Additional results of the MANTO approach, at different levels, are linked to the following **goals:** 1) reduce the down time of expensive BME in Hospitals with little maintenance.2) upgrade Engineers to Clinical Engineering by means of a 3-years Residency. 3) include 6-months Internship in BME, EE, ME undergraduate programs.4) use the teaching capacity of Professors as Residents and Intern supervisors.5) better the BME and CE capacity of health personnel within hospitals.6) increase availability and use of expensive BME in hospitals. The main result of application of MANTO is a better health care secondary to efficient use of Biomedical Equipment and Hospital Installations.
A typical MANTO implementation depends upon the type of hospital:
Hospitals .....External instructors Residents Interns Cost
< 100 beds or Primary Hosp. 1 1 4 $
100 - 400 b or Secondary H. 1 3 6 $$
> 400 beds or Tertiary Hosp 2 6 12 $$$$
Keywords: Clinical Engineering, Residency, Internship, Computerized Maintenance Management System, Latin America, MANTO, Health Care Quality

A3-Impact Measurement 1

Effects of War on Healthcare Technology in Sudan

By Mohanad Elfadil, Aisha Mamoon Ahmed Mohamed

Secretariat of the Biomedical Engineers Association, Sudan

The human impact: 1/ Many health facilities are out of service due to occupation by the rapid support forces or their presence in conflict zones, which has led to inadequate quantity and quality of medical services. 2/ Stopping of health facilities in Khartoum, which represent more than 60% of the size of medical services provided in the country: - This shutdown has put other states in a very difficult situation due to a lack of inventory of medical devices and supplies. - We also find that the concentration of most specialized centers such as oncology, kidney transplant, digestive system diseases, heart diseases and

advanced diagnostic services in Khartoum province has led to a semi-collapse of the health system in the country. Health Technology Impact: 1/ As a result of a power outage due to war, the following effects: - A lot of operational laboratories that require certain temperatures, whether in hospitals or corporate warehouses. - CT ccts expected damage from temperature rise due to cooling system failure. Some parts of electronic units, power supply units and their associated batteries are affected. - MRI devices average cost of devices in Khartoum state exceeds $ 15 million. There will be significant losses, less expected loss of helium due to the shutdown of the cooling system. 2/ The unavailability of medical engineers in hospitals because of poor security conditions, which negatively affected the provision of technical works of preventive, therapeutic maintenance and supervision of medical devices. 3/ Emergency evacuation conditions for hospital workers are a condition without locking and storing the devices in a good way and with poor storage conditions, this may lead to malfunctions: - Factors are malfunctioning in sensor internal parts. valve. Tube - Anesthesia and artificial respiration devices are malfunctions in the internal parts of the sensor. Guard - The presence of sterilization devices affects the performance of the devices. 4/ Health officers stopped working because of the breeding of mice and ticks that cause damage to the internal parts of devices especially in radiation devices, teeth, and kidney wash. 5/ Increasing pressure on peripheral centers and states: - Kidney washing machines: Most kidney centers in Khartoum stopped, leading to pressure on terminal centers in the state or centers in other states. Increasing the operating cost because of the consumption of spare parts and Service Maintenance Kit. This caused equipment to go out of service, in addition to the lack of supply of laundry consumption, electrical and water supply problems, and disinfectant availability. 6/ Several medical company warehouses containing medical devices, consumables, spare parts and other warehouses under inaccessible conflict zones were looted and vandalized, causing many devices to shut down and impact supply chains, and as the war continues the impact continues.
Preliminary committee of Sudanese Medical Engineers Association Sunday - July 2, 2023 AD
Keywords: war impact, clinical engineering, utilities

A3-Impact Measurement 1

The Expanding Role of Clinical Engineers in Modern Healthcare Delivery in India

By Niranjan D. Khambete

Deenanath Mangeshkar Hospital and Research Centre, India

In India, Clinical Engineers (CEs) have long been performing the conventional role of life cycle management of medical technology. However, it is important to acknowledge that CEs are unique professionals, who serve as a crucial link between direct patient care and medical technology and thus, also get an opportunity to closely witness the actual delivery of healthcare to patients. This exposure to nuances in patient care, combined with knowledge of engineering and good management skills, can enable CEs to seamlessly expand their role to allied fields of healthcare delivery. This paper discusses examples to demonstrate how the role of CEs is evolving, on the one hand, to address broader issues such as quality management and patient safety, while on the other, is getting focused in providing technology intensive specialised clinical care at the bedside. Increasing number of hospitals in India are seeking accreditation from national and international bodies in recent years. As a prerequisite, hospitals need to transform their functioning so as to align it with the requirements of the accreditation standards. Traditionally, these standards have been derived from the principles and practices of quality management followed in the engineering industry. Thus, many hospitals have considered CEs to be a natural choice in contributing to these efforts by appointing them as 'Quality Managers'. Enhancing 'patient safety' is also an essential aspect of the accreditation process. Traditionally, the engineering industry has given great emphasis on adopting robust 'safety culture'. Incidentally, in early years of evolution of their profession, CEs largely directed their efforts towards increasing electrical safety. Thus, in this context too, hospitals have considered it appropriate in giving additional responsibilities to CEs as 'Safety Officers' and/or 'Patient Safety Officers' to address general safety as well as specific patient safety issues. At the other end of the spectrum, due to their deep knowledge of Biomedical Engineering and a good understanding of its clinical aspects, CEs are increasingly being considered eligible to become members of clinical teams in specific, technology intensive and specialised clinical services. One such example is that of Intraoperative Neuromonitoring, but the potential role of CEs can expand into many other similar clinical services. Crucial to this evolution of the role of CEs is the need for periodic upgradation of their knowledge in multiple and cross-disciplinary fields, and acceptance among the medical fraternity to this changing role of CEs.
Keywords: clinical engineering, clinical outcomes, safety

A3-Impact Measurement 1

Consolidation of a Clinical Engineering Department: A 10-year Perspective

By Carmen Eloisa Martinez Cid, Leonardo Hernández de la Rosa, Blanca Estela Amaro Amaro, María Fernanda Guerrero Sáenz and Samantha Alvarado Jalomo

Sociedad de Beneficencia Española, Mexico

Since 2010, the Universidad Autónoma de San Luis Potosí, located in San Luis Potosí —a city in central Mexico with almost one million people, has been the only university in the state offering a degree in Biomedical Engineering, producing 174 graduates (actualized to 2020). Moreover, nowadays the city has around ten hospitals with a Clinical Engineering Department, each one with 3 employees on average and at least one vacancy for students training. This scenario proves the lack of awareness of proper health technology management and clinical engineering's fundamental role, abilities, and knowledge scope, which reflects an inadequate health technology lifecycle management and a delay in the development of the clinical engineering field, impacting the healthcare system. For the last 10 years, the Clinical Engineering Department of the Sociedad de Beneficencia Española Hospital (CED-SBE), thanks to our commitment to the CE profession, has earned the trust of SBE Board members and colleagues from health technology sales and services companies, achieving to position the CED-SBE as one of the most extensive in capacities and equipment CE departments in the region. Thanks to the continuous evaluation of healthcare staff and patient's needs, in this 10-year growth period, the CED-SBE has passed from being a 2-people administrative service to a department capable of covering the needs —through the coordination of 3 teams— regarding health technology maintenance, health technology training for healthcare staff good practices, minimally invasive surgery technical assistance, and Picture Archiving and Communication System management. Furthermore, the CED-SBE has a training program for biomedical engineering students to learn the clinical engineering profession and acknowledge the necessity of a figure to manage, evaluate, and promote health technologies use with a cost-effective approach. Currently, the CED-SBE team is formed by 11 engineers and 4 biomedical engineering students-in-training, integrated into 3 liaisons: engineering services, technology training, and surgical assistance. Together, in 2022, the CED-SBE team accomplished 1152 preventive maintenance, 122 corrective maintenance, and technical assistance in 255 laparoscopic and 577 endoscopic procedures. In addition, since its creation, the CED-SBE training program has formed 27 clinical engineers. Also, during the COVID-19 pandemic, the CED-SBE team managed the creation of an isolated hospitalization area for COVID-19-positive patients with the health technology and installation supplies required, a closed-circuit telemetry network for real-time monitoring of patients, and the development of protocols for disinfection and maintenance. Currently, the CED-SBE has achieved to be a clinical engineering department capable of covering health-technology-related hospital needs, seeking the continuous development of CED-SBE members' professional growth, and being considered by Board members in the decision-making related to the health technology lifecycle.

Keywords: health, technology, management, clinical, engineering, department

A3-Impact Measurement 1

Reducing the Environmental Impact of the Construction and Operation of Healthcare Facilities with a Sustainable Management Approach

By Eugenia Mercado and Claudio Meirovich

Meirovich Consulting, Spain

The healthcare sector is one of the industries that contribute the most to climate change, especially through the operation of healthcare facilities such as hospitals, which have intensive consumption of water, electricity, and fossil fuels, resulting in large amounts of waste disposal and emissions. According to Health Care Without Harm (HCWH), healthcare's climate footprint is equivalent to 4.4% of global net emissions. This work explores the environmental impact of the main functional areas of a hospital, identifying which ones generate the highest emissions of CO2eq. It also examines the levels of CO2eq reduction that can be achieved through facility adaptation and the implementation of sustainable technology, as well as the associated cost-benefit analysis. The main objective of this work is to show how sustainability criteria can be applied to hospital facilities and lead to achieve a reduction of management costs in the long term.

Keywords: healthcare environmental impact, sustainability management, CO2eq reduction

A3-Impact Measurement 1

CE as a Key Actor in the Management of Healthcare Projects

By Mery Vidal and Jesica Coronado

AUNA, Peru

Clinical Engineers have an important role in the designing, building and implementation of medical facilities. However, the participation of CE in healthcare projects is not common and they participate mostly in the implementation stage. AUNA is a Peruvian group of private hospitals and medical centers founded in 2008, whose mission is to transform the healthcare experience and to promote access to quality care in Latin America. AUNA has more than 20 facilities in Peru, Colombia and Mexico. AUNA´s Clinical Engineering Department was created in 2010 with the mission of managing healthcare technology with the objective to guarantee a quality service, operation continuity, user satisfaction and the profitability of the AUNA´s operation and projects. Over the years, clinical engineering participation in healthcare projects grew, so clinical engineers had to assume a key role to get these goals. Evolve the CE Project Management from being just a participant, seen as a technical specialist that delivers just information related to medical equipment and pre-installation requirements to be a key factor in the success of the projects. Prove that CE has the knowledge and experiences to contribute in project since the design stage. A new challenge arrives for CE project management, the deliverables increase and also must deliver in less time than before, the goal of projects management from CE Project is to achievement cost, time and scope score up to 90%. In 12 years, it has achieved: • Being an AUNA's Strategic area, a source of relevant information and part of decision-making table C-Suite. • Participate since early design stage of AUNA projects, making solution proposal to distribution issues, considering the patient save and hospital workflow. • Taking responsibility for the CAPEX related to medical equipment and actively participating in the purchase and negotiation process together with the clinical engineering purchasing area. • CE project management area contributes to developing all projects on time, scope and cost also considering solutions for unexpected events and simultaneity of projects in Peru and Colombia. In the last 5 years, the area was managing 8 projects with an investment of $45M USD just in medical equipment, with the following achievement score (goal > 90%): • Cost: 99.1% • Time: 96.9% • Scope: 98.5%. The following recommendation have been collected by experiences and learned lessons: • Learn from doctors and nurses, learn how the hospital units work, this will allow you to give better proposals to healthcare projects in the future. • To elaborate the implementation strategy and to solve unexpected events, go beyond medical equipment, focus on the project as a whole, remember everybody who works in the project has a common goal. • Sometimes even if you are not the boss, you should take over leadership, to get the project off the ground.
Keywords: Project management, Clinical engineering, Healthcare projects

A3-Impact Measurement 1

Applications of AI to the scheduling of complex diagnostic flows

By Giulio Iachetti, Ivan Porro and Joele Negro

Medipass S.p.a., Italy

Introduction: Nuclear Medicine is a set of diagnostic and/or therapeutic procedures based on the use of unsealed radionuclides. The procedures are non-invasive "in vivo": through the administration of these radiopharmaceuticals and the use of detection instruments, the physiological functions and their possible alterations are analyzed. **Methods:** In order to apply automatic AI-based scheduling tools to the various diagnostic protocols available (at the time of project document: 16 different) the value chain was built in Lean logic (value stream map). One of the basic principles of Lean is the pull line of action: the "customer" commands the flow by generating a chain of action and what is needed is produced when the organization receives the solicitation. Purely pull logic is not always plausible in conditions of highly-risk activity (healthcare in general and Nuclear Medicine in particular, given the use of radioactive substances). The number of diagnostic protocols and tracer production sequence constraints related to production techniques impose a predefined scheduling or at least one that respects some rules of precedence. By correctly selecting the representative cohort, it is possible to reconstruct the characteristic times of each protocol. Correlating them according to the production constraints (eg saturated occupation of the tomograph, limitation of the administration points, examination rooms for anamnestic interviews), we go back up to the administrative acceptance times and then to the scheduled time for each patient. In this way, the patient will present himself at the U.O. exactly at the time that will make the stay at the Diagnostic Center correspond to the "crossing" time of that diagnostic protocol. In this sense, in Lean logic, an inversion from push to pull takes place. **Results:** 8700 different exams have been analyzed selecting those which could be eligible to set a gold standard reference (5.988 exams). Each phase time

has been calculated considering averaged timing. Each protocol has been matched with averaged exam timing (from 0:31 minutes to 0:43 minutes) In consideration of each tracer, the standard deviation as well as the sampling number were set. Based on these considerations, a RIS module was designed and built, with automatic scheduling through the application of artificial intelligence and dynamic scheduling (use of historical time parameters to define the duration of each single exam slot, variability and respect of constraints). **Conclusion:** The Project achieves the possibility of detecting the variability of the different phases up to diagnostics, to exploit it in improving scheduling efficiency, as a better distribution of time for performing the examination on the patient (not necessarily as an increase in productivity). Among further advantages, we point out the possibility to relate data to quality system and the use for scenario analysis/verification in the field of technological or organizational innovations.
Keywords: lean six sigma, nuclear medicine, scheduling

A3-Impact Measurement 1

St. Kitts and Nevis Assistive Technologies

By Glenville Liburd

Community Based Rehabilitation, St. Kitts and Nevis

Persons with disabilities (PWDs) on St. Kitts and Nevis will now be "counted" as steps are being taken to create a database for them. At the end of data collection, the information will afford greater access and awareness to them and their needs. At the opening ceremony of the two-day consultation of the Universal Periodic Review Trust Fund Disabilities Project – St. Kitts and Nevis - on November 22, 2022, for members of civil society, and public entities, the Coordinator of the Sustainable Development Unit in the MOH on Nevis encouraged the stakeholders to throw their support behind the important move. "Today, as we begin the process here on Nevis – a similar exercise will also be undertaken in St. Kitts – I am asking all present here to actively participate in the process. This has been a long road and the journey has only now started with first these consultations and then the administering of the survey which should give a clearer picture of the numbers of persons with disabilities. "The creation of a database is crucial if programs are to be designed and implemented that would positively impact the lives of PWDs. We need to know how to allocate the necessary resources to ensure that PWDs are integrated into every facet of nation-building. The efforts are needed now more than ever to change the narratives to 'humanize' PWDs and give them every opportunity to explore their diverse potentials. "As a nation, if we are to achieve the 2030 global agenda of attaining the targets of the Sustainable Development Goals, we must have a paradigm shift with total inclusivity, embracing all citizens, irrespective of their colour, sexual orientation, and abilities," she said. The Coordinator described the consultation as a very worthy cause to debate and have discussions surrounding an important population, one with many vulnerabilities, one many feel have been neglected or overlooked in the greater scheme of things in many countries, and one which has the same rights to access their country's resources. She explained that the United Nations Universal Periodic Review Trust Fund has provided funding to St. Kitts and Nevis to undertake a survey to document the number of persons living with disabilities, the types of disabilities, and the severity of these disabilities among other things. "Not only will a survey be conducted that will gather useful information, but it is also very important to have the contribution of the wider community, hence why we are here today meeting with you as representatives of groups/organizations and as individuals who have been interacting with this community." Also present at the consultation were the Human Rights Adviser to the UN Resident Coordinator Barbados and the Eastern Caribbean; the Office of the High Commissioner for Human Rights (OHCHR) Regional Coordinator for the English-speaking Caribbean; the United Nations Country Coordinator for St. Kitts and Nevis; Dr. Glenville Liburd, Member UPR Trust Fund Disabilities Project in St. Kitts and Nevis; and Consultant.
Keywords: Assistive Technologies, Impact, MOH

A4-Regulation&Policy 1

Regulatory Framework for Medical Devices in Albania

By Ledina Picari and Andoneta Njehrrena

Ministry of Health and Social Protection of Albania, Albania

Albania has made steady progress and has implemented smoothly its obligations to advance the European Union (EU) integration process. Key priorities are addressed, and some necessary reforms are pursued for the opening of accession

negotiations. Medical Devices legislation as an important part of the free movement of goods is considered as a priority in the integration process. During the Bilateral negotiation process in February 2023, Ministry of Health and Social Protection (MHSP) introduced its commitment in the National Integration Act, to fully transpose the two European Regulations on Medical devices: Regulation (EU) 2017/745 "On medical devices" and Regulation (EU) 2017/746 "On in vitro diagnostic medical devices". Biomedical engineers at MHSP, part of the Unit for Medical Devices and Cosmetic products are directly involved in creating the regulatory framework for Medical Devices in collaboration with the Law Department combining technical, legal skills and competences. The goal is the full transposition of the EU Regulations for medical devices within 2024 by revision of the actual law "On medical devices" and all the bylaws and orders of the ministers from 2014 when the first law was approved. The new regulatory framework on medical devices will increase safety through identification and traceability of devices within the supply chain, establishment of the post-market surveillance system of the manufacturer, the obligation of the manufacturer to take the necessary measurements for the devices that pose a risk for the health and safety of the patients. The new regulatory framework will require for the first time the licensing of the manufacturers and distributors, will facilitate the process of registration by introducing the electronic registration of medical devices.
Keywords: regulatory framework, medical devices, European union

A4-Regulation&Policy 1

Overview of Medical Device Regulatory Landscape in India and Steady Progress Towards Digital Health

By Abhijit Ghosh

CDSCO, India

There are many global industries but none quite like the world of medical devices. It is because no matter the design of the device, origin of the device, intended use of the device. Every single device is united under the single mission of improving the quality of life. India's medical device market is one of the top 20 medical device markets in the world. Medical device industry has been recognized as key industry under the Make in India initiative. As a result, of this, the Government of India has taken several initiatives to boosts the status of medical device industry. This includes the launch of the 'Production Linked Incentive Scheme for medical device 2020 'by Department of Pharmaceuticals (DoP) also establish the guidelines for the scheme for 'Assistance to Medical Device Clusters for Common Facilities (AMD-CF) ', setting up of medical device park, initiating action towards setting up of the Export Promotion Council for medical device by the Department of Pharmaceuticals. Proposal of separate Medical Device Advisory Board in the Draft of the Combined New Drugs, Cosmetics & Device Bill and submission of Parliamentary Standing Committee report on Medical Device regulation and Control by the Union Health Ministry. This presentation covers the recent 'Medical Device (Amendment) Rules 2020' that notified all medical devices to be treated as drugs. Discussion on other notifications related to transition timeline of licensing process of different classes of devices, registration, manufacturing, import and sales of the medical device in India including special emphasize on classification of Software as Medical Device. Department of Pharmaceuticals published notification on National Medical Device Policy, on 2nd May ,2023. As mentioned in paragraph 4.3. of said policy 'Facilitating R&D and Innovation: Medical Device sector is highly innovation and technology driven. Next generation technologies including 5G& 6G, IoTs and AI are envisaged to play an important role in medical devices in the diagnostic equipment, data analytics, personal devices, and patient care'. Indian Healthcare system is already performing on digital platform with the launch of Ayushman Bharat Digital Mission (ABDM). Due to changing patterns of diseases, ageing population, Artificial Intelligence (AI) based Software as Medical Device (SaMD) is used for its nature of sensitivity and adaptability. AI/ML based software function intended for intervention, innovation, implementation and improvement of all the field of healthcare i.e. Radiology, Dermatology, Cardiology and Oncology. The critical nature of health data and its supply chain has made it highly susceptible to cyberattack, which result not only in data breaches but also increase healthcare delivery cost and they can ultimately affect patient health outcome including privacy. Now it poses unique challenge for regulators all over the world to control the integrity, confidentiality and availability of patient data. This presentation shares the view of implementing Software Bill of Materials (SBoM) as cybersecurity tool for continuous performance of medical device in the healthcare delivery organization and making it difficult for counterfeiters to infiltrate the supply chain.
Keywords: SBoM, classification, SaMD

A4-Regulation&Policy 1

Surveys as part of Post Market Clinical Follow Up

By Federica Miola, Ilaria Sirotich, Stefano Bergamasco, Eliana Monaco, Roberto Belliato and Luigi Cuorvo

Medtech projects, Italy

SURVEY as part of Post Market Clinical Follow Up. To European manufacturers of medical devices available on the market, MDR (EU) 2017/745 requires a proactive strategy for the collection and analysis of post-market data. The post-market surveillance, key process of the company quality management system, shall be capable of actively and systematically collecting, recording and analyzing relevant data on the quality, performance and safety of a device throughout its lifetime, drawing the necessary conclusions and determining, implementing and monitoring any preventive and corrective action (crf. Chapter VII and All. III, MDR). Given the role of interface between healthcare professionals and the Manufacturer, the clinical engineering of a facility could be involved to: -Data collection for Post Market Surveillance; -Management of Post Market Clinical Follow Up activities; -Supervisory activities as member of ethics committee. As part of Post Market Clinical Follow Up activities, a proactive tool that allows the Manufacturer to collect data from the field in a structured way is represented by Surveys. These are questionnaires to be submitted to professionals or patients that potentially allow for the specific device to: - Confirm its security; - Confirm its performance;- Identify side effects;- Monitor side effects or declared contraindications; - Investigate any emerging risks; - Identify possible systematic or off-label misuse; - Identify future product improvements. The key point of the activity is represented by the definition of the content and the broadcast strategy. In particular, with regard to content, closed-ended questions (example: multiple choice, percentages, scale) allow a more structured collection of data and easily analyzed compared to open-ended questions that are instead suitable for collecting proposals for improvement directly from users. From the point of view of the broadcast strategy, in addition to the definition of the number of questionnaires to be sent and the acceptability of the response rate, it is necessary to profile the recipients of the survey in terms of level of experience of using the device. This is an important data for the Manufacturer in order to adequately analyze and interpret data collected. One of the most challenging aspects of the process is represented by the availability of clinical professionals to fill in questionnaires providing real word data. This work is aimed at creating a tool to be allocated to Manufacturers so that it can be used in collaboration with clinical engineering teams for the collection of clinical data, experience of use, any complaints, and investigations for the purposes of the MDR requirements relating to Post Market Surveillance.
Keywords: post market clinical follow up, surveys, regulatory

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A4-Regulation&Policy 1

Medical device regulations – the Zambian overview

By Ganizani Phiri

Biomedical Engineering Association of Zambia

According to the World Health Organization (WHO) Medical Devices Publication. The current approach to device safety is to estimate the potential of a device becoming a hazard that could result in safety problems and harm. This estimate is often referred to as the risk assessment. In the Zambia scenerio, there is no medical device regulatory authority. The mandate to control medical devices has been given to Zambia Medicines Regulatory Authority (ZAMRA). **Goals:** The goal of the project is to work with the Zambian Government to establish necessary laws to guide and regulate medical devices in the country. The current scenario ZAMRA issues importation licences to vendors and companies importing medical devices in the country. As Biomedical Association of Zambia, we have noted the following shortcomings. 1. No risk-based Classification system; 2. Lack of essential principals; 3. Lack of conformity assessment; 4. Lack of national medical devices testing laboratories. We have proposed to the Zambian Government through the Ministry of Health to constitute a team of experts and stake holders to develop standards and regulations of medical devices in Zambia. We have also proposed a roadmap as guided by WHO on medical devices regulation as outlined below. Roadmap: • IMPORT CONTROL• DEVICE LISTING • ESTABLISHMENT CONTROL • RECALL PROCEDURE • PROBLEM REPORTING • COMPLAINT HANDLING • IMPLANT REGISTRATION • DISTRIBUTION RECORDS • ADVERTISING CONTROL • PRE-MARKET EVALUATION • (LOCAL TEAM) Typical process for standards development according to the WHO on Medical Devices: 1. CONFIRM THE NEED FOR A STANDARD; 2. DETERMINE WHETHER RELEVANT STANDARD (LOCAL OR INTERNATIONAL) EXISTS THAT CAN BE ADOPTED; 3. IDENTIFY NECESSARY FUNDING; 4. SET UP TECHNICAL COMMITTEE AND ENSURE INPUT FROM ALL INTERESTED PARTIES; 5. DEVELOP STANDARD; 6. INVITE PUBLIC VIEW OF DRAFT STANDARD; 7. COMMITTEE VOTE IN RESPONSE TO COMMENTS; 8. RESOLVE NEGATIVES AND REVISE DRAFT; 9. SECOND-LEVEL REVIEW; 10. APPROVE STANDARD; 11. PUBLISH STANDARD; 12. REVIEW AND REVISE STANDARD AT APPROPRIATE INTERVALS

Keywords: medical device regulation, World Health Organization, national CE society

A4-Regulation&Policy 1

Revolutionizing Cost-Effective Analysis in Healthcare: Introducing SIDDHI®, a Cutting-Edge Economic Evaluation Tool

By Keerthan Rm, Dr. Kavita Kachroo, Prince Singh and Moinudeen Sak.

Kalam Institute of Health Technology, India

Description: Economic modelling is the process of creating a model that serves as a condensed representation of reality and aids in decision-making. To assess a certain result, such as an incremental cost-effectiveness ratio, modelling is used to combine clinical, epidemiological, and economic information from relevant (and various) sources into an evaluation framework. Economic modelling aids in informed decision making for selecting the best suited intervention from all the available interventions using cost effectiveness / cost utility analysis. Health economic models are instruments designed to show the effectiveness of a new healthcare intervention and its financial effects. In markets with established and growing Health Technology Assessment (HTA) institutions, they are crucial tools for obtaining payer reimbursement. SIDDHI stands for Solution for user Interface models using Decision tree Design for Health technology and Innovations. Decision tree models have been in use for decades. The tool was developed to facilitate automated analysis of complex economic calculations in a timely manner. The web-based tool will provide comprehensive economic analysis by providing round-the-clock support. The tool will also provide training and support at each level based on the client's requirement. Health economic modelling exercises are heavily time consuming. One of the major challenges faced by health economics in developing health economic model were challenging timelines and insufficient time to fully understand the relevant issues. Although this will not affect developing a model, however, makes it difficult to tease out the major weaknesses of the model for the policy makers, who are the end users of HTA reports. SIDDHI will bring down the time to perform a complete economic analysis by about 70%. This will enable the health economists to dedicate more attention to details of the parameters taken into consideration. SIDDHI will also enable budding health economists and professionals such as strategy managers, policy makers, midlevel managers with limited knowledge on advanced health economics to perform economic analysis. This subscription-based platform enables the clients to obtain the services for short term and long-term enabling them to utilise the services for their convenient period. All the health economic modelling services can be accessed through the user profile. Extrapolating desired results outside the scope of a clinical study is made easier with SIDDHI. Health economic models developed using SIDDHI platform can be included in the HTA dossier submission or given to specific payers (insurance firms, health funds, or other decision-makers in charge of listing or allocating funding for new medications) independently as it ensures highest level of data accuracy. **Conclusion:** SIDDHI will assist decision-makers and organizational leaders in anticipating future costs and managing potential trade-offs, economic decision models quantify the clinical and economic advantages and harms associated with treatments. The software enables health care professionals, especially from LMICs to get access to automated health economic modelling thereby improving the accuracy of modelling exercise significantly.
Keywords: cost-effective analysis, healthcare, revolutionizing, siddhi®, economic evaluation tool

A4-Regulation&Policy 1

Justification for Policy Change in Health Technology Management and Maintenance in South Africa: Insights from Stakeholder Interviews in the Western Cape

By Joel Philpott, Shannon Pincus, Mladen Poluta, Abdelbaset Khalaf and Sudesh Sivarsau

University of Cape Town, South Africa

Between 40% (Perry and Malkin, 2011) to 70% (WHO) of medical equipment in low and middle-income countries (LMICs) is estimated to be out of service, posing challenges for South Africa's healthcare system. Limited funding for procurement and maintenance negatively impacts patient health and safety. This study aims to identify problem areas in health technology management and maintenance, informing policy changes in South Africa. The outdated national frameworks and the recent passage of the National Health Insurance (NHI) Bill that aims to establish a unitary health system create a pressing need for reform in the face of procurement and maintenance challenges in the public sector. Fourteen interviews were conducted

with key stakeholders, encompassing both the public and private sectors, with a focus on the Western Cape Province. The interviews shed light on the current state of medical equipment maintenance. Key themes emerged, including staffing issues, inadequate information systems, and the decline of clinical engineering. The shortage of qualified staff, particularly experienced and entry-level technicians, emerged as a major concern across both sectors. This shortage hampers effective management and maintenance of medical equipment, and the diminishing number of senior technicians limits the training of the next generation. Additionally, the absence of a standardized asset management and maintenance system in the public sector underscores the need for budget allocations and robust information systems to support optimized life-cycle management of medical devices. Stakeholders expressed concerns about the lack of awareness and appreciation for the clinical engineering profession. They emphasized the importance of increasing educational capacity and bridging the skills gap among recent graduates. The study proposes policy amendments to promote increased numbers of clinical engineering technicians, administrative support staff, and educational capacity. It highlights the risks associated with unfilled vacancies and advocates for the implementation of tools and supporting systems to improve asset life-cycle management. In conclusion, this study underscores the need for national policy changes in health technology management in South Africa. A funded and implementable strategy is likewise necessary to enhance the system's ability to manage and maintain medical equipment effectively. Ultimately, these changes will improve patient care and safety and related outcomes.
Keywords: staffing issues, information systems, asset management, educational capacity, skills gap, policy change

A4-Regulation&Policy 1

Integration of a Vigilance System in the Management of Medical Equipment

By Spilios Zisimopoulos and Nicolas Pallikarakis

Institute of Biomedical Technology (INBIT), Greece

Background and **Objective:** Medical equipment is an inseparable part of the modern healthcare environment and is used to diagnose, treat and manage various medical conditions. Through the lifecycle of medical equipment, adverse events are common. Various vigilance systems have been established worldwide at national levels to prevent the recurrence of such events. In addition, distributors and manufacturers are responsible for informing healthcare providers about equipment distributed to them, that is involved in a relevant event or has risk of manifesting one. However, these vigilance databases cannot be easily utilized by clinical engineers to find information about equipment relevant to them. Moreover, miscommunication between the distributors and clinical engineers of a healthcare unit or inability to identify crucial affected devices instantly, may pose risks to the patients or users. INBIT (Institute of Biomedical Technology) has developed a process for accessing European and international vigilance databases and identifying medical equipment of various healthcare units that may be associated with a recall or safety notice. Materials and **Methods:** Eleven Hospitals and one Regional Healthcare Authority were monitored for a total of approximately 18 months until April 2023. Data regarding their medical equipment inventory was derived from INBIT's Medical Equipment Management Software (MEMS), web-Praxis. Recalls, Field Corrective Actions and Field Safety Notices (FSNs) regarding medical equipment were identified weekly in vigilance databases such as FDA's Medical Device Recalls, Germany's Federal Institute for Drugs and Medical Devices (BfArM), UK's Medicines and Healthcare products Regulatory Agency (MHRA) and Greece's National Organization for Medicines (EOF). Those were then registered in a standardized format. Using data such as the model and serial number, the notifications were matched with the unique equipment ID codes of each healthcare unit, down to the device level. Finally, the healthcare units were informed about their specific affected equipment. **Results:** A total of 751 Recalls and FSNs have been registered up to 04/2023. Of those, 505 were posted during 2022. 118 of the notices were excluded, due to insufficient information publicly disclosed. A total of 104 notices were associated with at least one healthcare unit, potentially affecting up to 555 devices. Associated notices per unit ranged between 45 and 4, heavily depending on the units' inventory sizes. On average 5.7 notices per month were linked to the existing inventories. However, many notices were recurrent and false positives are expected to be frequent, as in some cases (i.e., specific software versions affected) exact identification was not possible due to lack of relevant information from the healthcare units. Other parameters to be considered were the determined cause and the class of each recall. **Conclusion:** A medical device vigilance system is a critical component of safety in the use of medical technology in modern healthcare. The implementation of a reactive system is facilitated by the existence of a MEMS that enables easy localization of affected medical equipment and immediate actions by the clinical engineers.
Keywords: vigilance, recalls, field safety notifications, mems, medical equipment management

A4-Regulation&Policy 1

A Paradigm for Risk Management of Medical Laboratory Equipment

By Neven Saleh

Biomedical Engineering Dept., Higher Institute of Engineering, El-Shorouk Academy, Egypt

One important tool for diagnosing a patient in healthcare institutions is medical laboratory equipment (MLE). Since clinical laboratory testing is essential for making medical choices, it must be dependable and precise. In the study, a method for lowering the risks connected to the management of MLE is presented. Failure Mode and Effects Analysis, or FMEA, was the methodology's cornerstone. To address the limitations of conventional FMEA, a technique called TOPSIS (Technique for Order of Preference by Similarity to Ideal Solution) was implemented. A risk priority number (RPN) was given to each MLE component under evaluation to indicate the level of risk. By using the RPN values that were acquired, maintenance tasks may be prioritized and equipment performance can be enhanced. Goals: (1) Reduce risks associated with poor management of medical laboratory equipment.(2) Maximize the use of medical laboratory equipment. Users: Healthcare providers. Clinical engineers.
Results L This work has been applied to real laboratory data from 15 different hospitals in Egypt utilizing a data set of 150 MLE, taking the haematology analyzer, the chemistry analyzer, and the centrifuge into consideration. New RPN values were obtained to rank the MLE risk by employing the TOPSIS approach. In comparison to the conventional FMEA, the TOPSIS technique has been validated for its robustness in prioritizing the risk value of MLE. In order to decide on the best incoming maintenance and scrapping procedures, a prioritized list of MLE was established.
Keywords: laboratory equipment, risk, Quality

B1-Pandemic Response 2

Evidence-based, Standardized and High-quality Knowledge Products on Management of Medical Oxygen and Respiratory Care Devices for South and South East Asia

By Barun Kumar Rauniyar, Sushmita Das, Pushpa Ranjan Wijesinghe, Nilesh Buddha, Edwin Ceniza Salvador, K G Venkateswaran, Namrata Agarwal, Neeraj Jain

WHO South East Asia Region and PATH

The surge in COVID-19 cases during 2021 caused an unprecedented demand for medical oxygen to save patients with life-threatening respiratory symptoms. As the health systems across the World Health Organization's South East Asia Region raced to install various medical oxygen generation and delivery systems in the health facilities, the gaps in capacity to manage medical oxygen systems presented a key challenge in getting medical oxygen to the patients. Very few personnel in the health systems, especially at sub-national and secondary-level facilities, had the knowledge to understand the complexity of the integration and maintenance of respiratory care devices, especially these newly installed oxygen systems. Even fewer had the relevant skills to operate and manage these newly deployed oxygen systems. Furthermore, the training provided by oxygen equipment manufacturers and vendors at the time of installation of the oxygen systems varied immensely in quality, content, and approach from one training to another.To supplement the medical oxygen infrastructure developed by the Member States in WHO's South East Asia region, WHO-SEARO together with PATH, has developed two high quality and reliable knowledge products to strengthen biomedical capacity for oxygen and respiratory care devices in WHO'S South East Asia Region (SEAR) – a) A regional manual on Operating Guidelines on maintaining respiratory care ecology, maintenance of equipment and equipment handling and other key biomedical aspects of oxygen and respiratory care, and; b) A regional training module for Biomedical Engineers on (i) establishing, maintenance, upgrading, expansion of oxygen/ respiratory care systems, and (ii) setting up of and ensuring functionality of the biomedical equipment needed for influenza pandemic response in the long run and managing surges of SARI patients due to COVID-19 in the short run. These knowledge products fill the oft-felt need for standardized, evidence-based, and high-quality training and learning materials on the management of medical oxygen and respiratory care systems in SEAR. Developed specifically for the Biomedical Engineers and technicians, they include essential information on medical oxygen systems, from its source, such as Pressure Swing Adsorption (PSA) oxygen generation plants to storage, such as in liquid medical oxygen tanks and cylinders, to its delivery to patients, through medical gas pipeline system, mechanical ventilators and bilevel positive airway pressure (BiPAP) machines, among others. Considering the evolving nature of respiratory infections, the knowledge products also cover diagnostic devices,

such as ultrasound machines, electrocardiogram (ECG), and X-ray machines. They will serve as regional goods of WHO for use by health facility managers, biomedical engineers, and technicians in biomedical engineering, especially for oxygen and respiratory care devices to strengthen oxygen ecology in the health facilities and in the region. These documents will also be readily available for use as reference materials in the public domain to improve the technical skills for management, upgrade, and extension of existing medical gas pipeline systems and maintenance of oxygen and respiratory care devices for all Member States throughout WHO's Southeast Asia Region and beyond.

Keywords: oxygen systems, respiratory care devices, medical oxygen, influenza, COVID-19, management

B1-Pandemic Response 2

A Global Perspective of Lessons Learned in the Implementation of Oxygen Generation Plants in LMICs as an Emergency Response During the Pandemic

By Jia Xin Kiki He, Florestan Boualame, Laura Alejandra Velez, Ruiz Gaitan and Janet Diaz

WHO

Background: The COVID-19 pandemic highlighted inequities in availability to medical oxygen and the inherent challenges in the process of generation, distribution, and delivery of this life-saving medicine to patients, particularly in low-to-middle income countries (LMICs). As a response to the global health emergency, WHO, as well as other international entities, supported the procurement and implementation of oxygen systems at scale, specifically oxygen generation plants, to enable autonomy in health care settings. These oxygen plants have been installed at increased rates during the pandemic due to their advantages in minimizing the reliance on external medical oxygen suppliers that have various concerns such as price variability, logistical difficulties, and weak regulatory frameworks at country level. **Description:** Over the past three years, WHO has supported 18 countries with the assessment and implementation of 41 oxygen generation plants. There are five main challenges in the implementation process, which are listed below: 1) Expenses: These plants require large upfront capital investment and ongoing operational costs. Not only related to the equipment itself but the need of electrical source, infrastructure, human resources, and maintenance service. Comprehensive funding plans are commonly lacking. 2) Accuracy of oxygen need-gap estimation: Often, there is discrepancy in the actual needs with the proposed technical solution, resulting in under sizing or oversizing the oxygen systems procured. This is due to inaccuracy or absence of oxygen needs assessment. 3) Supply chain and logistics: The complexity of global logistics in emergency procurement affects the proper implementation. Reaching certain contexts due to security or environmental constraints, together with the lack of local or regional suppliers, have affected considerably the shipment timeframe. Moreover, these plants are an assembly of different components/containers, which present higher risks for part damage or loss. 4) Interdisciplinary management: The lack of planning, coordination, and project management with the appropriate stakeholders, that might engender technical errors and cause project delays. 5) Human resources: Scarce multi-disciplinary staff to contribute throughout the projects from planning to operationalization and upkeep maintenance. This challenge encompasses the scarcity of technical professionals at country level; low wage, absence of health systems planning, and the unavailability of workshops and basic tools for the operation, maintenance and troubleshooting of equipment, among others. **Conclusion:** To address the challenges above, there should be holistic efforts, initiatives, and resources across multiple stakeholders for an optimal and sustainable implementation of oxygen systems, and integration into country scale up roadmaps. Herein, it is proposed one key action that could be implemented to face each challenge from a global international organization, such as WHO. Key considerations include the following: - Develop comprehensive funding plan for capital, operational and infrastructure costs; - Implement user-friendly tools and provide training on proper oxygen need's assessment at national and subnational level; - Enable qualified suppliers to reach LMIC and maintain the quality of goods & services provided; - Develop proper operational guidance and support site preparation plan, ahead of the procurement of oxygen plants; - Promote recognition and inclusion of biomedical technicians and engineers into the health systems planning.

Keywords: oxygen generation, plant medical, oxygen Covid-19 pandemic, low-to-middle income countries

B1-Pandemic Response 2

Maintaining Momentum on Improving Access to Medical Oxygen Therapy for Newborn Care Beyond the COVID19 Pandemic through the NEST360 Program

By Millicent Alooh

NEST360, Nairobi

Globally, 2.5 million children die in the first month of life. More than half of these deaths are due to conditions that could be prevented or treated with access to simple, affordable interventions. At birth, a baby's lungs must transition from fetal to neonatal life in three key ways: (1) Fluid in the lungs must be absorbed and replaced with air, (2) Lungs must expand fully, and regular breathing must be established, (3) Pulmonary blood flow is increased. When these three things do not happen, a baby will have respiratory distress. Respiratory distress syndrome is when there is deficiency of surfactant that is needed to prevent alveolar collapse, especially common in premature newborns. Prematurity, respiratory distress syndrome, pneumonia and other severe infections, such as asphyxia, along with difficulties in the transition from fetal to neonatal life can all result in hypoxemia. Yet, despite its importance in acute severe illnesses, hypoxemia is often not well recognized or managed in settings where resources are limited. Keeping momentum of oxygen therapy provision is important in the care of newborns as hypoxemia, or low levels of oxygen in the blood, are life-threatening conditions that result in increased mortality and morbidity. Ensure health workers know the clinical signs that suggest the presence of hypoxemia and Ensure HCW know how supplemental oxygen can appropriately be used as an essential lifesaving treatment. An oxygen concentrator can concentrate oxygen from the air for use with a multitude of devices. They typically output oxygen between 85-100% FiO2, with flows between 2-10 liters per minute (LPM) with typically one or two outlets. The percentage oxygen a patient will receive depends on each mode of delivery. Pulse oximeters use a non-invasive sensor to measure pulse rate and blood oxygenation levels with the primary purpose is to detect SpO2 in infants. According to WHO, pulse oximetry is the most accurate non-invasive method for detecting hypoxemia, used to measure the percentage of oxygenated hemoglobin in arterial blood. The device consists of a computerized unit and sensor probe attached to the patient's finger, toe, or earlobe. If RDS occurs, assisted breathing with continuous positive airway pressure (CPAP) is started. Bubble CPAP therapy is a common mode of treatment for RDS in premature neonates and for respiratory illness in young children. bCPAP provides a continuous flow of pressurized air into the patient's nostrils via nasal prongs or a mask, preventing alveolar collapse during exhalation. A flow splitter allows the output of a concentrator or other oxygen source to be split between multiple patients while independently monitoring and adjusting each flow rate. Outputs should measure from 0-2 (LPM or L/min) and should have the same FiO2 as the source gas it is attached to. Neonatal units seeking to provide comprehensive care should consider the procurement of splitters and flow meters with precision adjustment at a minimum of 0.1 – 0.125 L/min. A flow splitter allows the output of a concentrator to be split between multiple patients while independently monitoring and adjusting the flow rate to each.

Keywords: clinical engineering, oxygen therapy, neonatal care

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B1-Pandemic Response 2

Functionality of Oxygen Concentrators in DRC Hospitals during COVID-19, and Oxygen Needs Being Met in Chad

By Maombi Edison

WHO Health Technology Advisor, Chad

Introduction: The Nord-Kivu province of DRC faced a high prevalence of hypoxemia diseases requiring the use of oxygen concentrators during COVID-19 in 2022. This abstract describes the level of functionality of oxygen concentrators in 31 hospital structures, in North Kivu province of Democratic Republic of Congo (DRC). A descriptive cross-sectional study carried out a survey of managerial and maintenance personnel and the removal of parameters on the operation of oxygen concentrators from 31 hospitals handling Covid19 cases in North Kivu. The collected data was encoded and analyzed using SPSS version software. **Results:** The oxygen concentrators were of 28 different brands, and in 65.8% of cases with a 5-liter

capacity. They were used in 70% of cases in 4 departments (Intensive care, operating room, emergency room, internal medicine). They were donated in 66.2% of cases (n=225), without accessory equipment in 33.6% of cases and without training of maintenance technician in three of five cases or users in one in two cases. In 45% of cases, maintenance was provided. In 67.6% of cases oxygen concentrators were not functional (n=225), with impaired volume flow in 54.9% of cases and oxygen levels in 34,6% of cases. The oxygen deficit was variable depending on the type of hospital structures (p=0,005) but not the volume flow (P>0.05). **Conclusions:** Low functionality of oxygen concentrators increases patient risk and shows the interest to implement a provincial strategy for the management and maintenance of bio-medical equipment and its integration into regional health development plan. The presentation would also address how oxygen needs are being met in Chad post COVID-19. For example, On December 19th and 20th the Chad WHO Representative handed over to the Minister of health and prevention two PSA plants which have been installed in Bongor and Moundou with WHO funds. Deaths related to lack of oxygen can now be avoided in this part of the country.
Keywords: pandemic, oxygen therapy, oxygen concentrators

B1-Pandemic Response 2

How to Dramatically Increase Local Production of Medical Oxygen: Case study of Rwanda

By Umutesi Francine

RWANDA BIOMEDICAL CENTRE

Introduction: According to WHO, medicinal oxygen is an essential medicine with no substitution. Healthcare professionals use it to treat respiratory diseases like COVID-19 and pneumonia. It is administered to patients as an inhalation gas. Solely medicinal oxygen shall be applied to patients. Compared to industrial oxygen, medical oxygen is tested to meet authorized specifications for its identity, purity, and content. It is produced, stored, and distributed following good manufacturing practices for patient safety. Rwanda is among countries who took the lead and availed needed oxygen to cater for Covid19 case management while strengthening the existing systems. **Objective:** To describe the increase of medical oxygen production in Rwanda Public hospitals. **Methodology:** The findings were collected using primary data, online survey, and telephone calls in 32 public hospitals. Findings: Before the covid19 pandemic, of the 52 Public Hospitals that existed, only 8 had PSA plants (10 plants) while the rest were using oxygen cylinders and concentrators to deliver oxygen to patients. Driven by the high need of medical oxygen to manage COVID-19 cases, Rwanda heavily invested in medical oxygen production to ensure access for all patients across the country. This was implemented by investing in renovation and upgrading of existing PSA plants (10), and acquisition, installation, and operation of 26 new PSA plants. For safe distribution to patients, medical gases piping infrastructures were installed in all hospitals' clinical departments. Oxygen production rose from 148Nm3/h to 536 Nm3/h, the medical piping systems usage to link PSA plants and clinical department shifted from 0 to 100%. In hospitals without PSA plants, oxygen cylinders get connected to manifolds and a piping system to serve the same purpose. Risks based on use of oxygen cylinders inside clinical services settings were eliminated and all patients have oxygen and air outlets at their bed points. PSA plants were installed strategically to allow safe and timely distribution to other hospitals, and oxygen tariffication is under review. Other oxygen generation, distribution and monitoring devices were acquired including oxygen concentrators, oxygen cylinders, pulse oximeters, oxygen masks, and more. Clinical staff were provided with refresher training, and biomedical technicians given technical training to ensure quality assurance in production and delivery of oxygen to patients, specifically on how to properly operate and maintain these PSA plants. **Conclusion:** Complaints of oxygen shortage have significantly decreased. The ideal situation would be to ensure that all hospitals have access to onsite oxygen generation. Since 90% of diseases burden in Rwanda are treated at primary healthcare level, it is imperative to avail oxygen infrastructure at all levels. Continuous capacity building will be key to ensure quality and safe delivery of oxygen.
Keywords: medical oxygen, PSA plants, healthcare facilities, oxygen piping

B1-Pandemic Response 2

Experiences in Oxygen Pipeline Network Design depending on Hospital Structure and Oxygen Supply availability during COVID-19 pandemic

By Edgardo Diaz, Claudio Meirovich, Ulian Rotar

Meirovich Consulting, WHO Moldova

Since the outset of the COVID-19 pandemic, the need for medicinal oxygen to treat severe and critical patients and the lack of access in many countries have become more evident worldwide. Different attempts were done to forecast needs at national, sub-national, and facility levels requiring technical assistance to assess the existing and surge capacities. Clinical service layout, existing hospital networks, and the absence of oxygen suppliers forced tailor-made solutions from the source to terminal outlets. An oxygen inventory template has been used to collect data and provide a quick calculation of the needed gap as part of the completed assessment. Changes in oxygen distribution were considered focusing on total oxygen demand scenarios. Safety training was developed and given. Uzbekistan, Ukraine, Armenia, North Macedonia, and Gambia were the main countries involved.
Keywords: COVID-19 pandemic, medicinal oxygen, oxygen systems, needs assessment, oxygen networks, oxygen PSA

B1-Pandemic Response 2

Development of a training and maintenance strategy for oxygen generators as part of the response to the covid19 pandemic

By Didace Foro

Burgina Faso

Description: As part of the response to the COVID-19 pandemic, a large amount of medical and technical equipment has been made available to hospitals to enable them to treat COVID-19 patients. Given the difficulties in accessing medical oxygen, many hospitals in sub-Saharan Africa and Haiti have been supplied with oxygen generators. The main oxygen generators on the market are pressure swing adsorption (PSA) and vacuum swing adsorption (VSA). This equipment enables hospitals to produce oxygen and is a reliable and cost-effective alternative to supplying oxygen in cylinders from the cryogenic manufacturing process. The use and operation of this equipment requires compliance with the manufacturer's instructions and the relevant norms and standards, as many equipment breakdowns are linked to poor operation and failure to take maintenance into account. The aim of this study is to propose a training and maintenance strategy to ensure the proper operation and long life of oxygen generators. Hospital management must ensure that the necessary financial resources are available to carry out corrective maintenance tasks. These tasks can be carried out internally or externally via a maintenance contract. To reduce the effect of oxygen generator breakdowns or failures on the quality of care and the operation of healthcare services, professional biomedical engineers and technicians must give priority to implementing preventive maintenance. It is therefore important for biomedical maintenance departments to draw up maintenance plans that are approved and funded by the governing bodies of the beneficiary health facilities.
Keywords: pandemic, oxygen systems, clinical engineering

B1-Pandemic Response 2

Building Capacity to Strengthen Medical Oxygen Security

By Devin Nagle, Eric Buckley, Andrew Johnston, Steve Mtewa, Jen Morin, Britta Johnston and Noah Hudelson

Building Health International, USA

The medical oxygen scarcity suffered during the COVID-19 pandemic was in large part due to a lack of ongoing investment in medical oxygen systems and in the human resources needed to ensure their sustainable operation. While procurement of oxygen production and delivery equipment has reached an unprecedented level, considerable knowledge gaps exist amongst

operators, maintenance staff, managers, and policymakers about how to maintain these systems. Pressure swing adsorption (PSA) oxygen generation plants pose a particular challenge, with components requiring regular and highly specialized maintenance. However, hospital-based PSA plants are often the best source of bulk oxygen available in low- and middle-income countries where infrastructure does not support large-scale production of liquid oxygen.To address this knowledge gap, health infrastructure non-profit organization Build Health International (BHI) developed a program of onsite training and post-training virtual support for management and maintenance staff responsible for PSA plants. Over the past year, BHI trained over 200 biomedical equipment technicians, facilities maintenance staff, and hospital/Ministry of Health leadership in Lesotho, Liberia, Nepal, Sierra Leone, Sudan, Rwanda, Guinea, and Cameroon. BHI developed training programs in English and French for different audiences and modalities, including a maintenance training program for biomedical equipment technicians (BMETs), a senior management training program for decision-makers to integrate PSA plants into their health systems, and a training of trainers so that experienced BMETs could provide training to their colleagues. The maintenance training program for BMETs is a 5-day training including interactive classroom presentations, practical onsite sessions, and daily assessments. Technicians receive a daily maintenance checklist, preventative maintenance plan, and repair log, with training on how to use these tools with their PSA plant when they return from training. They also receive physical toolsets and personal protective equipment to safely carry out maintenance. Post-training, BHI develops an online community of practice via an active WhatsApp group connecting trainers to trainees. BHI continues to provide ongoing remote technical support and engagement to trainees responsible for their plants. The aim with this community of practice is to maintain knowledge retention and encourage best practices while providing a platform for ongoing issues or challenges to be discussed and escalated as needed. BHI's medical oxygen training aims to save lives by ensuring the sustainable function of PSA plants and thus the continued supply of medical oxygen to patients. Through teaching essential skills, preparing trainees to complete a daily checklist and conduct routine maintenance, providing physical toolkits, and establishing a community of peers to provide support, the maintenance training empowers BMETs to keep these large investments running and delivering medical oxygen to patients. It helps prevent rapid decline of plants due to lack of maintenance and breaks dependency on expensive service contracts. The management training allows Ministry of Health and hospital leadership to gain the information needed to make sound procurement decisions, plan for maintenance, and integrate PSA plants into their systems. In this presentation, BHI will describe lessons learned in capacity building and methods for measuring impact of activities.
Keywords: medical oxygen, oxygen, medical oxygen security,pandemic preparedness, biomedical equipment maintenance,-capacity building,biomedical equipment maintenance training, training, COVID-19

B2-Capacity Building 2

A Case Study of Successful Participation in Entrepreneurial Education Programs for Medical Device Development through Medical-Engineering Collaboration in Japan

By Keiko Fukuta, Kazuki Bando, Akihiko Watari, Hiroyuki Saitou, Yu Moriguchi, Daisuke Nakatani, Satoshi Fujita, Takeshi Machino, Hiroshi Noguchi, Noriyuki Masuda, Yoshihiro Arakawa, Katsumasa Fujita and Akira Myoui

Medical Center for Translational Research, Department of Medical Innovation, Osaka University Hospital, Japan

Background: The development of medical devices through medical-engineering collaboration is accelerating globally. Conversely, there are various processes such as regulations, clinical trials, and reimbursement that are characteristic of medical devices, and it is challenging due to complicated processes that are needed. Aims: To enable academics to fully develop their business in the development of medical devices and other products with consideration for overseas expansion. **Methods:** Practical development of medical devices through "The Biomedical Global Expansion Accelerator (B-GEAR) program of Research Studio," an entrepreneurial education program for medical start-ups ventures from academia that has been sponsored by the University of Tsukuba, with Osaka University Hospital participating as a cooperating institution for the past five years. The program provides academics to develop medical devices and other products efficiently with consideration for overseas expansion, mentoring by top mentors from Japan and abroad, and multiple Target Product Profile (TPP) sessions facilitating technology to business adaptation of the developed product through group work. **Results:** At the beginning of participation of the program in FY2022, the technology from Osaka University was rated low by evaluators due to tech-push and early-stage product development, so it was unable to clearly explain the clinical needs. However, at the end of the program, the team from Osaka University were selected as one of the top three teams in the final business pitch due to a clear demonstration of the product's usage and benefit, therefore, they were awarded the chance to train in the University of California San Diego (UCSD). Considerations: It is conceivable that the reasons for the use of technology and the team's participation in this program, resulting in high marks includes: 1. Dug deeper into the search for medical

requirements from general theory to searching for papers and other sources, and then interviewing experts based on these searches together with my mentors repeatedly. 2. Formed an autonomous team with distinct roles including engineers, physicians, data analyst, business partner, and an expert of regulation and reimbursement. 3. By cultivating a mindset of staying motivated, believing in one's technology and concept, and switching from a research mindset to a business mindset, the presentation improved dramatically. **Conclusions:** This is one of the methods to educate people to effectively develop medical devices, and there is still a long way to go before the developed product is finally put into practical use and becomes successful. However, we hope that by introducing it, it will benefit people who aim to develop innovative medical devices in the future.Acknowledgments: The Biomedical Global Expansion Accelerator (B-GEAR) program of Research Studio was supported by Japan External Trade Organization (JETRO). This study was partially supported by JST COI-NEXT under Grant JPMJPF200 medical-engineering collaboration.
Keywords: entrepreneurial education programs, medical devices development, medical-engineering collaboration, capacity building, business

B2-Capacity Building 2

Innovative Approach to Strengthen MD Maintenance Capacities in the Democratic Republic of Congo

By Cathy Blanc-Gonnet, Benoît-Pierre Ligot, Clarisse Delaspre and Emilie Durand

Humatem (NGO), France

The lack of medical device (MD) maintenance is a recurring problem in low- and middle-income countries (LMICs) and the Democratic Republic of Congo (DRC) is no exception. It can be explained by the lack of trained biomedical professionals and maintenance procedures fit-ting local constraints, excessive cost and therefore inaccessibility of conventional testers and simulators, difficulties in the procurement of spare parts and accessories on the local markets, and finally the weakness of peer networks, leaving technicians quite isolated. The French NGO Humatem presents an innovative approach which was implemented as part of the Jenga Maarifa II project (2020 – 2023) led in North and South Kivu, DRC, in partnership with 2 Belgian NGOs: Médecins Sans Vacances and ULB-Coopération. This project, focused on emergency and resuscitation MD as part of the Covid-19 response, aims to build capacity in health technologies management (HTM) and maintenance, to improve the quality and safety of care. It reached 24 hospitals through the following activities: • 20-day training for 35 hospital biomedical technicians on level 1 and 2 preventive maintenance and to some extent on corrective maintenance. Each training was delivered by a pair of trainers: a French biomedical engineer and a Congolese biomedical technician as local co-trainer. The program combined theory and practical work on functional MD as well as 4 Repair cafés sessions on non-functional MD brought in by the trainees. Collective intelligence and the supply of intrants by NGOs led to the repair or troubleshooting of 48 MD. Trainees were also involved in both the drafting of 8 maintenance procedures that ensure quality control without using any expensive testers, and in the production of 5 maintenance video tutorials. • 20-day training for 57 medical and paramedical staff addressing best practices in the use and upkeep (level 1 maintenance) of the same MD, with interventions from the biomedical co-trainers. Trainees were involved in the drafting of 7 protocols and 5 video tutorials on MD use and upkeep. • Technical support to fit out, equip and organize 3 hospital biomedical workshops, including the provision of technical tools, furniture, and management tools. • 2-day awareness-raising symposium aimed at healthcare stakeholders, designed to underline the importance of HTM and more specifically maintenance, and the consequent need to allocate resources to develop them. • A WhatsApp group to promote mutual support between biomedical technicians. The new biomedical and medical tools are now being used respectively by Congolese biomedical staff and healthcare staff and by personnel of other French-speaking LMICs. They can use them in their daily work or to train colleagues in turn. Humatem will continue to implement this approach in other LMICs and is also developing some additional tools with French biomedical volunteers such as procedures and video tutorials presenting in-house making and use of alternative testers and simulators. This education material is meant to be compiled into a handbook that will be made available online for free.

Keywords: health technology management (HTM), maintenance, biomedical technician, strengthening capacities, democratic republic of Congo (DRC), LMICs, NGOs, maintenance procedures, maintenance video tutorials, testers and simulators

B2-Capacity Building 2

Workforce Development for Digital Health Innovations in LMICs

By Manish Kohli, Tom Judd, Elliot Sloane

Beyond Horizon Health, GCEA, Villanova University, USA

WHO's has articulated three key objectives to promote the adoption and scale-up of digital health and innovation: (1) Translating latest data, research, and evidence into action; (2) Enhancing knowledge through scientific communities of practice; (3) Systematically assessing and linking country needs with supply of innovations. These three objectives identify the goals and indirectly the gaps for most LMICs. Clinical engineers support and advance patient care outcomes by applying engineering, life sciences, and managerial skills to optimize healthcare technology during its life cycle deployments. They are sought for their systems thinking expertise, to conduct an independent validation of healthcare products, identify support requirements, and ensure that medical device users' needs are met and that products are accessible and ready for patients. They assess and manage the use of health technologies, which WHO defines 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 care and/or life," including both traditional medical devices and emerging digital health tools. During the first 2 years of the Covid-19 pandemic, WHO's World Health Assembly focused on the need for intensive care ventilators (2020) and medical oxygen (2021). WHO has specifically recognized clinical engineers (CE) for optimally managing assets such as medical devices, personal protective equipment, oxygen, and digital health tools, particularly in low-resource settings. Clinical engineers were a key part of the group that evaluated various Innovations submitted to WHO in 2020-2021, many of them proposed Digital Health solutions. For clinical engineering to build on current successes before and during the global pandemic, transition from localized point of care to population health, certain systems competencies must be in place: Education of the workforce to create greater collaboration and resiliency. Collaborative interdisciplinary educational training will ensure the systems skills needed to maximize the benefits of health technologies. With demonstrated competencies and internationally coordinated professional credentialing, CEs will be prepared to be equal partners with the other members of a healthcare team, participating in new clinical roles and workflows to free physicians and nurses for direct patient care. National health technology policy to address priority national challenges. Pandemic-related impacts necessitated rapid implementation of national health technology policy in many countries. This and experiences with other disasters clearly show the need for international coordination of new national guidelines to sustain access to, availability of, and the transfer of critical healthcare technology tools. Clinical engineers can play an important role in informing and implementing such policies. National and international alliances and partnerships to share expertise and lessons learned. Such alliances will coordinate meetings of healthcare stakeholders to examine areas of concern where CEs can make a difference. Educating a changing workforce is possible and significant, despite their challenges in every country of the world. Continued collaboration with global, regional and local partners like CED, GCEA, WHO, HIMSS, CAHO, educational institutions etc., will be key to meeting current and future needs.
Keywords: workforce, LMIC, partnerships, digital health, innovation, capacity building

B2-Capacity Building 2

Empowering Excellence: A Comprehensive Overview of the Competency Program for Medical Device Management in Healthcare Delivery Organizations

By Thangavelu Sasikala

Policy, Code & Standard Division, Medical Device Authority, Malaysia

This article provides a comprehensive outline of the Competency Program developed for technical personnel engaged in the installation, commissioning, testing and maintenance of medical devices within Healthcare Delivery Organizations. The

program furnishes insights into the competency framework, encompassing four main categories of medical devices, along with corresponding proficiency levels for each device listed in the category and product specialist. Furthermore, it delineates potential career trajectories for biomedical engineers and technologists within the healthcare sector. Additionally, the program extends its reach to non-biomedical engineers aspiring to specialize in the installation, commissioning, testing, maintenance, and disposal of medical devices within Healthcare Delivery Organizations, outlining their career pathways and prerequisites. A notable aspect of the program is the establishment of a special grandparenting initiative, tailored to assess and certify existing technical personnel engaged in medical device management and related activities. The article underscores the meticulous structure of the training regimen, incorporating compulsory modules, medical technology training, assessment and certification, and Continuing Professional Development (CPD) endeavors. The versatility of this competency program enables its seamless integration and customization, aligning with the policies and specific needs of medical device regulatory requirements, Healthcare Delivery Organizations and Health Ministries.
Keywords: medical devices, competency, biomedical engineers, technologist, medical device management

B2-Capacity Building 2

Staff Demographic Change in Clinical Engineering at CHEO: Transition towards Diversity Reflective of the Canadian Population

By Kim Greenwood, Kajal Madhusudan and Jean Ngoie

CHEO (The Children's Hospital of Eastern Ontario), Canada

Organizational diversity is crucial for fostering innovation, inclusivity, and improved outcomes in the healthcare sector. This article explores the transition of the Clinical Engineering department at CHEO (Children's Hospital of Eastern Ontario) from an all-male, European ancestry team to a more diverse workforce that better reflects the Canadian population. In 1997, the Clinical Engineering department at CHEO consisted of six individuals of European ancestry, which mirrored the historical trends in the engineering field. However, as society evolved and emphasized diversity and inclusivity, organizations recognized the need for more representative staff. Embracing diversity in Clinical Engineering departments enables a better understanding of the needs and preferences of patients from diverse cultural backgrounds, ensuring inclusive and accessible medical technology for all. Additionally, diverse teams bring unique perspectives, ideas, and experiences, leading to enhanced problem-solving and innovation. CHEO's Clinical Engineering department acknowledged the value of diversity and embarked on a journey to transition towards a team that better represents the Canadian population. This involved implementing key strategies: 1. Recruitment and Hiring Practices: CHEO implemented inclusive practices to actively seek candidates from various ethnicities, genders, disabilities, and cultural backgrounds, widening the talent pool and ensuring equitable opportunities; 2. Education and Training: The department prioritized diversity and cultural competency training to create an inclusive work environment that celebrates differences and fosters respect among team members; 3. Mentorship and Leadership Development: By providing guidance and career development opportunities, the department encouraged diverse individuals to pursue leadership positions; 4. Collaborations and Partnerships: CHEO engaged with community organizations, educational institutions, and professional networks to establish partnerships that promote diversity and inclusion. These collaborations provided access to diverse talent pools and facilitated the exchange of knowledge and best practices; Over time, these efforts have yielded significant results. Over the last decade CHEO Clinical Engineering has seen a substantial growth in the portion of female and visible minority team members. The team's ratio of female and visible minority members now stands at an impressive 39.1% and 49.5%, respectively. By exceeding the goal set by Engineers Canada of having 30% female representation in engineering teams by 2030, CHEO's Clinical Engineering team has demonstrated that a diverse and gender-balanced team can become a leader in its field. The team's commitment to diversity and outstanding performance was recognized with the IFBME CED Outstanding Teamwork Award in 2016. By recognizing the value of diversity, CHEO has created an environment where staff members from various backgrounds can thrive, contribute their unique perspectives, and collectively work towards providing the highest quality of care to their patients. The department's commitment to embracing diversity serves as an example for other healthcare organizations, illustrating the transformative power of a diverse and inclusive workforce in the pursuit of excellence in healthcare delivery.
Keywords: equity, diversity, disabilities, mentorship, collaboration, partnership, education, leadership, visible minority

B2-Capacity Building 2

Health Technology Management for Integrated Medical Device and Information Systems

By Elliot Sloane

Villanova University, USA

The COVID-19 pandemic inspired innovative integration of medical device and information systems to increase health system capacity to support extraordinary numbers of patients. For example, the UK NHS leveraged their primary care clinician, communication, and information resources by provisioning patients with inexpensive pulse oximeters to create a novel "Pulse Oximetry at Home Program" for pre-hospital triage and care. They also created a "Virtual COVID Ward" program for post-discharge patients incorporating home oxygen therapy and other instrumentation as needed. Both NHS programs enabled patients, physicians and nurses to use medical devices, electronic and paper medical records, phone and e-messaging, and local caregivers to rapidly expand NHS's COVID-19 capacity. Globally, diverse medical specialists like cardiologists, dentists, dermatologists, ophthalmologists, pediatricians, primary care physicians, and psychologists rapidly created and deployed phone, app, and home computer technologies to provide remote car. While these innovations filled many critical gaps during the pandemic, implementation was not always easy or perfect, nor was sustainability and affordability necessarily recognized or prioritized. For example, the UK clinical engineering team led by Professor Dan Clark was called on to rapidly evaluate and recommend devices like ventilators and pulse oximeters during the pandemic, for which he was officially recognized and elevated to an Officer of the Order of the British Empire (OBE). In short, they found not every model of every medical device is suitable for widespread local deployment to patients because of accuracy, reliability, operational, or maintenance characteristics. Many devices like ventilators and oxygen concentrators require periodic safety inspections and preventive maintenance, too, which may not be readily or safely performed locally by untrained laypersons. COVID-19 telemedicine adaptations often required consumer versions of medical devices like blood pressure monitors, pulse oximeters, and thermometers, therapeutic devices for oxygen or wound care, many over-the-counter and prescription medications, photographs, videos, teleconferencing, and voice, text, and email communication. ALL of these technologies – and persons – must reliably and consistently work together to produce safe and effective patient care. Such systems help extend patient access to medical care for underserved and inaccessible dense urban and sparse rural areas where expensive hospital infrastructure is infeasible. This presentation describes a System of Systems Engineering (SoSE) approach to applying and updating clinical engineering and health technology management best practices to support integrated medical device and information systems that are now being deployed around the globe. Integrated systems like these will likely be the only way to conquer the growing global crises of supporting aging populations in an era of insufficient numbers of clinicians and limited financial resources. The basis of this SoSE approach is known as the "V-Model," used in aviation and other industries. The V-Model builds on a hierarchy of unit, subsystem, and system verification and validation to assure proper whole-system performance. Verification confirms that each element meets its design specification, whereas Validation ensures the system performance is valid for the intended application.
Keywords: health technology assessment, health technology management, medical devices, health information systems, system of systems engineering, HTA, HTM, SOSE, clinical engineering, interoperability, interdependence, workforce development

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B2-Capacity Building 2

Education Based on 4.0 Technologies for Biomedical Engineering and Related Programs

By Ana Cristina Colorado Canola, Lina Cruz and Elisha Sanoussi

Institución Universitaria (ITM), Medellín, Colombia

Description: The Institución Universitaria ITM, of the city of Medellín, is a public and municipal university institution that offers higher education services for the comprehensive training of human talent with excellence in research, innovation, development, teaching, extension and administration.a) The ITM Biomedical Engineer appropriates professional skills in clinical engineering, bioinstrumentation and rehabilitation engineering for the evaluation, design, development, management and innovation of health technologies, in the prevention, diagnosis, treatment and rehabilitation of patients conditioned by national and international regulations and standards. b. Among the programs offered by the ITM at the postgraduate level is the master's degree in biomedical engineering. c. Additionally, the ITM, under the direction of the Department of Applied Sciences, designed the Hospital Infrastructure Specialization program. This program will be face-to-face-virtual and has the following profile: "The ITM Hospital Infrastructure Specialist establishes and evaluates the diagnosis, design,

intervention and management processes related to hospital infrastructure and maintenance, based on in the technical requirements of buildings and network systems." Proposed: Through Education 4.0, the desirable skills of graduates can be improved, turning them into innovative and creative employees, with the ability to adapt to the use of new technologies. Some of the characteristics of Education 4.0 are: - The basis of teaching is the cooperation between teacher and student; - The main way to learn is through communication; - Problem solving is exercised as close as possible to real life; - One of the main engines of learning are games and the creation of real environments; - The use of ICT as a tool for accessing, creating, organizing and disseminating content. In other words, Industry 4.0 will require the world to produce a new type of worker: a knowledge worker! Tomorrow's industry leaders and managers must possess new skill sets to adapt, manage, and take advantage of Industry 4.0. They must be critical thinkers, problem solvers, innovators, communicators, and provide value-driven leadership. They must be able to see beyond the technology at stake and the implications for society of using that technology. These traits define the knowledge worker. They must know the technology but be able to face and solve all aspects of the challenges generated by this technology. This type of leader requires a new approach to education. ITM is developing a project in the research hotbed for the creation of various biomedical equipment so that the student can get to know them using industry 4.0, especially Virtual and Augmented Reality for when the student is in a work environment can carry out a good management of technology in the health environment. On the other hand, the ITM intends to carry out a CE Laboratory - Hospital Interactive Laboratory, with the purpose that students can interact with simulated environments associated with a surgery and hospitalization room, emergency room and Care Unit. Intensive - ICU, etc. and a space to give educational and training guidelines before entering to interact in the laboratory.

Keywords: CE education 4.0, VR and AR, capacity building

B2-Capacity Building 2

"One health": Closing the Distance between Engineers and Clinicians

By César Burgi Vieira

Centro Hospitalar Universitário de Lisboa Central, Lisbon, Portugal

The recent coronavirus pandemic highlighted the importance of access to medical devices in all settings. The sudden need to deploy large quantities of medical equipment and upscale existing infrastructure and facilities posed a unique challenge. The mounting pressure to cope with the ever-growing number of patients leads to improvised facilities with an assortment of different types of ventilators, patient monitors, and infusion pumps—all operating on strained power and oxygen grids. As a result, clinical engineers were placed front and center in the pandemic response. However, at least in some settings, these uniquely skilled professionals were not always readily available. This forced clinicians to learn medical technology operation and management, as well as facility engineers to understand many aspects of patient care.

This grey area represents a field of opportunity for improving patient care. However, while the field of clinical engineering has seen a tremendous development, the uptake of engineering skills by clinicians seems to be slower. The discussion on the need of technical skills for the physician of the future is recent. Medical physics has been a part of the undergraduate curricula for many years, but the inclusion of engineering is a recent discussion. A deeper understanding of medical technology will be required by the increasing use of advanced diagnostic and therapeutic equipment. Other benefits can be found in the introduction of clinical engineering in undergraduate curricula, as the problem-solving mindset that defines engineering can provide clinicians with valuable cognitive tools when analyzing complex cases. Clinical graduates will have learned a common language, shared with clinical engineering teams, to facilitate exchanges on all levels. Furthermore, it can serve as a building block for new developments and inventions.

Departing from the initial example, the healthcare organizations in low-resource settings benefit particularly from close clinician-engineer interactions. Use of available resources can be optimized if patient needs are adequately assessed and transmitted to the engineering team. Reversely, identification of existing resources to the clinical team can help define the type and level of care that can be delivered. This closed-loop communication circuit ensures efficiency and safety in daily operations, while also ensuring early identification and transfer of patients with needs exceeding a facility's capability. Furthermore, if clinicians are aware of operational constraints and maintenance requirements, they can assist engineering teams in maintaining equipment and facilities, improving care, and limiting downtime.

Conclusion: The increasing technical complexity in modern medicine requires clinicians to have a better understanding of the principles underlying new technologies. Simultaneously, the need to deliver adequate care to a growing global population requires expert management of finite resources. Engineering will increasingly become a common language across teams, improving health for all.

Keywords: clinical engineering, pandemic, clinician partnership

B3-Impact Measurement 2

Clinical Engineers Responsibilities to Sustain their CE Journal

By Kallirroi Stavrianou and Yadin David

GCEA, UK

Global Clinical Engineering Journal (GlobalCE Journal) purpose is to advance and disseminate knowledge, to promote professional networking among practitioners and other stakeholders in academia, industry, government, and other decision-makers in the healthcare field. The Journal provides a forum for the exchange of knowledge, best practices, and research, helping to advance the field of clinical engineering. The journal covers a wide range of topics, including education, practice, and research and is open to submissions from all over the world. The journal is peer-reviewed, indexed by Scopus, and is free for authors as well as readers, placing GlobalCE Journal among the preferable journals for exchange, knowledge sharing, and engagement of clinical engineers across the globe, as it is an affordable option for authors who are looking to publish their research in a high-quality journal. The Editorial Board consists of 20 distinguished CE professionals (academia, industry, WHO) and physicians from around the globe. In just 4 years, GlobalCE Journal has reached more than 500 registered users, about 250 volunteered reviewers who timely review and provide feedback for improving the content of submissions. GlobalCE has received over 100 submissions and enjoys an acceptance rate of 83%. It published 5 Special Issues (proceedings of the 3rd, 4th, and 5th ICEHTMC), and 5 regular Volumes with 13 Issues. The DOI resolution successes received the Journal received shows a huge increase in readership with successful DOI attempts reaching 54,662 for the 89 unique DOIs on May 2023. Readership of papers addressing critical subjects registered about 4,000 reads. As an open-access international CE journal, we are responsible for delivering pertinent, timely and quality content to readers. However, clinical engineers and technologists have essential obligations, as readers, that can impact the journal's future. Dedicated promotion through GCEA's newsletter, combined with the Journal announcements and social media can reach higher impact when the field is more engaged with the Journal. Readers' responsibilities include: • Submit manuscripts and review papers; • Promote the Journal to colleagues, share articles, and encourage novices to write; • Write feedback about topics you like to know/read more; • Stay updated and suggest new subjects the Journal should cover; • Report ethical concerns if you identify plagiarism or unethical practices; • Volunteer to serve as a reviewer in the area of your expertise; • Active participation and responsible behavior as a reader can contribute greatly to the success and impact of our online Journal. We are making efforts to further reach new authors and readers around the world by translating issues into Chinese language and publishing it online. Global CE Journal is a valuable resource for clinical engineers, healthcare professionals, and researchers. If you are a professional CE, we encourage you to subscribe to the Global CE Journal. It is a valuable resource that will help you to stay up-to-date and network with experts. But you must fulfill your obligations as a reader to sustain this Journal's successful start because this is the only international Journal founded by and for Clinical Engineering professionals with no fees!
Keywords: clinical engineering, global hournal, clinical engineer, open access

B3-Impact Measurement 2

Demonstrating The Impact of Clinical Engineering in Health Systems Globally

By Saba Hinrichs-Krapels, Lorena Aguilera-Cobos and Shauna Mullally

Delft University of Technology, Netherlands

Enabling countries to respond to pandemics and/or maintain basic health care requires due attention to the management of its health technologies, including medical devices and equipment. According to the World Health Organization (WHO), health technology management (HTM) includes "planning, needs assessment, selection, procurement, donations, inventory, installation and maintenance of medical equipment, training for safe use and finally decommissioning". This requires national oversight and governance of HTM, in addition to supporting the crucial role that local biomedical and clinical engineers play in safeguarding performance of hospitals and other health providers. Indeed, during the COVID-19 pandemic, many clinical engineers were named the 'silent heroes', alongside the critical healthcare workers working to battle the sudden surges in patient care. However, despite these advocacy and policy efforts, most empirical studies in global health research and health systems strengthening have not demonstrated how the biomedical/clinical engineer contributes to health systems performance. Our aim in this project was to identify the ways in which biomedical and clinical engineers have contributed to specific outcomes and impacts across different health systems globally. Through a survey released via the IFMBE network, we collected a broad range of responses that tell the story of the value clinical engineering plays in the lives of patients, their families and healthcare workers. We used these stories to create a 'theory of change' model, which serves to demonstrate the variety of ways that clinical engineers create changes and impact health systems in their respective regions. The 'theory of

change' model shows how things clinical engineers do (activities) cause things to happen (outputs) that contribute to larger changes (outcomes) which ultimately lead to longer-term goals (impact). Where possible, we linked long-term impacts to broad health system goals that align with the WHO's core priorities of increasing universal health coverage, responding to health emergencies and ensuring healthy lives and well-being for all at all ages. The study does not aim to compare country performances, or assess the degree to which CE creates impact, but simply to provide a descriptive overview based on practical experiences. Preliminary findings: 51 responses were received to date (June 2023), representing 16 countries. Activities in which respondents were most involved were incoming inspections, installations and commissioning (n=39, 87%), repairs (n=36, 80%), preventative maintenance (n=33, 73%), procurement (n=30, 67%) and service contract management (n=30, 67%). Clinical engineers shared experiences of contributing to reduction in equipment related incidents, working closely with Ministries of Health for procurement decisions or general health technology management activities, and building capacity of the clinical engineering function in their respective countries. The long-term impact areas in which participants felt they had contributed the most were patient safety (n=32, 73%), improved diagnostics (n=27, 61%), cost savings (n=27, 61%), and health access (n=25, 57%). Through these vignettes we are taking the first steps in building a global picture of the ways in which clinical engineering contributes to crucial functions in health systems.
Keywords: impact measurement, clinical engineering role, health technology management, health systems performance

B3-Impact Measurement 2

Medical Equipment Management Status in the Private Healthcare Sector in Mexico: A Comprehensive Analysis

By Luis Fernandez

TINC CMMS, Mexico

Introduction: The efficient management of medical equipment plays a critical role in ensuring the quality of healthcare services provided in any healthcare sector. The abstract aims to provide a comprehensive analysis of the current status of medical equipment management in the private healthcare sector of Mexico. Drawing upon available online resources and information, this study investigates various aspects of medical equipment utilization, maintenance, training, and procurement practices within private healthcare facilities across Mexico. **Methods:** To gather insights into the medical equipment management practices in the private healthcare sector of Mexico, an extensive review of online sources, including healthcare publications, academic papers, industry reports, and reputable websites, was conducted. Key information related to medical equipment utilization, maintenance protocols, staff training initiatives, and procurement strategies was extracted and analyzed to paint a comprehensive picture of the current state of medical equipment management in Mexico's private healthcare sector. **Results:** The findings of this study reveal several important aspects of medical equipment management within private healthcare facilities in Mexico. Firstly, a significant emphasis is placed on the utilization of advanced medical devices, including ventilators, oxygen delivery systems, pulse oximeters, and other critical equipment, particularly in the context of the ongoing COVID-19 pandemic. Private healthcare facilities have made substantial investments in acquiring and maintaining such equipment to ensure the provision of high-quality care. However, challenges related to maintenance and repair of medical equipment are evident. Limited resources and expertise pose obstacles to timely and effective maintenance practices. While some facilities have implemented robust preventive maintenance programs, others struggle to maintain equipment in optimal working condition. Adequate training programs for staff members responsible for equipment operation and maintenance are essential but vary in availability and comprehensiveness across different facilities. Furthermore, procurement practices for medical equipment in the private healthcare sector show a diverse landscape. While some facilities have well-established processes for assessing the quality, safety, and performance of equipment before acquisition, others may face challenges related to vendor selection, budget constraints, and limited access to comprehensive market data. **Discussion:** This study sheds light on the current status of medical equipment management within the private healthcare sector in Mexico. The findings underscore the importance of implementing standardized maintenance protocols, ensuring adequate training opportunities for staff members, and establishing efficient procurement mechanisms. Collaborative efforts among private healthcare facilities, regulatory bodies, and industry stakeholders are crucial to address the challenges and improve overall medical equipment management practices in Mexico. **Conclusion:** Efficient management of medical equipment is pivotal in delivering quality healthcare services. This abstract provides an overview of the medical equipment management status in the private healthcare sector of Mexico based on available online resources. The findings highlight the need for targeted interventions to enhance maintenance practices, training programs, and procurement strategies. By addressing these areas of improvement, private healthcare facilities in Mexico can ensure the availability of reliable and safe medical equipment, ultimately improving patient care and outcomes.
Keywords: clinical engineering, impact, private sector

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Case Study: Improving Pakistan's Health System Through CE BME and HTM and Recommendations

By Tazeen Bukhari

Pakistan

Pakistan is a large country with a growing population and a significant burden of disease. In recent years, the country has made significant progress in improving its health system, thanks in part to the work of Clinical/Biomedical Engineers (CE/BME) and Health Technology Management (HTM) leaders. This paper presents three case studies that illustrate the instrumental role of CE/BMEs in improving Pakistan's health system. The first case study describes the development of a Biomedical Equipment Resource Centre (BERC) in Punjab province. The BERC has helped to improve the availability and functionality of medical equipment in the province, leading to better patient care. The second case study describes the impact of COVID-19 on innovation in Pakistan's medical device industry. The pandemic created a shortage of personal protective equipment (PPE) and oxygen devices, which led to a surge in innovation in these areas. As a result, Pakistan is now able to produce most of its own PPE and oxygen devices and is even exporting these products to other countries. The third case study describes the role of the Drug Regulatory Authority of Pakistan (DRAP) in regulating medical devices. DRAP has played a key role in ensuring the safety and quality of medical devices in Pakistan and has helped to protect patients from harm. These case studies demonstrate the important role that CE/BMEs and HTM leaders play in improving health systems. By working together, these professionals can help to ensure that all patients have access to safe, effective, and affordable medical care. Recommendations: Based on the findings of this paper, the following recommendations are made for improving health systems in Pakistan and other countries: 1.Develop a comprehensive framework for medical devices that includes regulation, quality assurance, business enabling environment, infrastructure development, R&D and innovation, human resource development, health technology management, and awareness. 2.Establish a working group with experts from the field, stakeholders, and decision makers to focus on implementing the recommendations in this paper. 3.Continue to invest in the development of CE/BMEs and HTM leaders. Collaborate with other countries to share best practices and develop global standards for medical devices.
Keywords: clinical engineer, biomedical engineer, policy, innovation, equipment policy, medical devices

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Embracing Appropriate Health Technology for Affordable Healthcare: A Path Towards Sustainable Innovation

By Sudesh Sivarasu

University of Cape Town, South Africa

Efforts to make healthcare affordable often overlook the critical role of appropriate health technology innovations. The transformative potential of digital technologies to revolutionize healthcare quality and coverage cannot be underestimated. However, achieving true affordability goes beyond simply reducing manufacturing costs. This abstract highlights the complexities of the healthcare industry and the need to address them through appropriate health technology innovation. The discussion explores the challenges facing healthcare systems globally. While reducing the cost of technology may seem like a straightforward solution, it fails to account for the practicalities of integrating technology into diverse healthcare environments. Donated health technologies often prove incompatible with local healthcare systems, rendering them less effective or unusable. Factors such as infrastructure limitations and lack of local support systems hamper the effectiveness of well-intentioned donations. Imported healthcare technology often dominates healthcare landscapes, accounting for a substantial portion of expenditure. However, this reliance on imports fails to address the unique nuances of local contexts, including climate conditions and infrastructure limitations. The key lies in embracing appropriate health technology solutions that are tailored to local needs and challenges. Creating an enabling environment for innovation requires a shift in mindset and incentives. Successful models employed in various countries demonstrate the importance of balancing imported technologies with home-grown solutions. Such approaches transform the import/export balance, establishing a support infrastructure vital for innovation. Overcoming risk aversion and fostering a supportive ecosystem for local innovation are critical factors for sustainable progress. Academic institutions play a crucial role in building an ecosystem that fosters innovation and supports graduates in the local market. It is essential to broaden the focus of appropriate health technology beyond specific diseases and address healthcare needs holistically. This requires collaboration among academic institutions, the public sector, and the private sector to drive tangible business benefits while advancing innovation. Achieving affordable

healthcare is a complex challenge that requires a systemic change. By embracing appropriate health technology solutions, fostering a supportive ecosystem for innovation, and encouraging local production and job creation, countries can build self-sustainable economies in healthcare. This shift towards sustainable innovation will not only make healthcare more affordable but also improve its accessibility, effectiveness, and relevance to local populations.
Keywords: health technology innovation, medical devices, frugal innovations, stakeholders

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Accelerating The Adoption of New Technology: The Role of The Clinical Engineer

By Daniel Clark

Nottingham University Hospitals NHS Trust

Small companies often drive innovation in Healthcare Technology. However, while these small companies have flare and imagination and develop wonderfully innovative technology, by their very nature, they tend not to have the experience or expertise to support the adoption of that new technology into healthcare, to facilitate deployment and use and to provide hospital managers and service buyers with convincing evidence to procure the new technology. For example, small companies do not always have: • capacity and capability on regulatory matters • experience and knowledge on how healthcare providers test and evaluate technology • the knowledge of how healthcare provides buy new technology • an understanding of the wider clinical pathways and systems with the result that many brilliant new technologies never deliver their promise to patients because the companies lack the skills and experience needed to get them adopted. Clinical Engineers, however, very often do have these skills and experience: • working in healthcare technology management we are generally experts in local regulatory systems for medical devices • often embedded within healthcare providers we have wide experience of testing and evaluating new technology • working on behalf of health providers we are experienced in the purchase of medical equipment and its subsequent commissioning, deployment and use • we understand the local hospital environment but also the wider picture on technology of healthcare technology applications. Recognizing both the need to support small healthcare technology companies and the resources and capabilities of clinical engineering professionals, we established a unique service dedicated to providing adoption services to small companies: the Centre for Healthcare Equipment And Technology Adoption (CHEATA.) CHEATA was established 8 years ago. Based in a large teaching hospital in the UK, it draws on the skills and experience of clinical engineering professions to provide adoption support services to medical device technology companies and has supported over 100 products along their adoption pathway. This presentation will explore the background and rationale of this service, how it started and has developed and give insight to the role that clinical engineers can play to support the medical technology industry and ultimately, to accelerate the adoption of new technology for the benefit of our patients.
Keywords: innovation, healthcare technology, adoption of technology, clinical engineers

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Impact of NEST360 Program on Newborn Technology Management in NEST360 Countries

By Millicent Alooh

NEST360

While most women in Africa now deliver their babies in health facilities, these hospitals lack the life-saving technologies, equipment and trained staff that are necessary to manage preterm babies and newborns in distress. United Nations set a Global Sustainable Development goal to end preventable newborn deaths by 2030. The Every Newborn Action Plan (ENAP), roadmap sets a target for 80% of districts to have at least one level-2 in-patient unit with respiratory support including CPAP for small and sick newborn care(ENAP coverage target 4). SDG 3.2 strives to end preventable newborn deaths, with all countries aiming to reduce neonatal mortality to at least as low as 12 per 1000 live births. The main goal of Newborn Essential Solutions and Technologies(NEST360) is to reduce newborn mortality in African hospitals by 50%. The life-saving technologies, equipment, and trained staff are necessary to manage preterm babies and newborns in distress. Among the goals is to collaborate with governments to strengthen health systems with innovative technology, education, and policy resources. Participating in different TWGs to support HTM policies development and implementation and to deliver and

sustain a package of affordable technologies for small and sick newborn care. These include CPAP, pulse oximeter, Oxygen concentrator, and Phototherapy light, among others. Additional aims are to prepare clinicians, biomedical technicians, and students to support small and sick newborn care and foster innovation and enable countries to implement evidence-based care for small and sick newborns and make the investment case to sustain quality care. NEST360 has developed both clinical and technical modules for all the NEST bundle of devices which are readily available through the website. **Results:** 1. Streamlined education ecosystem which has enabled both biomedical and clinicians to be able to confidently use the devices to deliver care. This has led to a reduction in breakdown and zero graveyards for NEST360 devices. 2. It has enhanced collaboration between clinicians and biomedical as most of the trainings are combined. 3. Series of biomedical engineering technical training which has led to improved implementation of planned preventive maintenance across the four countries and beyond. 4. The provision of biomedical engineering working tools has played a major role in ensuring the implementation of PPM. 5. NEST360 is also very much cognisant of equipment quality assurance and hence the provision of test equipment like oxygen analyzers and phototherapy light meters ensures the equipment doesn't deviate from the original specifications.6. Introduction of KPIs to monitor has motivated the biomeds to go the extra mile to achieve the target, as the say goes what doesn't get measured isn't done. 7. Employment opportunities for BME as some governments have management to employ BME due to NEST360 program.8. Increased accessibility to newborn devices with optimum uptime hence access to care leading to reduced mortality. Documentation is still a major challenge for most of the biomeds making it difficult to quantify the amount of work done by each hence difficult to justify the required BME staffing per facility. Moreover, the shortage of BME staff across all the facilities jeopardizes the PPM implementation and turnaround time for corrective maintenance.
Keywords: newborn technologies, planned preventive maintenance, corrective maintenance, NEST360, KPIs

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Innovative Diagnostic and Therapeutic Technologies for The Protection of The Hip Joints in Children

By Irina Akizhanova MD,Konstantin Osipov

Rehabilitation Center "ARDI", Almaty, Kazakhstan

From a prognostic point of view, the pathology of Hip Bone Synovitis (HBS) is always a threatening condition, and the outcomes of HBS diseases with a belated diagnosis and inadequate treatment are often coxarthrosis, dislocation hips, uneven size and deformity of the limbs, scoliosis, etc. According to numerous literary sources, critical damage to the growth zone bones of the hip joints, especially in the first 5 years, when bone "matrix" is set, with congruence laid for life, SDA, verticalization skills and a stereotype of gait are formed. Unfortunately, the existing algorithm for the protection of growth zones for hip bones, depending on the total assessment of pathological factors need to be revised. The purpose of this pilot study: analysis of available diagnostic methods and conservative treatment of HJ pathology in the early stages in children in Kazakhstan and the development of an effective algorithm for the protection of HJ due to using a combination of innovative conservative technologies diagnosis and treatment. We analyzed the data of 1500 HJ sonograms for the period from 2010 to 2020 for children under the age of 1.5 years, in normal and pathological conditions, who applied on an outpatient basis in various medical centers in Almaty. Ultrasound of TBS in infants was carried out according to recommendations of R. Graf, polypositional ultrasound of the hip joint in children older than a year was carried out by the author, with additional scanning muscles of the hip joint area according to the author's method. A retrospective analysis was carried out case histories and X-rays of HBS in children with cirrhosis receiving rehabilitation in the Rehab Center "ARDI", for the period of 2018. - 2020 Determination of X-ray indicators of SDU, acetabular angle was carried out according to the Hilgereiner scheme, first introduced HBK migration index - according to Reimers according to the CPUP program. Retrospective analysis of HJ radiographs of 20 children receiving treatment with a diagnosis of Perthes disease for the period 2018 - 2020 carried out in accordance with the international classification of osteonecrosis of the femoral head ARCO . Proposed new algorithms for diagnosis, treatment and monitoring HJ pathology, including CPUP, ICF WHO criteria: Proposed the algorithm of radiation diagnostic methods covers the main pathological patterns of disorders in the formation of hip joint in children, includes markers of congenital and acquired pathology. And within of the presented treatment algorithm, the results are provided safety and efficacy of PRP - therapy, which is used for the first time for the treatment of osteonecrosis of HBK in children as an intra-articular injection. This technique was developed by the authors and patented, an analysis was made effectiveness of PRP therapy in therapy in combination with the use of a rotational corrective apparatus for hip dilution. Implementation of a treatment algorithm demonstrated that in children with neuromuscular pathology, the skills of active verticalization in the TCP and movement with these devices improved significantly, with the Reimers index showing throughout growth spurts from 2018-2021 did not exceed 40%.
Keywords: diagnoses and treatment, imaging, quality

B4 -Regulation & Policy 2

We Learn: Regulating Healthcare Technologies for the Future

By Hanan Al-Awadhi

Kuwait Association for Biomedical Engineers

In May 2012, the Kuwait Association for Biomedical Engineers jointly launched the #Safe_Care initiative with the IEEE EMBS Kuwait Chapter to promote the use of safe healthcare technology in Kuwait. Medical devices are not appropriately regulated in Kuwait, and counterfeit devices, especially home health products, are widespread across the country. Through this initiative, we have been calling to establish an independent body (the Kuwait Authority for Healthcare Technology) that would carry regulatory duties as well as learning duties. These duties include, but are not limited to: • Provide patient education programs (with a focus on home health products and assistive technologies) • Provide professional development and continuing education programs in healthcare technology management, health informatics, clinical systems engineering, biomedical engineering, standardization, etc. • Research & development in healthcare technology • Providing and maintaining an open-access platform for managing health technology knowledge (K4Health Hub) • Regulatory duties shaped by our proposed philosophy "We Learn". In the "We Learn" approach, we propose a new philosophy for regulating healthcare technology products, those that are still manufactured in traditional settings as well as those that are anticipated to enter the market in the near future and developed in laboratories such as 3D-printed medical devices, AI technologies, e- and m-health products. This approach does not compromise the clinical safety of such products yet provides an avenue for collaborative learning and knowledge sharing, starting from the conceptual design phase of a product to its disposal. We strongly believe that support for healthcare innovations starts with an effective regulatory framework that prioritizes safety yet values the flexibility needed for non-traditional manufacturing. And, for that, "We Learn!"
Keywords: health technology, medical devices, regulations, knowledge management, learning organizations, safety

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The Case for Health Technology Management and Public Procurement Policy Alignment in Senegal and Indonesia

By Betsy Wilskie

PATH

This 5th ICEHTMC Congress presentation will bring together public procurement and clinical engineering experts from PATH, Indonesia's public procurement agency (LKPP), and Senegal's Ministry of Health, Division of Infrastructure, Equipment, and Maintenance (DIEM) to introduce recent initiatives to align health technology management (HTM) and public procurement policies and practices. These initiatives reflect the hard-earned experience that when purchasing durable medical devices (medical equipment), long-term value for money (VfM) is a more important target than lowest purchase price. Public procurement and HTM systems in many countries, including most low- and middle-income countries (LMICs), do not deliver the full benefits of health technologies to primary health care (PHC) systems. As a result, up to 70 percent of medical equipment in LMIC health facilities is partly or totally unusable due to failure to accurately identify needs at the final installation site; inaccessible lifetime budgets for lifecycle costs (LCC); weak training programs; and difficulty accessing spare parts and repair services (Diaconu et al., 2017). Value-based procurement (VBP) of health technologies looks at criteria beyond the lowest purchase price to find sustainable solutions to complex health needs and deliver greater VfM. These value criteria are identified by key stakeholders and may include access to trained users, reliable energy supplies, and maintenance services. Unfortunately, public procurement is widely considered an administrative step rather than a strategic tool, and most public procurement policies and systems do not currently benefit from VBP approaches. Multisectoral, intra-ministerial, and multi-disciplinary collaboration is needed to identify and align the legislative, policy, and practice architecture that defines how health technologies and equipment management services are delivered to PHC facilities. From a procurement perspective, at the center of this change is the need to establish a legal foundation and robust evidence-base from which procurement teams can apply objective value criteria beyond purchase price when planning procurement approaches, evaluating bids, and negotiating contracts.Indonesia's LKPP first developed a procurement guideline specific to medical equipment in 2019 and is currently developing a multiple criteria decision analysis (MCDA) bid evaluation methodology to justify transparent, evidence-based decisions that look at value criteria beyond the lowest purchase price. Senegal's DIEM developed a 5-year health technology investment strategy in 2022, ensuring that DIEM leaders, who are clinical engineers, informed how public resources are used to deliver equitable, long-term, access to essential medical devices. While Indonesia and Senegal are both advancing VBP approaches, other countries have expressed interest in learning from these leaders.

Many challenges will need to be addressed before the full benefits of VBP of health technologies can be realized in LMIC, and this ICEHTMC Congress is an important venue to further this important transformation.
Keywords: public procurement, value-based procurement, health technology management, medical devices, medical equipment, low- and middle-income countries, policies, legislation

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Health Technology Assessment; Perspective of Medical Devices For Arab Countries

By Hashem Alfadel

TEMOS International Healthcare Accreditation and ISqua EEA, Jordan

Health Technology Assessment (HTA) is a multidisciplinary field of policy analysis that forms the largest single body of research. HTA is world renowned for improving the evidence-base and quality in the Healthcare System including medical outcomes, and ethical, social, and economic factors. It helps healthcare decision-makers work towards consistently high-quality healthcare provision, based on clear research and evidence of effectiveness and cost-effectiveness.The goal of HTA is to provide healthcare managers with the required information that will help them decide on alternatives. In general terms, HTA covers a number of disciplines among them Medical Devices, pharmaceutical products, medical support systems, information technology, disease management and others. With the explosion of innovation in medical devices in this digital age, HTA is a must for every country to provide the necessary advice to decision-makers. In this presentation the elements of HTA, its aim and benefits will be highlighted. Also, how it connects with medical devices in view of the current or recent pandemic. In addition, the experience of some Middle Eastern countries with HTA will be explained and how that improves the quality of service, economic and ethical factors. The presentation will examine HTA situation in some Arab countries by assessing the current situation including the pandemic situation with a desperate need for advice and changes that are taking place in this digital revolution. Also, with particular, Jordan's recent experience will be highlighted in HTA efforts since it's the first Arab country to initiate a national road map for the HTA program started in August 2021.
Keywords: health technology assessment, HTA in Jordan, HTA in Arab countries, HTA for medical devices

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Innovation in Chronic Diseases with Social Impact: Case of Renal Failure Treatments and its Application in Mexico's Health Public Policies

By Andres Moron-Mendoza, Joaquin Azprizo-Leehan, Fabiola Martinez-Licona,Raul Molina-Salazar and Gerardo Rosas-Abreu

Universidad Autonoma Metropolitana, Universidad Autonoma Metropolitana, CI3M, Mexico

In Mexico, nutrition problems, diabetes, obesity, and kidney failure diseases are very acute and linked among them. Although it is difficult to obtain reliable data, about 250,000 Mexican patients are estimated to require renal replacement therapy. At the same time, the health system and the private services only care for 150,000 of them. The kidney replacement techniques used by the health sector have been peritoneal dialysis and hemodialysis. There is no cure for chronic kidney disease, and the treatment generally consists of measures to help control symptoms, reduce complications, and slow the disease progression. The National Center for Research in Medical Imaging and Instrumentation, CI3M, is a national laboratory of the Metropolitan Autonomous University, UAM-Iztapalapa. The Center's functions include applied research, continuous education, and clinical services to the community, and one of the key projects currently working is related to hemodialysis. A set of machines are used to develop high-quality hemodialysis procedures to improve the patient's quality of life while lowering costs. These procedures are designed to alleviate the burden of the disease, mainly for the vulnerable profiles of kidney failure patients. A primary hemodialysis treatment protocol was developed. It aims to improve the performance characteristics of the patient undergoing a conventional hemodialysis regimen but with individual and continuous attention. An important factor

will be assessing simple intradialytic exercise to reduce the rate of adverse events such as hypotension. Additionally, it is desired to evaluate the improvement of the general state of health, including reinserting the patient to their productive activities and ensuring that patients report incremental physical, emotional, social, and sexual well-being. This proposal integrates innovations such as intradialytic recording of several physiological parameters that are not commonly used in clinical practice to improve the performance of advanced techniques further and achieve renal replacement therapy with results in duration and quality of life similar to those of a kidney transplant. A special consideration regarding the protocol is that if the results are positive at the end of the study, part of this cardiovascular performance analysis technique could be implemented, initially through heart rate variability analysis, in the design and development of low-cost and accessible heart rate detection devices to the entire population. The state of the policy in this matter is relatively static, there have been efforts to provide public hemodialysis services, but several barres prevent them from achieving it. Due to the potential impacts this protocol may achieve, enough documented evidence may be the basis for formulating public policies that aim to provide integral care to the kidney failure patient. Considering that a public policy is formulated to be implemented and further evaluated, the results from innovation-related research may point out to strengthen the decision-making process and provide high-confidence evidence that supports not only the outcomes but also the monitoring and evaluation processes, with high probabilities of continuity.

Keywords: chronic kidney disease, hemodialysis, intradialytic recording, health innovation

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Governance of Healthcare Technology Australian Standards and Hospital Accreditation

By Kyril Belle

Canberra Health Services, Australia

Introduction: The Healthcare Technology sector in hospital setting in Australia is regulated and governed by Therapeutic Goods and Administration (TGA) for introduction of technology , Australian standards AS/NZS 3551 that specifies the testing and inspection requirements for electrical medical equipment in Australia and New Zealand and Australian Commission on Safety and Quality in Healthcare sets the National Safety and Quality Health Service (NSQHS) hospital accreditation to provide a nationally consistent statement of the level of care consumers can expect from health service organisations. Over the years all three have undergone several revisions since its inception, reflecting changes in technology and advances in medical practices. This paper will explore the evolution of all over time and practical application of implementing the Australian Standards AS3551 and meeting the competing requirements in a public hospital setting by HTM department. .The lesson learned in the development of CMMS at Canberra hospital with examples and tips on how to adapt to these changes will be shared. **Methods:** Australian Standards for management of healthcare technology AS/NZS3551 was first published in 1994 and is currently being reviewed in 2023. This standard was based on the IEC 601-1 standard and specified the requirements for the testing and inspection of electrical medical equipment in Australia and New Zealand. The standard covered the safety and performance aspects of electrical medical equipment, including the requirements for electrical safety, electromagnetic compatibility, and environmental testing. The standard has undergone several revisions in 2004, 2012, 2016 and is currently being reviewed in 2023. The revisions have reflected changes in technology and medical practices. In 2023 it is being reviewed again to address convergence of technology space driven by digital, health agenda. The HTM department at Canberra hospital like many in Australia have to learn to navigate and practically implement the standards requirements in public health while satisfying the hospital accreditation requirements. The development of a CMMS to adapt and meet the evidence and reporting requirement will be shared. Discussion and **Conclusion:** AS/NZS 3551 has undergone several revisions since its inception, reflecting changes in technology and advances in medical practices. The standard has become an essential tool for ensuring the safety and performance of electrical medical equipment in Australia and New Zealand, helping to protect patients and medical practitioners alike. As technology continues to advance and medical practices continue to evolve, it is likely that AS/NZS 3551 will undergo further revisions to help ensure that it remains relevant and effective. It is crucial for HTM Departments to be adaptable to changes and be equipped with systems and skills to cater for these changes in a practical sense to be relevant and adding value to the patient safety space.

Keywords: standards, hospital accreditation, CMMS

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Establishing and Implementing a Comprehensive Medical Device Maintenance Program in Healthcare Institutions: A Focus on MS2058:2018 Standards in Malaysia

By Thangavelu Sasikala,Dzatul Ithri Binti Amra

Policy, Code & Standard Division, Medical Device Authority, Malaysia, Engineering Services Division, Ministry of Health Malaysia

Medical devices play a crucial role as essential components in providing high-quality healthcare services. It is imperative that these devices function effectively, safely, and in accordance with their intended purpose throughout their operational lifespan. Maintenance activities are pivotal in ensuring the continuous and optimal performance of these devices. This challenge is particularly pronounced in healthcare institutions, gaining paramount significance in low to medium-income and developing nations. Thus, this article underscores the imperative of establishing, upholding, and executing a comprehensive medical device maintenance program across all devices within healthcare establishments. The paper delineates the development and implementation of a maintenance management program based on the MS2058:2018 standard and international norms within a healthcare institution operating under the purview of the Ministry of Health, Malaysia.
Keywords: Medical devices,maintenance,maintenance management

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Medical Equipment Management Policy

By Conchita LeBert

Ministry of Health and Wellness, Jamaica

This abstract presents Jamaica's comprehensive Medical Equipment Management Policy, developed by the Ministry of Health and Wellness (MOHW) in alignment with the National Development Plan, Vision 2030, and the MOHW Vision for Health 2030. The policy aims to enhance the management of medical equipment by addressing key strategic outcomes outlined in Goal 6 of the MOHW Vision for Health 2030. The policy adopts a total life cycle philosophy, recognizing that the cost of acquisition represents only a fraction (approximately 20%) of the total cost of ownership. The remaining 80% is allocated to cover the equipment's life cycle costs. Leadership for the maintenance program is provided by engineering management staff at the MOHW Head Office, responsible for setting policies and ensuring adherence to the Medical Equipment Maintenance Management Policy. The Equipment Life Cycle encompasses two primary aspects: Planning and Management. Planning involves assessment, budgeting, acquisition, and replacement, while Management focuses on education, compliance, maintenance, and safety. Adequate workforce analysis is crucial, requiring the Regional Health Authorities (RHAs) and Common Health Facilities (CHFs) to determine the human resources necessary for an effective maintenance program. Prior to acquiring new equipment, an assessment of technical staff skills and availability of proper test equipment is conducted, with engineers and technicians receiving additional medical equipment training. External service providers/vendors may be contracted for maintenance services when required. Each region is responsible for establishing a yearly Medical Equipment Maintenance Plan based on the Planning and Management exercises.

The methodology employed for developing this policy involved training from PAHO in Healthcare Planning and Management and Healthcare Technology Management, online research, and insights from experienced engineers and technicians. Feedback on the initial draft document was sought from key individuals outside the contributors' group, as well as from engineers and technicians within the RHAs. The feedback was incorporated into subsequent drafts, which were then presented to PAHO for further input. Adjustments were made based on their feedback, resulting in the final policy document. Key lessons learned during the development process include conducting thorough research, utilizing an initial document as a collaborative starting point, and involving all stakeholders before finalizing the policy. The Medical Equipment Management Policy will serve as a valuable resource for the RHAs and CHFs in effectively maintaining the medical equipment assets under their control. By implementing this policy, Jamaica aims to ensure the consistent achievement of equipment performance standards, strengthen monitoring and reporting mechanisms, and optimize the allocation of resources across the equipment life cycle.
Keywords: medical equipment management, maintenance, policy, jamaica, mohw, vision 2030, strategic outcomes, life cycle, planning, management, workforce analysis training, collaboration

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Assessment of the Implementation of Medical Equipment Policy in Mongolia

By Gerelt-Od Namdag, Munkh-Erdene Luvsan and Amarsaikhan Dashtseren

Ministry of Health of Mongolia

Background: Regulations on medical equipment and other products in the health sector in Mongolia are different as compared to other countries. These are related to the definitions, integrated policies, and regulations for medical equipment registration; therefore, it is necessary to improve the legal framework of the quality, safety, optimal capital planning, and maintenance management. **Purpose:** The purpose of the evaluation was to examine the implementation of policy documents related to medical equipment, and to compare them with indicators developed by the World Health Organization and other countries. **Method:** In order to compare and analyze the legal articles, provisions with the most significant and impactful provisions of the existing laws, and regulations related to medical equipment, the practical compatibility, and the implementation of similar legal norms in different environments. Comparative study, audit, control and evaluation reports, and other documents made by competent authorities, study and comparison, recommendations of the World Health Organization and the International Regulatory Organization, regulations of other countries were studied. In order to determine the implementation of legal documents related to medical equipment, the quality and availability of equipment, the competence and adequacy of human resources, and the identification of problems, information were collected from relevant experts, interview with target focus group interviews. The data were analyzed by content synthesis, and compared. For evaluation, 5 laws, 7 standards, and 17 orders were used. A total of 26 experts participated in the focus group interview.Result: There are low levels of regulation of medical equipment in laws used in health sector, and separate regulations in individual law. Health providers implement relevant policies, but implementation varies in hierarchy of the providers, particularly in rural areas where human resource and room requirements are insufficiently enforced. In the case of a private health care provider, regulation formulated not only by the organization's internal rules and regulations, but also more attention is paid to the customer's request. Although privatization, and performance-based financing reform in health sector bring positive impact on the supply of equipment, some hospitals are reducing budget on equipment maintenance in order to gain more profit. In total, 91.9% of the experts in the field said that there is no law and legal framework related to the quality and safety regulation of medical equipment, 91.7% said there is no law and legal framework related to optimal capital planning and regulation, and 25.7% answered that the regulation of special permits is sufficient. **Conclusion:** Medical equipment terms used in health sector in Mongolia doesn't correspond with international terms, and relevant law articles and policy regulations related to medical equipment are not comparable with term used in other countries, therefore, comprehensive legal framework have not developed in Mongolia which support equipment life cycle, starting from the equipment authorization to release to the market.
Keywords: medical equipment, regulations, World Health Organization

C1- Credentialing

Global CE Status 2023

By Thomas Judd

GCEA, USA

Many colleagues have written about the global reliance on health technologies whose innovation, deployment and support continue to improve worldwide healthcare and its delivery. The World Health Organization's-WHO 2007 Resolution WHA60.29 called for the effective use of health technologies (HT), in particular medical devices, through proper planning, assessment, acquisition and management. The community of professional clinical engineering (CE) practitioners' pre-COVID19 stories are captured in the Global Clinical Engineering Journal. An article from 2022 shows the reasons for the increased contributions of this community especially during the pandemic in The Growing Role of Clinical Engineering: Merging Technology at the Point of Care. This study answers questions such as to how this global reliance was demonstrated during the COVID-19 period. How the status of the Clinical/Biomedical Engineering (CE/BME) profession that serves at the point of care changed as the world emerges from the huge stresses of the pandemic. The article reviews the evolution of the CE profession since 2020, how it partnered with WHO between 2020-2023 and what lessons were learned in the process. It reports future CE priorities to improve country, regional, and global practice in 2023 and beyond. This timely report shares important findings related to patient care support services and expected improved clinical outcomes.
Keywords: clinical engineering, COVID19, World Health Organization

C1- Credentialing

Multi-Sectoral Maintenance Strategy as a Key Enabler of Community Wellness in Less-Resourced Settings: A Leadership Opportunity for Global Clinical Engineering

By Mladen Poluta

GCEA, South Africa

There is much anecdotal evidence confirming the challenges faced by low-resourced countries in managing and maintaining their medical device and healthcare infrastructure fleets. Challenges include (i) lack of standardization and provision of training and spare parts for donated equipment; (ii) low priority for needed facilities, tools, equipment, and training given resourcing constraints in the health system as well as in government generally. Maintenance cadres – as a transversal collective – face major challenges in the lack of employment and professional development opportunities. The related government structures are also under-capacitated and characterized by poor infrastructure, limitations in availability of tools and test equipment, inadequate information systems, not recognized as being a core capability and operate in silos determined by their roles in the case of each government department. What is suggested is a multi-sectoral, society-wide maintenance and improvement initiative to develop both common and specialized skills and capabilities, provide appropriate infrastructure and physical as well as information system tools and resources in support of the maintenance function. Such an initiative is more likely to receive adequate and sustained funding. All engineering assets1 used in healthcare delivery (physical infrastructure, plant, machinery, equipment and vehicles) as well as those needed in the broader health system, e.g., for provision of clean drinking water and sanitation and waste management systems as upstream determinants of disease burden, inter alia, should be in scope. Such an initiative would exhibit great efficiencies including those related to curriculum development, program delivery, training centers, support systems, etc. and the interdependencies amongst different streams would serve to strengthen the initiative as a whole. A desired outcome scenario would see both general and specialized maintenance cadres being deployed down to community level, i.e., present at the service delivery coalface and able to respond to needs as they arise as opposed to usual top-down responses in government where appropriate actions can be delayed and caught up in bureaucratic inefficiency. To optimize investment and resourcing of such an initiative, the Health Technology Assessment (HTA) toolkit should be applied selectively to provide guidance and serve as a governance mechanism, identifying the most cost-effective approaches and maintenance strategies while monitoring their implementation and impact. To do so, HTA must itself move from focus on individual technologies or interventions at a specific phase in their development (HTA 1.0), to methodologies that consider the full technology/intervention life cycle (HTA 2.0) and finally to those that consider optimized health-related intervention packages that impact on community wellness (HTA 3.0) as part of a true health system2. In closing, it is suggested that clinical engineering practitioners – together with their counterparts in the hospital engineering and facilities management spaces – lead the initiative as part of collective social responsibility. Templates for plans and actions at the global, regional, national and district levels should be developed and used as guiding beacons for resourcing and implementation.

1. As per the ISO 55000 family of International Standards for Asset Management
2. https://documents.worldbank.org/en/publication/documents-reports/documentdetail/999031468325227625/connecting-sectors-and-systems-for-health-results

Keywords: maintenance, low-resource settings, multi-sectoral initiative, HTA governance

C1- Credentialing

Addressing Quality and Capacity Building Challenges in Medical Device Donations: Health Technology Management and Credentialing

By Lori Warrens

MedSurplus Alliance Program, USA

Medical device donation to low-resource settings is a frequent and essential strategy to strengthen healthcare and improve patient outcomes. While anecdotal reports identify ineffective and wasteful donation practices, studies, reported experience and formal evaluation, the evidence on the frequency and causes of donation failure need to be improved and applied. However, there is agreement that a concerted effort to increase awareness of device donation guidelines among healthcare providers

and product donors is essential. This abstract describes the MedSurplus Alliance's approach to addressing the challenge and ultimately benefit clinical care providers and patients.The MedSurplus Alliance (MSA) was formed in 2012 to address inappropriate, unsolicited, and unusable donations, including equipment, devices, and related supplies by Medical Surplus Recovery Organizations (MSROs). MSROs collect new and usable surplus medical supplies, devices, and pharmaceutical products from hospitals, manufacturers, and distributors. MSROs process these donated materials to ensure quality and make them available to under-resourced healthcare providers through direct shipments to healthcare settings, to supply medical volunteer teams, and support teaching institutions. A review of MSRO surveys, extensive grey research, and published research sources found that despite over 30 identified guidelines addressing device donations, MSROs required specific guidance that was relevant, implementable, and measurable. The Alliance adopted a groundbreaking three-part approach to increasing the medical donation quality and building MSRO capacity tools to address this need.The Code of Conduct and Standards (COC) is a guide to creating equitable partnerships and an implementable framework to improve securing, preparing, transporting, and implementing donated medical devices. Guided by WHO donation principles and published in January 2013, the COC organizes seven sections that include standards defining best practices and performance elements that identify criteria for evaluating adherence to the standards. Medical device standards address needs assessment, quality and quantity, logistics, emergency donations, and disposal best practices.The MSA COC Self-Assessment enables MSROs or any donor to conduct an in-depth and comprehensive examination of the quality of its programs and practices. It also provides the foundation for the MSA Accreditation Program, which allows MSROs and other donation programs to assess their adherence to the COC and to improve donation practices through self-assessments. Participants report that the process enabled them to improve their operations, address previously unknown quality issues, and prepare for future accreditation. MSA Accreditation is an independent and objective assessment to authenticate MSRO competence and integrity in Governance, Needs Assessment, Quality and Quantity, Logistics, Monitoring and Evaluation, Donations in Emergency Situations, and Disposal. The MSA Standards and Accreditation Committee reviews the applicant's self-assessment form, document submission and conducts a site visit. Piloted 2017 – 2022, nine US-based and one Australian MSRO have been awarded full or provisional accreditation today. Full implementation begins in 2023.

Keywords: health technology management, medical device, standards, evaluation, quality, medical donation

C1- Credentialing

Enhancing Accessibility and Inclusivity in Clinical Engineering Certification: Virtual Exam Accommodations and Guidelines

By Marie-Ange Janvier, Andrew Ibey and Yin Yu Rachel Zhang

Children's Hospital of Eastern Ontario, University of Ottawa, Carleton University, Canada

As the field of clinical engineering certification continues to evolve, it is crucial to adapt examination processes to ensure accessibility and inclusivity for all candidates. This study focuses on the Canadian Board of Examiners for Clinical Engineering Certification (CBOE) and their efforts to implement virtual exam accommodations and guidelines during the COVID-19 pandemic. By transitioning from in-person exams to a virtual format, the CBOE aims to address financial, travel, and health-related constraints while maintaining the integrity of the certification process. This paper presents the guidelines developed by the CBOE to facilitate virtual oral exams, ensuring a fair, efficient, and secure examination experience. The guidelines outline communication channels between the CBOE, candidates, and potential proctors, along with the selection and preparation of suitable locations for the virtual exam. Furthermore, this study examines the strategies employed by the CBOE to enhance accessibility and inclusivity during the certification process. It explores technological infrastructure enhancements, security measures, and considerations for candidates with disabilities or specific needs. The CBOE also extended the validity period of certifications, provided online training resources, and utilized virtual platforms for continuing education and professional development opportunities. By analyzing the adaptations made by the CBOE, this study sheds light on innovative approaches to clinical engineering certification. The findings contribute to the ongoing development of resilient certification methods and provide valuable insights for certification bodies and professionals in the field. Understanding and sharing these best practices will enhance preparedness for future disruptions and ensure that certification processes remain inclusive and accessible to all candidates.

Keywords: clinical engineering, certification, virtual exams, accessibility, inclusivity, guidelines, accommodations, COVID-19 pandemic, continuing education, professional development, certification methods

C1- Credentialing

Skilling & Upskilling of Biomedical Engineers Through Certification Programs

By Nitturi Kumar, Karthik Raj V, Mohan Raghul, Somasekhar M, Mrutunjay Jena and Dr. Jitendar Kumar Sharma

Indian Biomedical Skill Council, Andhra Pradesh MedTech Zone, India

Indian Biomedical Skill Consortium (IBSC) set up by Andhra Pradesh MedTech Zone Ltd (AMTZ) in collaboration with Association of Indian medical device manufacturers (AiMeD) and Quality Council of India (QCI) to support the resource infrastructure of healthcare sectors by providing certified skill biomedical engineers to the nation. The IBSC skill programs are approved by National Skill Development Agency (NSDA) under the Ministry of Skill Development and Entrepreneurship has been able to contribute massively to capacity building at the national level in a niche area of Medical Devices. To address the lack of a system for certifying qualified manpower in the Biomedical field, IBSC has been formed.India has been importing Medical Devices worth INR 63,000 crores. Notably, Andhra Pradesh MedTech Zone, Visakhapatnam, has demonstrated the ability to build in India and upskill human resource through IBSC, which is competent across the globe. IBSC objective is to provide quality biomedical skill-based training in the medical device domain, which will benefit the medical device manufacturers and the nation. IBSC has five approved courses by NSDA (i.e., Certificate in Biomedical Engineering, Certificate in Biomedical Maintenance, Certificate in Biomedical Manufacturing, Certificate in Biomedical Quality Assurance, Certificate in Biomedical Project Management) and eleven other courses; combining all, more than 2500 Biomedical engineers have been trained and certified. There are participants from other countries who have undergone courses such as certificate in Biomedical Maintenance and Certificate in Biomedical Quality Assurance for upskilling their skill sets. Henceforth IBSC Certification can be accepted globally.Through the IBSC training, biomedical or clinical engineers can improve their skill sets by doing the course of their area of interest and the courses are delivered by biomedical engineers who have sound experience in the biomedical domain.
Keywords: Biomedical Engineering, Capacity Building, Skill Training Program, Upskilling

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C1- Credentialing

Certification for Facilities Services and Its Impact on Networks of Healthcare Organizations

By Ricardo Sa Maranhão, Gilvane Lolato

Associação Brasileira de Engenharia Clínica (Abeclin), Brazil

The ONA Qualification Seal Manual contemplates organizations that provide services to health organizations. These services must be legally constituted of a state or private nature, with or without profit. For Clinical Engineering, one of the services contemplated in the Manual, companies that provide management services for health technologies used to provide patient care are eligible, considering preventive and corrective maintenance routines, as well as the Clinical Engineer responsible for the service. **Objective:** To present the impact of accreditation for facilities services focused on Clinical Engineering. **Method:** In the projects of revision of the manuals the ONA counts on professional specialists of the market, evaluators, Accredited Accrediting Institutions, among other interested parties. Before starting the review, ONA raises some information such as: market analysis to evaluate the inclusion of other services, research results of accredited organizations, evaluators and Accredited Accrediting Institutions, indicators of internal processes, manifestations of the general public, among other relevant information. After the collection of information, some steps are considered for execution, such as: Elaboration of the Project, Definition of the work teams, Survey and study of external references, Review of ONA concepts, Compilation of external information, Statistical analysis, Benchmarking visits, Public Consultation, Field testing, Preparation of the final version of the manual, Submission to the Board of Directors, Official release of the manual. ONA believes that

with the accreditation for facilities services, more of the Health Sector will have a qualified network. Both companies that provide health services are already increasingly seeking qualification to achieve accreditation, as well as health service organizations have included this requirement in the qualification of product suppliers and service providers. **Results:** In the last revision of the ONA Qualification Seal Manual 2020-2024, there was the inclusion of three new outsourced services including CE requested by health organizations and society. Observed 99% increase in requirements between the 2016 and 2020 versions. The standard "Operation Management" that evaluates the main process of the organization, has the largest number of requirements, and consequently obtained the largest increase in the number of requirements (97%) compared to others. The standard dealing with "Organizational Management and Leadership" achieved a 73% increase in the number of requirements compared to previous. In the next version we are analyzing the inclusion of two new services that have a high impact that are: Property Security and Building Maintenance. It is understood that by increasingly opening the range of qualified and accredited organizations, more will be able to sustain patient safety.The new version of the ONA Qualification Seal Manual has evolved in terms of the number of new services and standards with guidance and suggestion of evidence, as well as its methodology, eliminating subjectivity through the application of the scoring method, and with an evaluation model structured in organizational guidelines, organizational and support management. We understand that the insertion of CE service in the ONA qualification process brought a gain in quality to health units, since outsourced companies increasingly seek to meet the requirements proposed by the new ONA Seal.
Keywords: accreditation, clinical engineering, benchmarking

C1- Credentialing

Equipment Maintenance Scheme for Enhancing Better Quality in Equipment Maintenance

By Karthik Raj V, Mrutunjay Jena and Jitendra Kumar Sharma

Andhra Pradesh MedTech Zone Ltd, India

The global medical devices market size was valued at USD 488.98 billion in 2021. The market is projected to grow from USD 495.46 billion in 2022 to USD 718.92 billion by 2029. Quality of Equipment Maintenance for Biomedical Equipment will define the criteria for how well the equipment can be used without any breakdown event. Proper maintenance and proper use of medical equipment are critical aspects in any large or modern hospital to ensure that all patients receive healthcare facilities without compromising on equipment failure. Biomedical equipment maintenance presents a challenge for many countries, especially those with low human and infrastructural technical resources. So, there is a need to develop a maintenance scheme that can be used globally that addresses how to manage medical equipment effectively and efficiently, providing quality, performance and safety aspects to the patients. Therefore, in collaboration with the Association of Indian Medical Device Industry (AiMeD) and the Association of Healthcare Providers India (AHPI), Andhra Pradesh MedTech Zone Ltd (AMTZ) started a voluntary scheme on biomedical equipment maintenance, which is known as the Biomedical Equipment Maintenance Certification (BEMC) Scheme on Oct 15th, 2022. The primary purpose of this Scheme is to address the efficacy of maintenance of medical equipment's function after Installation, Servicing, and Repair so that the quality and safety aspects have adequately cared for the patients and equipment end users. This is the first Scheme that addresses the medical equipment maintenance certification process based on ISO/IEC 17065:2012. The scheme documents are developed through a multi-stakeholder consultation process. This voluntary scheme can be implemented by the Hospital (through the biomedical maintenance department), Maintenance by the OEM and Third-party maintenance provider (AMC/CMC Provider). This scheme takes into consideration of IAF MD 9 document, from which, four main technical areas (category) are taken into account. They are non-active medical devices, active medical devices (non-implantable, IVD instruments and sterilization method for medical devices. This scheme is applicable for all except Implantable medical devices, Single-use or disposable medical devices and Software as a medical device category. The scheme uses a common checklist for a category and specific checklist for scheme product category. This Scheme is intended to significantly eliminate/reduce the maintenance breakdowns in hospitals, improve the patient safety and quality and performance of the medical equipment.
Keywords: medical equipment maintenance, hospital, patient safety, medical devices

C1- Credentialing

Why is Accreditation/Certification Important

By James Wear

GCEA, USA

Before we consider why accreditation and certification are important, we need to understand what is meant by the terms. Sometimes accreditation and certification are used interchangeably, however, they are not synonymous. In fact, registration and licensure need to be considered in this discussion. Certification is used for verifying that personnel have adequate credentials to practice certain disciplines. Certification is performed by a third-party, non-governmental agency. Certificates are not certification but may be provided for training or institutional validation of experience. Accreditation is used to verify that programs or institutions are competent to perform the work or the training that they are established to accomplish. Accreditation is the process of any agency recognizing that a separate organization has met certain criteria and standards. Individuals are not accredited. Licensure is a process by which a government-associated agency gives individuals permission to practice an occupation. Licensure acts as an endorsement that an individual has met minimum competency standards. Reviewing the terms Accreditation, Certification and Licensure, it becomes obvious why it is important for programs and individuals to obtain these conditions. It is important for individuals to be trained in biomedical/clinical engineering programs that are accredited. Accreditation agencies assure that proper academic material is presented to students including hands on experience in these programs. Once individuals work in the biomedical/clinical engineering field, they should work to become certified. It is important for these employees to be certified to assure that they can properly maintain medical equipment, teach medical staff to properly use the equipment and provide medical staff with recommendations for the best equipment to do their patient care. It is important that biomedical/clinical engineering programs in the medical care setting be accredited. This is to ensure that there is adequately trained staff of engineers and technicians, adequate equipment to maintain the medical equipment to be used for patient care and a proper management system for the program. To support patient care in the medical care facility, the staff should be certified, and the department accredited.
Keywords: clinical engineering, credentialing, certification

C2 - Capacity Building 3

Developing Effective Educational Programs to Prepare Future Clinical Engineers

By Shankar Krishnan

IFMBE

Technological advancements have been occurring in multiple disciplines and the healthcare domain has been adopting applicable advances for improved patient care. In collaboration with physicians, nurses, and clinical staff, clinical engineers (CEs) play an essential role in design, development, and implementation of innovative solutions in diagnosis and therapy from bench to bedside and beyond. Due to continual increases in healthcare load, the demands for well-trained CE s are growing worldwide. However, the CE education programs lack comprehensive coverage and harmonization due to significant variations in needs and resources across different regions. The objective of this presentation is to focus on the major challenges for preparing future CEs and to propose effective educational programs enabling them to meet their functional requirements and expectations in the healthcare spectrum. The field of clinical engineering has expanded tremendously with the applications of new technologies such as artificial intelligence, machine learning, mobile and digital health, cybersecurity, additive manufacturing, wearables, robotics, nanotechnology, Internet of Medical Things, and regenerative medicine. The incorporation of these advancements into the CE education programs poses a major challenge. The other challenges include determining the necessary breadth and depth of CE coverage, integrating theoretical, laboratory, and practical components, designing prerequisite, core, and elective courses, ensuring compliance with graduation and accreditation requirements, preparing students for job readiness, recruiting dedicated faculty with diverse expertise, and attracting and retaining students. These complex challenges make developing CE educational programs within four years a formidable task. For sustained success, the CE programs should incorporate product design, prototyping, project-based learning, clinical immersion, cooperative experiential learning, internships, industry visits, study of ethics, regulatory affairs, management, and communication skills. Three models are proposed to tackle the CE curricular design challenges. The models are characterized as general or track-based and tailored to be site-specific. The training programs provide students with real-life

experiences in collaboration with hospitals, research centers, med tech industry and regulatory agencies. Program Model A focuses on classroom teaching, laboratory and project work, and cooperative experiential learning/internship modules. Program Model B accepts students with an Associate or Polytechnic degree in a related engineering field and requires them to take the necessary courses to earn a baccalaureate CE degree. Program Model C is designed to accept transfer students from other engineering or technology disciplines, and life sciences or other fields, and offers foundation, core, and elective courses to meet the CE graduation requirements. The proposed models may be modified to suit institutional needs.The proposed solutions are derived from the success of existing site-specific Clinical and Biomedical Engineering programs. It is essential that the CE programs continue to evolve, adopt new technologies, provide software expertise, and sharpen multimodal communication skills. In conclusion, development of innovative and effective educational programs to prepare future CEs must address several challenges. With proper training, continuous skill development and life-long learning, future CEs will be equipped to tackle emerging complex problems and contribute to improved patient care on a global scale.
Keywords: educational programs, program models, continuous skill development

C2 - Capacity Building 3

Three Decades of Clinical Engineering Study Programs in Trieste

By Agostino Accardo, Francesco Bassi and Milos Ajcevic

Department of Engineering and Architecture, University of Trieste, Italy

Continuous and up-to-date education through dedicated study programs is essential for delivering high-quality Clinical Engineering services to a national healthcare system. In this regard, the University of Trieste has had a noteworthy experience with its study programs over the past 30 years.The first study programs in Clinical Engineering in Italy were established in 1991 as a biannual post graduate specialty school. This program was established after a series of studies conducted at Trieste University Hospital's Technical service, directed by Diego Bravar, jointly with CNR (National Research Council, Pisa, Italy) that demonstrated important savings by introducing internal management of maintenance and repair of medical devices compared to annual service contracts offered by manufacturers. As a result of this experience, an internal clinical engineering team was established at the Trieste hospital. Building upon that success, an external clinical engineering service company was subsequently created to serve other hospitals. Consequently, the emergence of this new reality necessitated the education of new professionals to support it. In this frame, the first field experts together with academics of the University of Trieste emerged to support the higher education study programs in clinical engineering. In 1993, the first generation of students completed their studies and some of them, along with other engineers employed in hospitals and the early clinical engineering companies in Italy, came together to establish the Italian Association of Clinical Engineers (AIIC).In 2003 the initial study program evolved into a study path composed of a master's degree study program followed by a one-year postgraduate professional course. The study programs encompassed a range of courses taught by both academic faculty (such as biology and physiopathology, MDs, and signal processing) and professionals from hospitals and private companies. These professionals offered expertise in areas like regulatory affairs, hospital IT, HTA and HTM, risk assessment and prevention, hospital plants and systems, management of clinical engineering services, procurement, and quality assurance.The continuous and rapid evolution of healthcare related technologies and management models places a constant demand on Clinical Engineers to acquire new knowledge and skills. As a result, the study programs and specific courses are managed and updated yearly having constant interaction with the professionals, as well as private and public companies. This allows a fast and appropriate educational response to the novelties that arise in the clinical engineering world, such as product innovations, change of national policies, introduction of new clinical paradigms, etc. Over the course of 30 years, the University of Trieste has trained a total of 860 clinical engineers who are currently employed in clinical engineering services, both in Italy and abroad. These professionals actively contribute to the operations of both internal and external clinical engineering services, along with their valuable contributions to MD manufacturers. In conclusion, the Clinical Engineering program at the University of Trieste provides a comprehensive education that covers essential management skills required by clinical engineering services. Additionally, the program addresses important aspects related to production, regulatory affairs, and quality systems, which are in high demand by MD producers.
Keywords: education, capacity building, clinical engineering

C2 - Capacity Building 3

Improving Quality of Services Through Setting up CE Departments and Proper Maintenance Workshops in Hospitals

By Francine Umutesi

Rwanda Biomedical Centre

Problem: One of the reasons for the poor quality of services is the inadequate condition of medical equipment for diagnostic and treatment in health facilities. Reasons include lack of proper structure to allow efficient equipment management and maintenance, lack of skilled biomedical technicians, absence of a well-equipped workshop and proper tools for repair as well as sufficient funding for spare parts and accessories. **Description:** In Rwanda, management and maintenance of all medical equipment used to be done by a specific maintenance division at Central level. This proved to be ineffective and inefficient to address all facilities requests and respond physically to provide needed support. This paper describes the setup of provincial level technical coordination teams, and setting up of well equipment hospital workshops that will provide most preventive, and some curative maintenance works at all public hospitals across the country. Four provincial offices have been identified to be decentralized offices in support of some Rwanda Biomedical Centre's divisions. A technical team made up of 1 biomedical engineer and 4 technicians will be stationed at these sites, to help with management of clinical engineering activities in the province. Provincial and hospital-based workshops have been renovated and are being equipped with relevant tools. Capacity building on specialized equipment has been given to hospital biomedical technicians, recently focusing on oxygen production and distribution equipment among others. Their scope of work was defined to cover preventive maintenance, as well as 1st and 2nd of curative maintenance of medical devices in all health facilities, including the Health Centers in their catchment areas. Maintenance contracts for specific technologies that require manufacturer interventions will be outsourced at central level to ensure that they are negotiated fairly for all facilities; giving healthcare facilities ownership and self-reliance when it comes to management and implementation of needed interventions. Mentoring, supervision, and monitoring activities will continue to be handled by the central team, an emphasis will be made on quality assurance, regulation and enforcing a quick intervention policy. Lessons learned and next steps: Ensuring effective medical equipment for diagnostic and patient care is essential. The decentralization process has started, but to be successful, it requires involvement of many stakeholders and a clear strategic vision and operational plan for healthcare facilities. Setting up a proper clinical engineering department that combines skilled biomedical, electromechanical and civil engineers, definition of maintenance service packages for hospital technicians and outsources contracts, and implementation modalities, availability of skilled staff, workshop space and tools, funding, mentoring and close monitoring are key requirements for successful achievements.
Keywords: quality services, healthcare technology, maintenance, equipment, decentralization

C2 - Capacity Building 3

Clinical Engineering in Puerto Rico

By Wilfredo Farinas Coronado, Jonathan Marrero Rosaly

Polytechnic University of Puerto Rico Biomedical Engineering Department, Puerto Rico

The state of biomedical and clinical engineering in Puerto Rico showcases a thriving ecosystem that supports both healthcare facilities and biomedical manufacturing. The island is home to several prominent healthcare facilities, including hospitals, clinics, and research institutions, which rely on skilled biomedical and clinical engineers to ensure the optimal performance and safety of their medical equipment. According to the Registry of Hospitals and Health Facilities, prepared by the Assistant Secretary for the Regulation and Certification of Health Facilities (SARAFS acronym in Spanish) of the Puerto Rico Department of Health, currently, there are 67 hospitals, 12 of which are public and the remaining 56 are private. This represents that 16.7 percent of hospitals are public while around 83.3 percent are in the private sector. The Metropolitan region has the highest number of hospitals per inhabitant, with a ratio of 1 hospital for every 40,420 inhabitants. Both the public sector and the private sector have at their disposal significant technological resources for the service of people's health. In recent years, at over $300 million, the government has acquired highly sophisticated equipment for diagnosis and

treatment and the most advanced information security and data processing technologies available to patients. However, none of the health centers, both public and private, have clinical engineering services or biomedical engineering services. In Puerto Rico, only the Polytechnic University of Puerto Rico offers a bachelor's degree in biomedical engineering, where a minor in Clinical Engineering is offered. Although the Polytechnic University has graduated five classes of Biomedical Engineers, there is an urgent need to offer Clinical Engineering services in Puerto Rico and for the government to associate with Clinical Engineering entities to modernize and update the administrative structure of their healthcare facilities. In addition to the robust healthcare sector, Puerto Rico has a significant presence of biomedical manufacturing facilities. The island's biomedical manufacturing industry is known for its production of medical devices, equipment, and supplies. This sector provides numerous employment opportunities for biomedical and clinical engineers, who are involved in the design, development, and manufacturing processes. With a focus on innovation and quality control, these engineers contribute to the production of cutting-edge medical technologies that are utilized not only locally but also exported globally, bolstering Puerto Rico's reputation as a center for biomedical excellence. The collaboration between healthcare facilities and biomedical manufacturing facilities in Puerto Rico fosters a mutually beneficial relationship. Clinical engineers often work closely with manufacturers to ensure the seamless integration and functionality of newly acquired medical equipment within healthcare facilities. This collaboration facilitates innovation, research, and knowledge exchange, ultimately enhancing patient care outcomes. Moreover, the presence of biomedical manufacturing facilities in close proximity to healthcare facilities allows for efficient access to technical expertise, spare parts, and repair services, supporting the continuous operation of critical medical equipment and reducing downtime.

Keywords: clinical engineering, education, manufacturing

C2 - Capacity Building 3

CE-IT Capacity Building in Kosovo

By Nexhdet Abazi

Smart Engineering, Pristina, Kosovo

Description: The majority of cases of failures of medical equipment in developing countries are a consequence of insufficient maintenance and lack of qualified experts in the field Clinical Engineering, based on the statistics. Clinical engineering professionals are continually review and improve their management strategies in order to keep up with improvements in equipment technology, as well as with increasing expectations of health care organizations public hospitals are faced with challenges in the prevention of failures of medical equipment and the proper maintenance. **Goal**: As a consequence, medical equipment are not repaired in an optimal time, as a consequence of the domestic lack of a cadre of clinical engineers and the very lengthy and bureaucratic procurement process of professional services. These delays directly influence the availability and the access of health care services which involve the availability of medical equipment. **Results:** In order to implement a system of effective health care management, then their management should be integrated in a system of monitoring from the distance, in real time, from the specific designated department of the Ministry of Health, which will have a monitoring data center. Through this monitoring from distance, we will be able to have access to the technical situation of the medical equipment remotely, which would enable us to have real time alarms of failures, maintenance schedules and the due dates for preventive measures. The final users that will benefit from this project are hospitals and patients. This applies to both traditional medical devices and the emerging class of devices that can be or are integrated into electronic medical records (called CE-IT devices.)• Building the political will inside the Ministry of Health to support CE and HTM. • Increasing awareness among health care professionals on the necessity of incorporating CE and HTM as an integral part of the work in any hospital • Increasing the interest of young engineers and engineering students for the field of CE, CE-IT, and HTM preserving through logs the access and work history.

Keywords: CE-IT, capacity building, ministry of health

C2 - Capacity Building 3

Insights and Opportunities to Transform International Health Workforce Recruitment and Capacity

By Bruce Compton

Global Health and International Outreach at Catholic Health Association, USA

Catholic Health Association Global Health Workforce – CHA Report on Accenture Research
Goals: • Provide health leaders with greater awareness and understanding of the significance, interconnectedness, and repercussions of the current Global Health Workforce Crisis.• Begin a dialogue with leaders on this critical global health issue and our response as a global health ministry. This report addresses the global healthcare workforce shortage and its impact on healthcare systems. It examines current practices, showcases case studies, and highlights the role of healthcare leaders in developing a fair and globalized healthcare workforce. The research for the report was conducted independently by Accenture, who worked with CHA's Working Group on Global Health Workforce to shape the scope and obtain feedback on data collection. The report provides valuable insights and recommendations for shaping talent pipelines. It was developed for leaders in the Catholic health ministry, including Sponsors, C-suite members, Chief Human Resource Officers (CHROs), Chief Nursing Officers (CNOs), and global health leaders. The research was conducted independently by Accenture in collaboration with CHA's Working Group on Global Health Workforce for the Future. It involved a comprehensive literature review and interviews with over 30 global stakeholders from high, medium, and low-income countries, many associated with the Catholic health ministry. Key insights and opportunities highlighted in the report include the significant risk posed by the global healthcare workforce shortage, contributing factors such as the COVID-19 pandemic, burnout, violence toward healthcare workers, and an aging workforce. The report also discusses challenges in recruiting local health workers, the negative consequences of brain drain, and the overreliance on international recruitment. The report discusses the global context, policy landscape, and initiatives promoting ethical international recruitment practices. It highlights current practices, critical needs and challenges, and areas for improvement. The report proposes a framework for ministry leaders that emphasizes ethical international recruitment to address these issues. The framework includes the following:• investing in strengthening the healthcare workforce in low-and middle-income countries,• practicing ethical behavior in global recruitment,• advocating for improvements in domestic and global pipelines and working conditions,• driving systemic change to enhance global health capacity. The report concludes by emphasizing the need for leadership to redefine ethical practices, strengthen the global healthcare workforce, advocate for new recruiting standards, and recognize the collective responsibility in solving the international recruitment crisis and workforce shortage. Implementing the report's insights and recommendations allows health leaders and partners to transform international recruitment practices, strengthen global healthcare capacity, and uphold the right to health for all.
Keywords: workforce, global healthcare, policy

C2 - Capacity Building 3

Building Human Resource Capacity for Medical Device Maintenance and Management in Zimbabwe

By Connellius Njini

ZIBEA, Parirenyatwa Group of Hospitals, Zimbabwe

Capacity building involves processes that strengthen the capacities of individuals, groups and communities. These processes might include leadership, creating links and networks, encouraging initiatives, facilitating, training and finding resources. For effective health service delivery, additional resources are required to strengthen and expand the pre-service education of qualified biomedical equipment technicians and engineers. This should be coupled with interventions at health facilities and provincial maintenance centers to make spare parts available. The Government of Zimbabwe has implemented an ambitious plan to expand the number of healthcare facilities at all levels, with a goal of four specialized hospitals, 8 general hospitals, and several primary centres, by 2030, plus more than 80 private hospitals and diagnostic centres. The estimated Biomedical engineer requirements will be approximately 200 in number. However, expanding the size of the medical device workforce is not the only challenge. Existing biomedical technicians and engineers must be equipped with the skills needed to manage medical devices and keep pace with emerging healthcare technologies. To meet the growing demand for biomedical technicians and engineers, the Government of Zimbabwe engaged local partners which include Universities and Technical colleges as banks for financial assistance. The objective is to improve health outcomes for all Zimbabweans by improving

human resources for health management; and increasing the availability of skilled Biomedical Technicians and Engineers to maintain the equipment in Hospitals. **Goals and Objectives:** The HRH Project sought to increase the supply of qualified biomedical technicians and engineers and thereby ensure the availability of working medical devices. Specific objectives were to: • Strengthen the management of medical devices; • Improve the quality of education of biomedical technicians, and • Strengthen the competence of biomedical engineers and technicians. Problem statement: Most of the equipment in Hospitals was frequently down hence poor health service delivery. The government through the Ministry of Health and Child care on a project to resuscitate the health system by capacitating Biomedical engineers and Technicians in government institutions. Policies were crafted that made sure that manufacturers who supplied equipment must train local biomedical engineers and technicians on first-line maintenance and also provide specialized tools required for repair and maintenance. Inhouse refresher courses were conducted, and local colleges introduced programs for Biomedical engineering which were aimed at narrowing the knowledge gap on repairing and maintenance of medical equipment. Financial institutions were called in to provide financial support for those attending colleges. **Conclusion:** The service delivery started to improve and equipment downtime started to improve. Equipment downtime was drastically reduced. This was due to the education and skills impacted to maintenance cadres. Tools including specialized tools were bought and made available.
Keywords: capacity building, biomedical engineer, service delivery

C2 - Capacity Building 3

Strategic Thinking in Decision-Making by The Clinical Engineering Professional And Reflections to Team

By Tayna Cabral, Alexandre Ferreli Souza

Hospital Regional de Registro Project, Sao Paolo, Brazil

Description: Importance of emotional intelligence and strategic thinking in decision-making by clinical engineering professionals. In This work classified 4 essential skills for the clinical engineer and 3 results achieved with the team in 1 year of application. **Goals:** Considering that the hospital environment requires a level of professional maturity from its employees, this work aims to present some characteristics that the authors considered important to be developed by new professionals in clinical engineering. In addition, the work shows how this professional profile supports team engagement and increased productivity. **Results:** Skills development: Active and proactive positioning; Constant analysis of processes involving hospital medical equipment to optimize time, human and financial resources. Prioritization of OSs; Team direction and parameterization of metrics for service prioritizing criticality and risk level. Decision making under pressure; In emergency cases, it is essential that a professional knows the processes so that they can quickly decide on the steps to be taken. Optimization of resources; Elaboration of feasibility analysis and direction of the hospital board for better decision regarding the use of resources; Strategic alignment. Periodic meetings to share results and define goals and objectives. Reflections on the behavior of employees:(1) 20,99% Improved results and team performance.(2) Motivation in positions and functions they perform.(3) Clarity in objectives and goals.
Keywords: clinical Engineering, early career development, young CE growth characteristics

C3 - Homecare

CE's HTA and HTM Skills and Perspectives for Safe and Sustainable Homecare

By Elliot Sloane, Bill Gentles and Tony Easty

Villanova University, USA

The COVID-19 pandemic ushered in a new era of global homecare innovations and challenges. Hospitals, clinics, physicians, and nurses were unable to meet the huge demand for diagnosis and treatment because of infection risks and capacity. Even small and low income countries rapidly adapted all available communication tools and mobile medical devices to create loosely-coupled and –federated networks of healthcare delivery which frequently reached the patient (and clinicians) at home.(1, 2) The COVID-19 literature is replete with stories of innovative remote diagnosis and treatment across the globe. Patients and clinicians created and maintained local paper or phone-based medical records in the absence of full-featured electronic medical records (EMRs), and adapted low-cost consumer health devices for pulse oximetry, blood pressure, and

temperature data, and supplies like medicines and oxygen were distributed by whatever public or private transport. In the ebbing shadow of the pandemic, many nations have the opportunity to take advantage of the lessons learned from 2-3 years of remote patient care to continue reaping the cost savings and increased patient and provider access that homecare offers. Since chronic disease management and elder care is such a large part of all nations' healthcare resource costs and clinician workload, if homecare can be made safe and sustainable, there may be long-term benefits to society. Several key and critical success factors need to be managed: A) appropriate and affordable telecommunications tools to connect patients with clinicians, B) appropriate supply chain resources to meet patient care demand, C) health technology assessment and management strategies for technologies stranded at patient homes, and D) creation and maintenance of a sufficiently safe environment of care in the home setting for the intended medical care. This presentation leaves the first two topics to others and focuses on items C and D because they are closely aligned with traditional CE and HTM competencies. Also, these aspects were subject to very intensive investigation by the authors in 2021 and 2022 on behalf of the CSA for the Canadian homecare market. That report is free to download. (3) In particular, understanding and managing a safe environment of care in the home was identified as a major HTM challenge. Physical space, temperature control, electrical and fire safety, and hygiene, infection, and waste management resources in most homes is rarely ideal and is far short of the goals set for hospitals, clinics, and physician offices. Some renovations may be feasible or mandatory, but cost, time, and resource limitations must be expected, accepted, and remediated in every possible way. HTA and HTM methods must also be fine-tuned to homecare needs. e.g., those devices demonstrating human factor design and operation and maintenance requirements suitable for laypersons should be favored for purchase. Also, a scheme is needed for replenishing device accessories and loaners or exchange devices for extensive repair or maintenance.

Keywords: homecare, health technology assessment, health technology management, htm, hta, environment of care, alternate healthcare sites, patient safety, accessibility, equity

C3 - Homecare

Development of the Power Assist Device for Transferring Patients with Severe Disabilities

By Ichiko Watanabe

Japan Assosication for Clinical Engineers (JACE)

In Japan, pediatric medical technology has developed rapidly, and the life-saving rate of newborns has increased dramatically. And if newborns are born with serious illnesses or disabilities, the number of such children who continue to receive advanced medical care and live at home has increased. Furthermore, since the Comprehensive Support for Persons with Disabilities Act was enacted in Japan in 2005, the number of people with severe disabilities who live at home has been increasing. Meanwhile, the aging society in Japan is facing with an aging caregivers' force. To reduce the physical burden on caregivers, various devices have been developed to assist with transferring patients, such as lifts, but they are not widely used in actual care settings for a variety of reasons. In this study, we used a power assist device which was developed in our laboratory as a previous study. We analyzed the caregiver's patient transfer assistance movements involving forward bending, half-sitting, and twisting of the upper body while wearing a wearable power assisting device. And we verified the effectiveness of the device in reducing the caregiver's physiological burden when wearing it. This has been shown in previous studies that the power assist device which developed in our laboratory is effective in reducing back strain when performing lifting movements of loads. This time, we verified complex transfer assistance movements for a person with severe physical disabilities that combines the movements of "positioning, lifting, rotating, and sitting". As a result, the assist effect was not demonstrated in all situations. One possible reason for this is that the knee fastening belt loosened during complex assistance movements, causing the device to move away from the caregiver's body, and the assistance effect was not perceived. From this, it became clear that the shape and position of the strap belts and the harness need to be revised to improve the assist effect and comfort.Focusing on the movements of the transfer assistance for people with severe physical disabilities, we study 3D motion analysis and c confirm the necessary conditions for the power assist device as nursing aids. We develop a lightweight, compact, and easy-to-use power assist device that reduces the physical burden on caregivers and patients for individuals with severe disabilities who wish to continue to live at their own home.

Keywords: wearable power assist device, physical disabilities, patient transfer, nursing care, home care

C3 - Homecare

Definition of a Standard Approach for the HTA of Home Care Systems

By Francesco Bassi, Milos Ajcevic and Agostino Accardo

Department of Engineering and Architecture, University of Trieste, Italy

Recent advancements in IoT technology and the growing trend of avoiding long-term hospitalizations have paved the way for the development of systems capable of monitoring patients' health directly from their homes. This new paradigm offers significant benefits to both patients and the local healthcare system. However, it requires careful design to ensure the provision of adequate care while avoiding excessive costs and ensuring data privacy and protection. The objective of this study, based on the EUNetHTA HTA Core Model Version 3.0 (HTA-CM3, https://www.eunethta.eu/wp-content/uploads/2018/03/HTACoreModel3.0-1.pdf), is to standardize the evaluation approach, defining a set of standard parameters concerning specific aspects of Home Care Systems (HCS) and implementing a sequence for the analysed domains, so the HTA process can be effectively applied to assess the viability and effectiveness of these technologies. The first step in this process, within the CUR and TEC domains of the HTA-CM3, involves specifying the objectives of the system. In the context of Home Care Systems, these objectives may be either: Environmental or Clinical Parameters Monitoring, logging Patient Diaries or managing Remote Rehabilitation. Clinical parameters monitoring can be in real time, in order to detect life threatening conditions in subjects, or scheduled, necessary for therapy monitoring and implementation. The second step focuses on the ethical, legal, and social aspects (ETH, LEG, and SOC domains). When transitioning from a hospital setting to a home environment, it is essential to establish national and regional protocols and gain the patients' and their families' consent for the implementation of Home Care technologies. Patients' unfamiliarity with the technology can generate fear and resistance, posing additional challenges to its successful implementation. Safety considerations (SAF domain) are paramount for Home Care Systems. Evaluating the effects of data loss and theft, as well as the accuracy of measurements and their latency in real-time monitoring, is crucial to ensure patient safety. The third phase of the process concerns organizational aspects and economic evaluation (ORG and ECO domains). These factors play a pivotal role in the widespread adoption of Home Care Systems. Apart from developing or acquiring a monitoring system with IT infrastructure and sensors, establishing a territorial care team or a monitoring center with specialized personnel and providing adequate internet infrastructure are imperative. This can be particularly challenging given that many patients in need of home care are elderly and may be unfamiliar with modern technologies. Overcoming these challenges necessitates a genuine commitment to the project and the active involvement of stakeholders. The last part of the evaluation is focused on clinical effectiveness (EFF domain) which is currently difficult to assess in the field of Home Care Systems due to the limited availability of scientific literature on general applications.
In conclusion, the HTA process applied to Home Care solutions is necessary since these systems, now at their starting point, can become a powerful tool for the care management of elderly and frail population.
Keywords: HTA, home care systems, telemedicine

C3 - Homecare

Analysis of Adverse Events in Medical Devices used in Home Care in Health Technology Management

By Mariana Brandão, Liandra Holanda, Alessandro Benedet, João Vítor Fogaça and Renato Garcia

Institute of Biomedical Engineering (IEB-UFSC), Brazil

The growth of medical devices in home environments, accentuated by the COVID-19 pandemic, highlights the need for Clinical Engineering (CE) to act in the Health Technology Management (HTM) in the ubiquitous scenarios involved with Home Care, especially in the participation in the management of occurrence of adverse events that may affect patient safety. In home use, many users are new to health technologies, which makes it a challenge for the HTM. This work analyzed adverse events from devices used in domestic environments with focus on patients with diabetes. The technologies chosen were used in the decision making of users in glycemic control were glucometer (GL), subcutaneous glucose sensor (SGS) and insulin infusion pump (IP). In the search for evidence, two databases between 2019 and May 2023 were used: Technovigilance Analytical Portal of the ANVISA-Brazil and MAUDE-FDA - USA. The total number of notifications of adverse events and technical complaints during the analysis period at ANVISA were: 636 from GL, 39 from SGS and no reports on BI. On the MAUDE-FDA platform, the total number of adverse event reports were: 45,095 on GL, 1,078,607 on SGS and 313,892

on BI. The main reports of problems with GL in the MAUDE-FDA were failure to turn on (56.96%) incorrect or inaccurate result (34.77%) and high test results (10.48%). With the SGS they were: wireless communication problem (36.88%), no device output (21.35%) and incorrect result or readings (11.95%). With the IP were: interaction problems with the patient (19.41%), breakage (18.82%) and energy and mechanical problems (16.98%). Main problems reported with the patient were: no consequence, insufficient information, hypoglycemia and hyperglycemia. In the period of analysis, 12 recalls were found in the FDA referring to GL, 11 to SGS and 3 to IP. The main reports were related to battery and cybersecurity vulnerability. The main limitations of the analysis are the lack of description of the problems, underreporting and standardization. This work reinforces the importance of Technovigilance in CE, highlights the need to encourage the practice of reporting to generate evidence and develop Standard Operating Procedures. The investigation of these incidents, analyzing the causes and effects, is a relevant tool for the HTM to establish preventive actions. Developing technologies centered on the user and inserted in an interdisciplinary ecosystem in the format of a Living Lab, considering aspects of usability and accessibility, are necessary methodologies to explore the problems and establish actions to improve the design and use of technologies. Medical devices that are increasingly interconnected open up opportunities for the ubiquitous management of technological processes throughout their life cycle, making it essential to implement policies to comply with the LGPD and structures for cybersecurity. Allied with constant training, analyzing failures and adverse events are actions that must be implemented by CE in order to manage risks in health technologies used in homecare and make their use safer.
Keywords: clinical engineering, technovigilance, adverse events, home care technology

C3 - Homecare

Real-World Evaluation of Technology Enabled Care for Remote Patient Monitoring of COPD in West Wales

By Chris Hopkins and Gareth Davies

Tritech Institute, Tritech Institute, Hywel Dda University Health Board, UK

Introduction: Technology Enabled Care (TEC) allows us to monitor patients remotely, giving us the opportunity to increase access to healthcare, especially in rural areas. Hywel Dda University Health Board (HDUHB) is currently utilising remote patient monitoring (RPM) for various chronic conditions, such as chronic obstructive pulmonary disease (COPD), heart failure and interstitial lung disease (ILD). Adoption of RPM programs could have the potential to improve the management of chronic conditions, with possible benefits such as reduced primary and secondary care requirements, improved adherence to medications and improved quality of life. **Methodology:** To undertake the real-world evaluation, a mixed-methods approach was utilized, in which quantitative and qualitative measures were used to evaluate the implementation and benefits/dis-benefits of the service. The evaluation incorporated multiple primary care sites across HDUHB. Patients were interviewed via telephone and invited to share their views on what they liked and disliked about the service. In addition, patients were invited to complete a survey to share their satisfaction of the service. Clinical staff were interviewed and invited to share their experiences, such as enablers and barriers to implementation of the technology. Preliminary **Results:** A total of 106 patients were included from 8 GP practices and one chronic conditions nurse. 20 patient interviews were conducted. Most patients interviewed provided positive feedback, with 80% of patients indicating they would like to continue using the service. 40 patients completed the satisfaction questionnaire, with the majority of patients providing positive feedback: 63% of patients (n = 25) were in agreement that the technology was useful for managing their condition, whereas 78% of patients (n = 31) were in agreement that the service gave them a sense of reassurance and peace of mind. Staff views were mixed; although most staff interviewed could see the potential for RPM to improve patient outcomes and reduce workload, staff were concerned about the time needed to monitor the system. **Conclusions:** Overall, patients with COPD reacted positively to the remote monitoring service. Patient satisfaction was very high, with many patients finding the service useful for managing their condition. Future work will focus on determining if the perceived benefits are reflected by improved patient outcomes.
Keywords: COPD, tec enabled care, patient monitoring

C3 - Homecare

The Status of Medicines Regulation & the Risk of Substandard Medicines In Somalia and Potential Impact on Home Care

By Saed Ahmed

National Medicines Regulatory Authority, Ministry of Health, Somalia

The problem posed by the substandard and falsified (SF) medicines is a rising global challenge. WHO estimates that sales of SF medical products in low- and middle-income countries is around US$ 30 billion whereby 1 in 10 medical is substandard or falsified. SF medicines have detrimental health and socio-economic implications. This companion topic to substandard health technologies is a global challenge in developing countries. The purpose of this abstract is to provide a brief case study enlightening the situation of medicines regulation in Somaliland, northwestern Somalia region with a specific focus on quality assurance. The literature was reviewed on the issue and authors' personnel experiences were employed where published data was absent. Legislative acts are not in a place where the National Medicines Policy formulated in 2015 and two ministerial decrees of 2016 that establish the National Medicines Regulatory Authority (NMRA) are available. Rapid benchmarking of the NMRA's capacity by WHO-IGAD Joint Initiative in 2017 found that only 16% of the total indicators for the regulatory system have been in place. There is a large but under-regulated private pharmaceutical sector estimated to import about 75% of medicines, and the rest comes through aid agencies. There are only two non-operational minilab kits due to a lack of supplies, developed by the Global Pharma Health Fund (GPHF). IGAD regional PMS survey conducted in 2019 to assess the quality of oxytocin and amoxicillin samples collected from cross-border sites of six member countries involving a total of 86 samples of oxytocin and 37 and 29 of amoxicillin DT & suspension respectively showed that 20.9 percent (18/86) of the oxytocin were substandard (8 out of 9 from Somalia) while all amoxicillin samples have passed the quality tests. One clinical example of the use of oxytocin is in-home infant deliveries, 43% of deliveries nationwide in 2022. Similarly, amoxicillin is used to treat bacterial infections, such as chest infections (including pneumonia) and dental abscesses, again via prescription, that can be widely used as part of home care. Considering this as well as the weak regulatory capacity and the porous national borders, the risk of SF medicines circulating in the supply chain is high and swift action needed to strengthen the laboratory capacity to ensure the safety and quality of medicines in Somalia.
Keywords: substandard medicines, home care, health technologies

C3 - Homecare

Virtual Clinic Implementation

By Sandy Rihana

Usek, Lebanon

Advances in information technology have brought telemedicine a new lease on life in recent decades. These advancements in telemedicine span the person to the community, allowing for the sharing of patient data for diagnosis and management of health conditions, primary care prevention, and physician education through distance learning. In both developed and developing countries, information and communication technology has the potential to solve the challenges of delivering high-quality, available, and affordable healthcare services. Telehealth is a method of overcoming distance barriers and improving access to healthcare by using information and communication technologies. It is gaining popularity as a new way to meet the health needs of patients outside of conventional healthcare settings. Telehealth is transforming the healthcare industry by reducing hospital visits, patient wait times, and the physical pain that patients experience. Since this type of remote monitoring will help free up scarce hospital resources for the treatment of even more severe illnesses, telemedicine usage has increased significantly since the strike of coronavirus pandemic. In this project, we aim to contribute and help develop the use of telemedicine in Lebanon.
Keywords: virtual clinic, telemedicine, digital health, vital signs monitoring

C3 - Homecare

The Perks of Developing a Healthcare Technology Startup as a College Student in Latin America

By Hugo Esteban Gonzalez Venegas, Eduardo Mendez Palos, Pedro Misraim Gomez Rodriguez, Ricardo Emmanuel Garcia Manzo, Felix Antonio Cepeda Garcia and Jessica Gabriela Gomez Casillas

University of Guadalajara, Mexico

With a growing elderly population, having specially designed technology for the elderly human body is the next step to prevent the future crash of the national healthcare systems. But what about the popular easy-access technologies on the market nowadays as smartwatches? One sign of the human body getting old is the coldness in hands or feet due to the lack of blood reaching these extremities. Doing an exercise of an elder using a smartwatch, you can see that the oxygen in the blood sensed by the wearable can be low, and if you have the device linked to emergency services, you could have a false positive for hypoxemia, increasing the stress in the local health care system, and loss of time for the user just because the technology to measure their health is designed for the younger average user's body. So, with VEBTECHMX, the measures of vital signs of the elderly body are made centrally to get accurate data avoiding false positives in cases of hypoxemia. VEBTECHMX is a startup initiated as a student project to help and take care of our loved ones even when we are not there to do so. Starting this project was challenging since it was inspired by the grandparents of one of our team members to take care of them if they fell or something else happened and there was no one to help them. Without any financial aid to start, and thanks to the effort and networking of the team, the project has gotten developed to a TRL 3, and we are working on getting to TRL 4. The project has used several methodologies, but the core ones are: 1. See the problem to solve. 2. Research why the problem is a problem. 3. How can caring for older people 24/7 be solved with technology designed for their needs and with their body's limitations in mind? 4. Look into the fundamental ways people deal with it. 5. Do field research on the industry, nursing homes, and Mexican households with older people living with their nuclear family. 6. Define who is the client, who is the final user, and who are potential partners. Experienced has reached through several participations in both local and national hackathons, talks to potential Mexican sponsors and international partners, and discussions that led to the development of the project and our professional and academic careers in several biomedical fields, like clinical engineering. To conclude, the development of the startup VEBTECHMX has taught us that with a sense of purpose, biomedical engineering or clinical engineering student can develop tremendous opportunities for themselves and their communities way beyond the topics taught in the classroom with no limits of evolution also taught us possible limitations on developing the project that needs to be taking care of as mental health, and balance between school workload, the project, and personal life.
Keywords: healthcare technology, startup, college student, Latin America, elderly population, VEBTECHMX

C4 - Regulation & Policy 3

SMART: Scan Maternal & Women Diseases using Advanced and Reliance Technology- An Integrated Solution for LMICs

By Md Ashrafuzzaman,Ananya Anower and Jitendra Kumar Sharma

Military Institute of Science and Technology, Bangladesh

Breast cancer poses one of the leading causes of cancer among females in Bangladesh. It showed an increasing trend over the past 10 years. Bangladesh experienced 1,56,000 breast cancer cases and 1,09,000 deaths from the disease in 2020. It is estimated that by 2030, there will be 21.4 million new cases of cancer in Bangladesh. Cervical cancer is another leading cause of cancer among females in LMICs like Bangladesh. As per WHO, cervical cancer is the fourth most prevalent cancer in women worldwide, with an estimated 604000 new cases and 342000 deaths in 2020. As per GOLOBOCAN 2020, the age-standardized caseload of cancer in Bangladesh was 1,56,775 and the number of cancer death was 1,08,990. Infant mortality remains a major public health concern in Bangladesh, and an array of factors play a role in this pressing issue. Recent statistics in 2021 show that there are 23 neonatal deaths for every 1,000 live births. Though, it is an improvement of 4.28% from 2020 but needs proper attention so as to reach a better result. There are some crucial problems identified which are still threatening the women's health index in Lower Middle-Income Countries (LMICs) like Bangladesh, India, and many more. To overcome these problems and establish a national database for breast and cervical cancer, and continuous

monitoring and giving assistance to pregnant women in these countries we have planned and developed SMART (Scan Maternal & Women diseases using Advanced and Reliance Technology) vehicle project as an integrated solution. This project will help the Women population of LMICs like Bangladesh to defeat Breast & Cervical Cancers and Expecting mothers can get nationwide 24/7 monitoring support from their homes. The strategic objectives of the SMART project are: To introduce the low-cost and non-invasive rapid screening of breast cancer using AI-based smart solutions and develop a national registry; To motivate women to cervical cancer examination with painless reliable probes for effective diagnosis and develop a national database to avoid fearsome cancers; To establish a robust regional & national fetal monitoring services and database for all pregnant women, especially in villages and remote areas with continuous assessments.
The potential outcomes of the SMART project are: Creation of a national registry for women-related cancers, so that the current scenario can be found out.Online-based low-cost platforms will be used to educate people about Breast Self-Examination for screening Breast Cancer. Non-invasive and inexpensive devices will be introduced to comfort the women during cervical cancer screening to avoid trauma and harassment happening during the test. AI-based smart devices or apps need to be created for mass screening so that diagnosis of breast cancer can be detected prior to an advanced stage which can reduce the mortality rate. The mortality rate will be reduced significantly, and women will have more confidence in maternity-related healthcare services. By 2040 a smart system must be developed to defeat the demon of Breast & Cervical Cancers as set by the government's priority action plan.
Keywords: SMART vehicle, breast cancer, cervical cancer, fetal monitor, lower middle income countries, smart women

C4 - Regulation & Policy 3

Guidelines for a CE Unit in Argentina

By Marcelo Horacio Lencina, Daniel Romero, Federico Paschetta, Luis Rocha and Eduardo Fernández Sardá

Universidad Tecnologica Nacional, Argentina

Given that the recognition of Clinical Engineering as a health profession is a topic that is debated in all countries, the Clinical Engineering Chapter of the Argentine Society of Bioengineering, SABI, during the past year took the initiative to establish contacts with the authorities of the National Ministry of Health to address this issue.
There was a positive reception by the authorities to the topic presented, so a work agenda was initiated to include the Clinical Engineering Unit within the National Program for Quality Assurance of Medical Care (PNGCAM acronym in Spanish). For this, it is necessary to establish guidelines that impose minimum norms that the Unit must have, so that the quality of provision can be ensured, and safe patient care can be provided. From the middle of last year to the present, two monthly meetings have been held between the members of the Chapter and the staff of the Quality Directorate of the Ministry of Health to agree on the drafting of the guidelines. They are currently finalized and in a revision stage. They include the following topics:
ANNEX 1
A. Introduction
1. Objective
2. Scope
3. General Framework
B. Organization and Operation Organizational
1. Structure of the Clinical Engineering Unit (SIC acronym in Spanish)
2. Organization and functions of the Human Resources of the SIC
3. Physical plant and equipment
4. Processes
5. Indicators of Good Practices in the operation of the SIC
C. Glossary
D. Bibliographic References
ANNEX 2
Processes of the Maintenance Plan
As expressed in the detail, not only objectives, scope and regulatory framework are established, but also guidelines are established as to how the unit should be organized, the necessary human resources (engineers, technicians and administrative) according to the complexity of the institution. The necessary physical spaces and the minimum equipment required to carry out the planned works. The processes to be carried out and the quality indicators to be taken into account. Within the human resources it is established that the person in charge of the SIC will be a university professional with responsibility in the matter and must be enrolled in the Professional Association. The Professional Association is a body of the professionals themselves, to which the State has delegated the control power of the profession exercise. It is therefore expected that when

this standard comes into effect, there will be more and better quality job for Clinical Engineers and Biomedical Technicians and Health institutions could warranty that medical devices are sure and effectives for both the patient and user.
Keywords: clinical engineering, guidelines, recognition, structures

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C4 - Regulation & Policy 3

Operational Research for Management of High Biomedical Technology Innovation: from the Algorithm to the Model

By Matteo Verga, Gian Luca Viganò, Martina Capuzzo, Claudia Duri, Lucia Maria Ignoti, Veronica Cimolin

ASST degli Spedali Civili di Brescia, Italy

Spedali Civili Hospital of Brescia, with regard to funding obtained on NextGenerationEU - National Recovery and Resilience Plan (NRRP), has been identified for the replacement of seven nuclear MRIs out of the total of ten present at company level. The replacement of each of these equipment represents not only an opportunity but also a challenge since it is an articulated procedure that, in accordance with the requirements dictated by the NRRP, has as a stringent constraint the complete implementation by the end of 2024. Also, this process may overwhelmingly impact health outcomes by compromising the delivery of the agenda with a consequent increase in waiting lists. Hence, the conception of this project, which was born with the ambitious aim of synthesizing the entire process by creating an operational research model capable of outlining an algorithm, subsequently coded at computational level.

The work is divided into different degrees: • Analysis Phase: development of a business process for interfacing PACS (Picture Archiving and Communication System) data with data obtained from Management Control Department (business department that regulates reporting about services provided at company level) to determine the production volumes, and their characteristics, associated with each nuclear MRI. • Operational Research of 1st Level - MedOP: definition of the best possible replacement schedule by devising a predictive algorithm to simulate the overall schedule delivered. • Operational Research of 2nd Level - MedSched: devising a tool for optimized reallocation of diagnostic agendas through integration of utilization data in the context of a linear programming computer system. Consistent with the transversal and organic nature of the analysis, the study involves the comparison of three different case scenarios: the application of the model in a perspective of technological continuity with the previous installed model, the case of the absence of this continuity, and the scenario in which the project is not applied. This project thus involves a strong innovative character: modelling and predictive analysis make it possible to optimize the technological transition. Both projections made in the case of project implementation identify the end of the last of the seven replacements by the end of 2024, in accordance with the European mandate target, and estimate a total delivery of examinations varying between 5.2 percent and 10.0 percent more, ranging from a minimum of 2000 to a maximum of 3500 additional diagnostic services. These predictions and projections would be missed if the model is not implemented. These significant projections have a great impact both from a health point of view by going to improve the management of waiting lists, and from an economic point of view by allowing the hospital company higher production volumes, greater economic return, and better use of resources. Finally, the ultimate goal remains the scalability of the models with a view to developing operational management programs. The potential of such a study lies in its declinability to different technologies as well to optimize not only the technology transition, but also the rate of use and proper utilization during the life cycle.
Keywords: operations management, technological transition, clinical engineering, hospital processes, biomedical technologies, thematic evolution

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C4 - Regulation & Policy 3

CE in South Sudan Humanitarian Crisis

By Rodrigo Acosta

The International Committee of the Red Cross ICRC, South Sudan

I am in Juba, capital city of South Sudan, for the International Committee of the Red Cross (ICRC) Medical-Surgical Team, where ICRC provides surgical and medical care to weapon wounded patients, mainly civilians, in Juba Military Hospital (JMH) and Akobo County Hospital. Patients come to JMH from all over, and many from neighbouring towns, so we transport

most of our patients by plane or helicopter from different cities where fighting continues. South Sudan is the youngest country in the world, with roughly 44% of the population under 15 years. Its journey to independence has been marked by conflict and unrest, resulting in displacement of millions, with more than 2.3 million refugees by June 2023 and a humanitarian crisis. The legacy of the civil war from 2013 to 2020, and political instability, dire socio-economic needs, and an overwhelmed basic health system, poses significant challenges, however, efforts are underway to address it.When working there, everything is a challenge; getting the needed food, medicines, medical equipment and supplies is already not easy, but delivering the last mile to reaching those in need requires a specialized team. Roughly the size of France, Switzerland and Netherlands combined, South Sudan has only ~400 kilometres of paved roads. The rest of the country is accessible only by air or connected by dirt roads that the seven-month rainy season makes impassable, making supply chain and logistics critical, where we need to ensure all necessary medical supplies are available in our hospitals. During my mission here, I have worked as a CE in the ICRC-JMH Hospital, a 70-bed surgical hospital where all admitted patients are directly affected by the conflict, gunshots and amputations the most common injuries. The hospital has a strong surgical and medical care system, including physiotherapy, MH and psychosocial support, but unfortunately the BME department has been neglected. We have tried to establish a well-structured BME Department in 2 months, starting with inventory and labelling all equipment. I also established an annual PM calendar, which my local biomed colleague is following. The hospital has roughly 90 unique devices, most of the equipment in our OR and High Dependency Unit. Patient wards have minimum equipment. This translates to 150 PM per year, as most equipment requires more frequent maintenance due to environmental and working conditions. As I am establishing the BME Department, we need to have clear protocols, therefore I also created PM guides on specific equipment for my colleague to follow, as well as Daily Maintenance protocols for clinical staff to ensure equipment is correctly used and care for. Before my arrival, there was also no evidence on corrective or preventive maintenance, so I established Maintenance Reports where we can document all our activities. As I noticed that clinical staff was not always comfortable with operating the equipment, during my 6 weeks mission, I organized 6 trainings with different nurses, doctors and technicians on how to operate, care, and do basic troubleshooting on the most common medical equipment present in the patient wards.

Keywords: humanitarian, clinical engineering, NGO

C4 - Regulation & Policy 3

IDEF0 Method Application in Pre-Hospitalization Process: Our Experience in a Multi-Disciplinary Hub Clinic in Northern Italy

By Anna Squara, Alessandro Bacuzzi, Silvia Beati, Battistina Castiglioni, Simona Cozzi, Sonia Fransceschetti, Ivan Sternativo

ASST dei Sette Laghi, Gestione Operativa e Next Generation EU,Varese, Italy

Pre-admission is crucial for the surgical activity of a hospital: an efficient and effective system allows fluid management of patients according to the surgical planning. The ASST dei Sette Laghi (Varese, Va, Italy) manages 50 operating rooms divided into 6 structures with a turnover of about 256 million euros for hospitalization and outpatient activities (2019). We decided to apply IDEF0 (Integration Definition for Function Modeling) methodology to re-organize pre-hospitalization process in ASST dei Sette Laghi. The aim of the project was threefold: 1) Production and efficiency for patients and healthcare professionals; 2) Quality for healthcare professionals; 3) Outcomes of treatments. IDEF0 is based on a structured representation of the activities/processes of pre-admission system. By this way, it was possible to systematically analyze the core activities of the process, focusing mainly on standard practices and controlling policies for corrections. At the same time, the resources, the results of the activities (output) and the «raw materials» (input) were monitored. IDEF0 allowed to optimize the diagnostic path, reducing the pre-admission times by 50% and making the patient's experience more efficient. The basic evaluation was implemented by introducing records of vital parameters and paperless ECG (under integration with medical report). To respond to the surgical planning, the production capacity was increased by 156%, going from 25 to 64 patients per day: thus, we were able to create a buffer of suitable patients for each surgical specialty. By standardizing the pre-admission, IDEF0 method allowed to ease pre-hospitalization process, improve surgical and outpatient activities, optimize human resources and minimize expenditures or surgical complications.

Keywords: pre-hospialization, IDEF0, operations management

C4 - Regulation & Policy 3

Workplace Learning in Clinical Engineering Training

By Peck Ha Tan, Abdiel Foo, Tji Leng Chua, Wai Sing Ong and Hock Wei Soon

Ngee Ann Polytechnic, Singapore

Workplace learning in a hospital helps biomedical engineering students to better connect what they have learned academically to a real-life work environment. One of the key job roles for a clinical engineering professional is the servicing of healthcare equipment in the hospital. Servicing of healthcare equipment includes the following processes: calibration, functional checks and electrical safety tests. Prior to the workplace learning arrangement, students viewed the servicing of healthcare equipment as one of their many academic practical sessions. Usually, they did not recognize the immediate relevancy of their hands-on experiences to an authentic job task in a hospital setting. With the workplace learning arrangement, the clinical engineering professionals were co-instructors during selected practical sessions and the sessions were held at an actual worksite, i.e., in a local tertiary hospital. A total of fifty second-year students from the Biomedical Engineering Diploma Program at Ngee Ann Polytechnic (Singapore) were involved in the pilot run of the workplace learning initiative. To optimize their learning experiences and the space constraints of the hospital's clinical engineering department site, this cohort was subdivided into four smaller groups. The practical lesson included the calibration and preventive maintenance of a non-invasive blood pressure (NIBP) monitor. Besides the usual practical materials, these groups of students had the opportunity to learn from clinical engineering professionals. These included the typical faults of the NIBP monitor and remedial actions taken by the clinical engineering professionals. The general feedback from the students who participated in the pilot run was good and they benefited from this learning experience. The main challenge was the timely arrangement of facilitating workplace learning in view of the tight schedule of the clinical engineering professionals and space constraints to conduct a meaningful practical session for the students.

Keywords: workplace learning,clinical engineering, learning experience

C4 - Regulation & Policy 3

Assessment of Technical Capacity and Proposal to Enhance Biomedical Engineering Services in Bhutan

By Tashi Penjorer

Ministry of Health, Bhutan

Medical equipment and devices are critical for the delivery of modern healthcare services. The level of technological advancement of the medical equipment determines the level of advancements in the healthcare system. In recognition of this, medical equipment of different types and complexities are installed at various levels of health facilities consisting of one National Referral Hospital (NRH), two Regional Referral Hospitals (RRH), 56 hospitals, 179 Primary Healthcare Centers and 53 Sub-Posts and 555 outreach clinics in Bhutan. Huge resources are spent in procurement of these equipment and devices and the Royal Government of Bhutan has mandated the Ministry of Health to ensure that more than 90 percent of medical equipment are functional at all times. The key professionals responsible for the design, development, regulation, evaluation and training in health technologies are biomedical engineers. Biomedical engineers and technicians are responsible for systematic planning, selection, procurement and management to ensure functionality, safety, effectiveness and efficacy at all times in the health facilities. The World Health Assembly adopted resolution WHA60.29 on health technologies in May 2007. The resolution covered issues arising from inappropriate deployment and use of health technologies, and the need to establish priorities in the selection and management of health technologies, specifically medical devices. The resolution urged member states to: "(1) to collect, verify, update and exchange information on health technologies, in particular medical devices, as an aid to their prioritization of needs and allocation of resources; (2) to formulate as appropriate national strategies and plans for the establishment of systems for the assessment, planning, procurement and management of health technologies, in particular medical devices, in collaboration with personnel involved in health-technology assessment and biomedical engineering …" In view of the above, technical capacity on providing biomedical engineering services is critical to delivery of healthcare services besides the availability of medical equipment and devices. Therefore, it is very important to assess the availability of required technical capacity and strengthen necessary capacity if required to ensure uninterrupted health services and optimal utilization of resources spent on acquisition of medical equipment and devices

in the country. This research is aimed at assessment of technical capacity and propose measures to enhance biomedical engineering services in the country.

1. Annual Health Bulletin 2022, Ministry of Health
2. WHO, Human Resources for Medical Devices, the Role of Biomedical Engineers, 2017.

Keywords: clinical engineering,technical capacity, assessment

C4 - Regulation & Policy 3

CE/HTM Practice in the Government Medical Institutions and hospitals of the Indian State of Tamil Nadu

By Jagadesh Kumar Dhayalan, Alfred Roger George

Tamil Nadu Medical Services Corporation Limited, India

Tamil Nadu Medical Services Corporation Limited (TNMSC) is a state-government undertaking of the Government of Tamil Nadu located in the Indian state of Tamil Nadu. TNMSC was set up with the primary objective of ensuring the ready availability of all essential drugs and medicines in the Government Medical Institutions throughout the State by adopting a streamlined procedure for their procurement, storage, and distribution. The TNMSC was incorporated under the Companies Act, 1956 on 1 July 1994 and commenced its operations from January 1995. Subsequently, TNMSC has assumed wider responsibilities for the following range of services to the Tamil Nadu Government Medical Institutions and hospitals but not limited to –

1. Procurement, Testing, Storage and Distribution of Drugs, Medicines, Surgical & Sutures, Kits, Reagents etc.,
2. Procurement, Supply, and Maintenance of Medical Equipment and Instruments to the Tamil Nadu Government Medical Institutions & Hospitals
3. Administration and operation of Drug Warehouses, Diagnostic Imaging Centres, Radiation Therapy Centres, Nuclear Imaging Centres, Lithotripsy Centres, Master Health Check-up Centres, Pay Ward Centres

The submission seeks to provide an overview of the CE/HTM practices adopted by TNMSC, their impact & share our experiences in the delivery of Medical Equipment Maintenance and management services to Tamilnadu Government Medical Institutions and hospitals.

Keywords:health technology management, clinical Engineering, government

D1 -Digital Health 1

Digital Health Innovation Accelerator Center

By Ricardo Silva

Foundation for Living, Wellness and Health USA

Research is taking money and turning it into knowledge and this is what Universities are used to doing. When I see an "innovation lab" I am still seeing research rather than true innovation. Innovation is taking the knowledge that has been previously generated and turning it into money (profit). In fact people tend to forget that the link between research and innovation is development (R+D+I). When we talk about student seed projects, we are only seeing the initial stage of a development process. This seed needs to be planted and watered so that it can germinate, it then needs to be protected from weeds, fertilized, watered some more and provided with the proper conditions to grow. If we want to create a fertile ecosystem for innovation, planting seeds is not enough. It does not matter how many seeds we plant, if we do not take care of them, even if they germinate, they are going to die. A complete project will require an incubator where those seeds can be further educated and trained to run a business. The incubator should provide skills and resources related to legal support, prototyping, project management, marketing, recruiting, financing, etc. At the end of the incubation process we should have established companies with a product, a market, leadership, a business plan and some funding. From the incubator companies should have access to a coworking space (greenhouse), a place where the young companies can access affordable space, share resources, access a network of mentors, advisors, investors, and share synergies. This should take the company all the way through Series A funding. That means that in parallel with the greenhouse we need an investment fund with capital that can be injected to fertilize these companies. Once the companies are out on their own, they still need help, becoming a big company is not easy and some companies are not even interested in the transition. But for those who

are, here is where the accelerator is needed. More than a space, the accelerator is a group of resources that can help a company move from 20 to let's say 120 employees. At this point we might require professional managers, these could be some of the investors, but they will need the proper skills. Here is where a relationship with a business school becomes extremely important. At this point the company will need to hire an HR manager, an accountant, and some other professionals to help run the business. They will need serious funding and they might want to prepare for an exit, merger, or acquisition. If we consider an ecosystem with all these parts in place, then we can ensure a successful future and we can organize programs and competitions around the different components. But in my humble opinion, we need to understand the process and set all the pieces in place.

Keywords: innovation, accelerator, digital health

D1 -Digital Health 1

Generative Artificial Intelligence and Biomedical Informatics

By Ernesto Iadanza

University of Siena, Italy

At the end of 2022 the global public suddenly became aware of a disruptive technology, based on the so-called Large Language Models (LLM). We are clearly referring to the product ChatGPT, an advanced language model developed by OpenAI designed to understand and generate human-like text based on the prompts and questions it receives. Being trained on a wide variety of data sources, including books, articles, websites, and more, up until September 2021, it rapidly became a game-changer in many different fields of knowledge, assisting users by providing helpful and informative responses, engaging in conversations, and offering insights on various topics. According to its own description of itself: "Please note that while I strive to provide accurate and up-to-date information, my responses may not always reflect the most current events or developments beyond my knowledge cutoff date". For those who - as the author - are familiar with the first steps of the video games for personal computers, this phase will easily remind the first text-based adventure games, where the interaction between the user and the machine was based on a rudimentary dialog. Like the evolution of adventure games, it is easy to predict a sudden evolution of Generative Artificial Intelligence (GAI) towards 2D, 3D and 4D content. The generation of synthetic data will be extremely useful for testing and training cutting-edge AI algorithms. Thousands of Fabricated Electronic Health Records (EHRs), as well as Computer Tomography (CT) or Magnetic Resonance Imaging (MRI) models, artificially generated from these records will soon be the base for training and testing novel algorithms. This is a disruptive revolution, that calls for a radical change of pace in the education and training of Clinical Engineers. Is the global community ready and capable of such an immense task? It might appear very far from the classical core business of clinical engineers, but today's patients are exposed to unreliable tools and information as never before. It is the author's opinion that ensuring a rigorous evidence-based functioning for the upcoming GAI-based medical devices will be the first and central role of the Clinical Engineers in the next few months.

Keywords: ChatGPT, clinical engineering, biomedical informatics

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D1 -Digital Health 1

Leveraging Robots, AI, and IoT for enhancing Clinical Engineering: the ODIN Project

By Leandro Pecchia

Università Campus Bio-Medico di Roma, Italy

Hospitals are witnessing remarkable advancements through the integration of robots, artificial intelligence (AI), and the Internet of Things (IoT). Clinical engineering (CE) is at its edge for embracing those key enabling technologies (KET) in a systematic manner. What is the potential of those KET technologies in reshaping the future of CE practices? What are the challenges? How can those KETs enhance patient care, optimizing medical equipment management, improving operational efficiency in healthcare facilities and reducing risks. The ODIN project experience (https://odin-smarthospitals.eu/), a multimillionaire EU flagship project, has deployed a comprehensive platform for integrating the use of AI, IoT and robots in hospitals across 3 key functions: clinical practice, clinical engineering, and disaster preparedness. Robots, AI and IoT have emerged as valuable assets in hospitals, offering benefits such as precise and minimally invasive surgeries, improved

patient monitoring, and enhancing rehabilitation. In ODIN, we are using those KET also for improving logistics of medical devices, their traceability and provide real-time accurate data on their use for improving health technology management. AI algorithms and machine learning play a pivotal role in CE by analysing vast amounts of medical data, optimizing equipment performance, and supporting decision-making. By leveraging AI, CEs can detect patterns and anomalies in data generated by medical devices, enabling predictive maintenance and proactive troubleshooting. This predictive approach can minimize equipment downtime, ensure uninterrupted patient care, and reduce maintenance costs. AI-powered imaging empowers medical equipment management and use. IoT technologies also have the potential for revolutionizing clinical engineering by enabling seamless connectivity, remote monitoring, and real-time data analysis. Medical devices embedded with IoT sensors can facilitate their management while collecting and transmitting vital information, such as patient vitals, medication adherence, and equipment performance, to centralized systems. This data can be analyzed in real-time, enabling early identification of potential issues and proactive intervention. Moreover, IoT is facilitating asset tracking, inventory management, and equipment utilization optimization, ensuring efficient allocation of resources, and reducing unnecessary expenses. The integration of robots, AI, and IoT in clinical engineering brings forth new opportunities and challenges. Ethical considerations regarding the use of AI in decision-making, data privacy and security concerns in IoT-enabled systems, and the need for rigorous testing and validation of robotic devices are some of the challenges that require careful attention. Additionally, comprehensive training programs must be developed to ensure healthcare professionals are proficient in operating and utilizing these technologies effectively and safely. In conclusion, the convergence of robots, AI, and IoT has the potential for reshaping CE practices, enabling enhanced patient care, optimized equipment management, and streamlined operations in healthcare facilities. Leveraging surgical robots for precise interventions, employing AI algorithms for data analysis and diagnostics, and harnessing IoT for remote monitoring and real-time data insights are transforming healthcare delivery. However, the ethical implications and technical challenges associated with these technologies must be addressed to fully unlock their potential. CE continues to evolve, the synergy between humans and technology will undoubtedly pave the way for improved patient outcomes and more efficient healthcare systems.

Keywords: AI, IoT, clinical engineering, robots

D1 -Digital Health 1

A Smart AI-Based UTI Detection System

By Atumanya Agabus, Gumisiriza John Burnet and Nuwahereza Ronald

Mbarara University of Science and Technology, Uganda

Description: Urinary tract infections (UTIs) are among the most common bacterial infections encountered in primary health care, and it is among the most common infections with increased resistance to antimicrobial agents. These infections have also become the most common hospital-acquired infections, accounting for up to 35% of nosocomial infections and the second cause of bacteremia in hospitalized patients. This ailment affects patients in all age groups and sexes, with females accounting for 87.5% of the cases compared with males (71.3%). Timely and accurate identification and determination of the antimicrobial susceptibility of uropathogens is central to the management of UTIs. Urine dipsticks are fast and amenable to point-of-care testing but do not have adequate diagnostic accuracy or provide a microbiological diagnosis. Urine culture with antimicrobial susceptibility testing takes 2–3 days and requires a clinical laboratory. Here in, we construct a smart AI-based UTI detection system that will collect strip images and identify the HSV values of the image with an image processing algorithm, learn from a large set of labeled data that contains images of different colors, that will in turn help to recognize different colors with a high degree of accuracy. This system will majorly focus on the specific parameters of Leukocyte esterase (LE) which detects the presence of white blood cells (WBCs) in the urine, which is a sign of an inflammatory response that occurs during infection. and Nitrites which detect the presence of nitrite-producing bacteria, that are commonly associated with UTIs. If LE is positive, it suggests the presence of a UTI and a positive nitrite test suggests the presence of UTI. **Conclusion:** The proposed device will help to provide satisfactory accuracy in the diagnosis of UTIs, hence minimizing human errors associated with comparing color changes of different parameters alongside the urine dipstick color chart. More so, this system is intended to aid the medical worker in providing rational prescriptions in the form of appropriate treatment and assessing the effects of that treatment. Finally, it will be intended to facilitate self-diagnosis as an application will be used to scan the urine dipstick during diagnosis, and this will be used for everyone with this application.

Keywords: urinary tract infections, timely and accurate identification, urine dipsticks, diagnostic accuracy, AI-Based, HSV values, image processing algorithm, leukocyte esterase, nitrites, satisfactory accuracy, rational prescription, self-diagnosis

D1 -Digital Health 1

Multimodal AI Analysis of Prostate Cancer Indicators to Reduce Patient Backlogs and Improve Patient Care

By Chris Hopkins

Tritech Institute, Hywel Dda University Health Board, UK

Background: An artificial intelligence (AI)/machine learning (ML) based MRI diagnostic aid for prostate cancer may support clinical decision making and reduce time to interpret MRI. JivaRDX (a class IIa medical device, pending MHRA approval) is a radiology facing application that predicts the presence of cancerous tissue from prostate MRI scans, and is intended for use as a diagnostic aid. Operationally, JivaRDX can integrate into the radiology workflow non-disruptively by automatically annotating imaging files and therefore requires minimal intervention and training. Jiva have previously demonstrated a proof-of-concept achieving detection and localisation of prostate cancer from MRI scans (87% sensitivity, 67% specificity); bone, tissue and organs differentiated with 96.8% specificity. It has been found to perform within reported MRI diagnostic accuracy in the clinic (58-96% sensitivity, 23-87% specificity).**Methods:** We built a data pipeline and acquired end-to-end data transmission in order to validate the machine learning model. The data collection and systems pathway is outlined below: • Inclusion and exclusion criteria applied to determine patient studies. • Anonymised patient studies were shared with a Consultant Urologist in order to validate Likert scoring data and biopsy results. • Anonymised patient studies were transferred by our cyber team to Jiva. ai via an encrypted file sharing platform. • Anonymised patient studies were passed through the JivaRDX ML platform. • The outcomes of the anonymized patients' studies were passed back to the Health Board via the cyber team and encrypted file sharing platform. • Anonymised patient studies were de-anonymised. • Patient studies were shared with our Consultant Urologist in order to clinically validate the outcomes of each patient study. Sensitivity, Specificity and Accuracy results were shared with Jiva.ai after each iteration. **Results:** The JivaRDX ResNet A model was applied to the HDUHB patient cohort data to predict the presence of clinically significant prostate cancer. Compared to the prior ProstateX JivaRDX assessment, the results indicated an sensitivity (77%) and specificity (65%) accuracy (69%) in detecting prostate cancer. **Discussion:** The findings from this work indicate that there is a clinical need for new diagnostic processes in prostate cancer. JivaRDX looks feasible in the real world and is popular at least with clinical staff. However, more work needs to be undertaken to improve JivaRDX accuracy with more training. **Conclusion:** The JivaRDX system has proven to be sensitive and specific in terms of its diagnosis potential and further studies are required to refine the model. We found that the system has the capability to integrate into our current clinical systems and pathways. Furthermore, our engagements with clinical teams and patients identifies a general positive reaction to the use of AI as long as there are safeguards in place.
Keywords: imaging, MRI safety, A.I, machine learning

D1 -Digital Health 1

Next Generation Artificial Neural Network

By Rachel Goeken, Chaitanya Mankala and Ricardo Silva

Villanova University, USA

This paper explores the limitations of the Perceptron algorithm commonly used in neural networks and proposes the incorporation of an evolutionary artificial neuroidal network to overcome these limitations. While the traditional Artificial Neural Network (ANN) is effective for solving linearly separable classes, it fails to capture the complexities and non-linearity observed in biological neural networks. In contrast, a neuroid, designed to mimic the operation of human brain neurons, offers greater flexibility by introducing additional parameters beyond weights. To address this, we first implemented a Neuroid class, a computational representation of a neuroid. Using the original three inputs from Argüello et al.'s paper, we were able to reproduce their results, validating the functionality of our Neuroid implementation. Building upon this, we extended our neural network by incorporating multiple neuroids, exploring various configurations to enhance the network's capabilities. Furthermore, we integrated the Neuroid class with a genetic algorithm, creating a framework that allows the model to learn iteratively. The genetic algorithm leverages principles inspired by natural evolution to optimize the network's parameters and improve its performance. By evolving the neuroidal network over successive generations, the model gains the ability to adapt and refine its behavior based on feedback and environmental factors. The results of our experiments demonstrate the effectiveness of the proposed evolutionary artificial neuroidal network. By utilizing multiple neuroids and a genetic algorithm, we observed significant improvements in the network's ability to solve complex problems that go beyond linear separability. This research provides valuable insights into the potential of incorporating neuroidal networks in the field of artificial intelligence. By introducing the concept of neuroids and expanding the capabilities of traditional

neural networks, we address the limitations of the Perceptron algorithm. The use of genetic algorithms further enhances the model's learning and adaptation capabilities, bringing it closer to the complexity and functionality observed in biological neural networks. In conclusion, evolutionary artificial neuroidal networks open new avenues for developing more powerful and adaptable neural network models. Potential uses of neuroidal networks in the field of clinical engineering would be in dynamic control, such as closed-loop infusion systems. The control algorithm would analyze the sensor data and compare it with predefined target ranges for each parameter. If the measured values deviate from the desired range, the algorithm calculates the appropriate medication dosage adjustment needed to restore the parameter to the target level. This is a highly dynamic process and the enhanced parameter variation of neuroids, coupled with the iterative learning facilitated by genetic algorithms, could allow for improved performance and the ability to solve non-linearly separable classes. Additionally, closed-loop infusion systems could enable individualized treatment based on real-time physiological data. This research contributes to the advancement of health information technology and artificial intelligence, by developing a new type of ANN that could dynamically adapt the medication dosage to the patient's specific needs, considering factors such as changes in metabolism, response to treatment, or variations in the patient's condition over time.
Keywords: artificial intelligence, artificial neural networks, neuroid, genetic algorithms, innovation

D1 -Digital Health 1

A low Cost Medical Device Interoperability Architecture Model for ICUs

By Javier Camacho, Sara Diaz and Felipe Duque

EIA University, Colombia

The exponential growth of data in the Intensive Care Unit (ICU) is an entirely novel challenge today, caused by a large amount of information and/or data present, which in most cases leads to their discarding and, as a result, no record is kept, which is one of the major causes for the compilation and implementation of clinical information at the level of public and individual health. Due to the above, it is necessary to investigate and implement tools that allow the use of data, for which an interoperability model is developed in a health institution, considering the information provided by the literature, medical equipment, parameters, and the EMRAM model. First, a characterization of the ICU's interoperable devices was performed. Following that, the architectural model was created to enable the extraction and storage of quality data in the health institution's medical records repository. Finally, an interoperability pilot test was conducted to determine whether the data given by the data extraction system was clinically reliable using statistical tests. Interoperability standards were required for the integration of biomedical data and its subsequent use and exploitation by medical and/or healthcare staff, so it was necessary to ensure that the data met the requirements to use the HL7 standard format so that it could be read and stored by any technology implemented in the health institution. Vital signs monitors, mechanical ventilators, infusion pumps, defibrillators, electrocardiographs and imaging equipment were analyzed. A pilot case was conducted for 4 months implementing an HL7 real-time data extraction from vital signs monitors from an adult ICU in Medellin Colombia. Mirth connect software and Postgres database were used to integrate this interoperability model. Heartbeats, respiratory, SpO2, Temperature, and mean pressure were stored and managed using Microsoft Azure. Using Pearson and Bland-Altman analysis, the correlation coefficient achieved > 0.8 for all the variables.
Keywords: interoperability, intensive care units, HL7, architecture

D1 -Digital Health 1

Four Diagnostic Data Governance and Intelligent Diagnosis and Treatment Algorithm of TCM

By Xiaomin Lou, Shi Hong Che and Dan Hou

HangZhou Chest Hospital Affiliated to ZheJiang University Medical College, China

The four diagnostic methods of traditional Chinese medicine are the basic components of traditional Chinese medicine diagnostics, specifically referring to the four diagnostic methods of observing, hearing and smelling, questioning, and palpation, which are used to form the differential diagnosis of patients by traditional Chinese medicine practitioners. Among them, through oberserving, one can look at the patient's spirit, color, and form; Hearing and smelling includes listening to sounds and smelling odors; Questioning is asking the patient about their symptoms; Palpation refers to the traditional Chinese medicine diagnostic method based on pulse cutting, including physical examination. In this project, we are supported

by artificial intelligence technology, through the following technical route: hospital heterogeneous information integration -intelligent semantic recognition -structured database of four diagnostic methods of traditional Chinese medicine - -knowledge map construction -treatment plan training -intelligent recommendation of treatment prescription auxiliary decision support. These methods help us to achieve the goal of inheriting the knowledge and experience of famous Chinese medicine doctors in Hangzhou Red Cross Hospital, assisting clinical diagnosis and treatment, and improving the overall clinical diagnosis and treatment level of the hospital. By integrating multiple data sources into a data system, collect and organize past patient diagnosis and treatment data from renowned traditional Chinese medicine experts in hospitals, and perform natural language recognition processing. The specific technical method is to use a dictionary and rule based automatic named entity recognition (NER) and medical relationship extraction, as well as a BiLSTM+CRF deep learning model, to form a parsing algorithm for traditional Chinese medicine diagnosis and treatment data expressed in Chinese documents. The data indicators of each patient's four diagnoses are structurally extracted, and a historical case of each famous traditional Chinese medicine is established that includes four diagnoses information, diseases and syndromes database of traditional Chinese medicine prescriptions for patient treatment.

Keywords: four diagnostic methods of traditional Chinese medicine, intelligent semantic recognition, knowledge map construction

D2- Health Technology Management (HTM) 1

HTM Knowledge Gap Among Healthcare Leaders in Africa as a Contributor to Increased Equipment Downtime

By Martha Tusabe and Francis Kalule

WHO AFRO, Congo RD

Description: Despite the increased access to appropriate medical equipment in Africa, there is still a burden of limited regulatory systems, human resource, and financial resources with respect to the global scale. P. Howitt mentioned that at least 40% of medical equipment is out of service in Africa with many other studies suggesting 50-80% and by comparison, less than 1% of the medical equipment is out of service in high income countries. In addition, a study conducted by THET in 2017 mentioned that 30% of equipment that's out of service is mostly obsolete, with difficulties in acquiring spare parts and lack of skilled personnel. Maintaining proper patient care within a hospital means having access to functional medical equipment. This requires a supply of appropriate medical devices, proper regulation, proper maintenance of that equipment, and a system for regular testing and servicing of the equipment. In an attempt to solve these gaps, a lot of focus has been put on deploying appropriate medical equipment and deploying more biomedical engineering professionals leaving out the healthcare leaders who are responsible for most of the decisions concerning medical equipment in MOH and Healthcare facilities. Over 90% of healthcare leaders in Africa are not well equipped with knowledge about HTM and this has led to slow response when it comes to prioritizing medical equipment. This has been proven through a study that was done in some blood banks in Sub-Saharan Africa where all the district blood bank managers had no knowledge about HTM and often found challenges when the Biomedical Engineers (BMEs) requested for funds to support the preventive maintenance of the equipment thinking that there was no need for this since the equipment were working. This left the equipment lacking and slowly led to a total break-down that would in the end double the costs for repairs, thus increasing the downtime for the majority of the equipment in the blood bank. An HTM training was offered to the blood bank managers (where most of them were medical officers) through a project funding of Knowledge for Change. **Results:** Majority appreciated the knowledge received about HTM and this led to a 20% reduction in equipment downtime. A follow up with one of the chief biomedical engineers in one of the countries acknowledged the importance of the training to the top managers and said that currently the medical equipment budget is prioritized and there is a quick response from the health care leaders. **Conclusion:** Therefore, the lack of healthcare leaders with knowledge to aid in health technology management and inappropriate operation of medical technology by health personnel due to lack of user training, all lead to a huge burden of constant equipment downtime. This creates a dire need for training healthcare leaders about HTM to cover the knowledge gap and also increase support of biomedical engineering activities thus improving HTM within the health facilities in African countries.

Keywords: health technology management, healthcare leaders, medical equipment downtime

D2- Health Technology Management (HTM) 1

Rwanda Public Hospitals on the Roadmap of Solid Biomedical Waste Management

By Jean Marie Vianney Nkurunziza, Jean Claude Udahemuka, Jean Baptiste Dusenge Rwanda Biomedical Centre, Martin Manzi, Francine Umutesi

Rwanda Association of Medical Engineers, Rwanda Biomedical Centre

Introduction: Healthcare facilities are regarded as lifesaving infrastructures with huge solid waste and water production. Biomedical wastes are pathogenic and pollute the aerial, terrestrial and aquatic spheres. In the 2019 WHO report, 1 in 3 healthcare facilities globally do not safely manage healthcare waste. Although only 15% of biomedical waste infections are enormous. Moreover, the global carbon footprint from healthcare facilities is found to be at about 4.4 percent of the world's total greenhouse emissions and is expected to be tripled by 2050, reaching six gigatons a year. The treatment of solid biomedical wastes in Rwanda hospitals is implemented through incineration, shredding microwave autoclave and deep burial. **Objective:** To present findings of the survey in Rwanda 47-hospitals regarding solid biomedical wastes management systems. **Methodology:** The findings presented were analyzed on basis of primary data, online survey and telephone calls in 47 public hospitals. Biomedical technicians were the respondents of the survey and data were analyzed using excel tool. **Findings**: This survey revealed that 100% of surveyed hospitals segregate their waste before packaging and transportation to treatment areas. This shows an improvement compared to 52% according to WHO report of 2019. The monthly average solid biomedical waste production was found to be 2764 kg (min 200kg- max 15000kg). Although neither hospital weigh wastes by category (infectious, non-infectious, sharps), 85% weigh and record their solid wastes production. Regarding treatment, it was found that 68% (n=32 hospitals) have a treatment facility (incinerator/ shredding microwave autoclave). Hospitals with no incinerator use external contracts (private company or nearby hospital) for their waste incineration. In 32 hospitals with incinerator or shredding microwaves autoclave, it was found that 87.5% (n=28), 71.8% (n=23), 65.7%(n=21) are satisfied with incineration-associated infrastructures status on electricity, wash water and shelter respectively. Biomedical waste management workers in all hospitals are trained before undertaking the duties.**Conclusion:** Biomedical waste management is essential for each healthcare facility. It requires equipment and trained waste workers for effective outcomes. Although the desired level of waste management in Rwanda hospitals is not yet attained, the progress is strongly promising. The pathogens spreading has to be curbed to limit the infections as minimal as possible.
Keywords: hospital, biomedical waste, incineration, placenta pit, ashpit

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D2- Health Technology Management (HTM) 1

Optimization of Biomedical Maintenance in the Main Hospitals of the Kara Region

By Sadikou Oussey

GFA Consulting Group, Togo

As part of the activities of the SRDS project, it is planned to acquire biomedical equipment on behalf of ten health facilities in the Kara Region in northern Togo. The success of biomedical maintenance activities requires mastery of equipment. In a country where biomedical maintenance faces many difficulties with very limited resources, the SRDS project, which has provided a fund for the maintenance and acquisition of new equipment, is an opportunity to rethink the organization of this area. The first work consisted in defining the parameters which allow to control the equipment. These are human resources (skills building), financial and material. Human resources calls on the control of different categories of people (intervening directly or indirectly in maintenance management), training, preventive and curative maintenance and the criteria necessary for quality equipment acquisition. It was therefore necessary to master the technical, financial and organizational constraints of the management of biomedical maintenance both in the target hospitals and at the Regional Health Department. This process was really launched from July 2022 and will continue until the end of December 2023. Categories of staff have been identified, training modules developed to train, equipment allocated with the implementation of maintenance through nine contracts, criteria necessary for the acquisition of quality equipment defined and taken into account in tender documents, management system documentation of maintenance has been drawn. The implementation of these activities has improved maintenance indicators in the Kara region. A similar project is scheduled to start in January 2024

in two other regions. The various activities carried out in the Kara region will be reproduced in the next two regions. The implementation of activities in these two (02) regions will help improve maintenance indicators and therefore contribute to improving maternal and neonatal care in the country. The general objective is to contribute effectively to the success of activities for the care of pregnant women and newborns through mastery of the contours of biomedical equipment. • develop and implement multi-year investment and equipment replacement plans; • set up an effective regional maintenance network; • have biomedical technicians trained for adequate management of maintenance; • have a pool of trainers competent in user maintenance, particularly maternity ward, in the OR and laboratory; • strengthen the proper use of equipment in health facilities; • adequately ensure user maintenance; • improve maintenance indicators at the regional level; • serve as an example for the organization of maintenance in other health regions of the country. **Results:** • maintenance budgets in target health facilities are appropriate; • plans are drawn up and implemented; • a regional maintenance network set up; • technicians trained for adequate management of maintenance are available; • trainers skilled in user maintenance is available; • proper use of equipment in health facilities is reinforced • maintenance in hospitals is adequately ensured • maintenance indicators at the regional level are improved • the Kara region serves as a model for the organization of user maintenance in the regions of the country.
Keywords: Clinical Engineering, HTM, Regional Hospitals

D2- Health Technology Management (HTM) 1

Medical Technology as a Service

By Roland Loeffen

Radboud University Medical Center, Netherlands

The growing number of administrative, logistical and auxiliary tasks result in healthcare professionals being increasingly under pressure to perform caregiving tasks. Therefore, the Radboud University Medical Center developed and implemented a new concept aimed at unburdening care givers and reducing costs by central management. One of the concept's main pillars is Medical Technology as a service. This service always ensures availability of well-maintained medical devices. This was done by centralizing the management of medical technology and implementing a logistic process with active restocking. In addition, centralization makes it possible to reduce costs by optimizing the use and management of Medical Technology. First, the ownership of all broadly used equipment of the various in- and outpatient clinics was transferred to the Medical Technology department. A large central storage, several local stocks on the wards, and areas for returns were introduced. Frequently used equipment is stored in the local storage rooms, which are managed by a newly set up care facility team. Restocking was done automatically by the logistics department based on par levels. No longer used equipment on the ward can be returned by placing it in the return area and is then transported to the central stock. Infrequently used equipment is stored by default in the central stock and could be "ordered" by the care professional or the care facility team. To automize these processes, the logistic system, asset management system, and a newly introduced Realtime Location System were integrated. This integration enabled monitoring the location of equipment and stock levels. This facilitates automatically creating logistic orders when stocks are below a threshold. The concept was successfully introduced and implemented. Initially it took some time for the users to get acquainted with the system and corresponding new way of working. Based on the users' first feedback and experiences, the system's usability was further optimized. An evaluation, performed 6 months after implementation, showed mixed results over de different users but overall, the users were positive. The different processes were scored as follows (out of 10): local stock: 5.9, ordering equipment: 6.1, return: 6.3 and repair: 6.1. The users on the wards were positive (7.1) about the availability of Medical Technology. Users primarily indicated that the service's digital system could be more user friendly. This was partly because we were not able to fully automate restocking on the basis of location data. Therefore, users had to manually scan equipment to determine stock levels. Furthermore, preliminary analysis on stock levels revealed the potential to reduce overall quantities of medical technology by up to 25 percent. In conclusion, we successfully developed and implemented the concept of medical technology as a service. The service showed that it unburdens care professionals and gives the opportunity to save costs. To fully achieve these goals, the concept has to be expanded and optimized. Future developments include further automation of the process by integration with the Realtime location system and improving the efficient use of equipment by optimizing stock levels.
Keywords: HTM, centralization, unburdening care, efficiency

D2- Health Technology Management (HTM) 1

Current Development within the Gambia Ministry of Health Biomedical Engineering Unit

By Andrew Demba

Ministry of Health, The Gambia

The Gambia is the smallest country in mainland Africa and has a population of 2.6 million residing in 10,689 sq.km of land. [1] The country currently faces a dual burden of diseases. Although infectious diseases remain the largest cause of mortality in the country, the burden of NCDs is gradually increasing. From 2009 to 2019 the percentage increase in prevalence of lower respiratory tract infections was 0.6% and TB was 1.6% while that for ischemic heart diseases was 42% and liver cancer increased by 41.2%. [2] To respond to the growing healthcare demands of the population, the systemic capacity to supply diagnostics and clinical devices is required to be strengthened. Currently, multiple development partners to the government have a major share in procurement and donations of medical devices. However, limitations in the availability of funds for regular maintenance of biomedical equipment remains a significant challenge. Therefore, considerable amounts of equipment after breakdown are maintained through frugal methodologies. In other to improve the current Biomedical engineering services within the country, The Government of the Republic of The Gambia applied for financing from the World Bank the objective of which is to prevent, detect and respond to the threat posed by COVID-19 and strengthen national system for public health in The Gambia. The Government advocates within this project to apply a portion of the proceeds of the grant to strengthen its Biomedical Engineering Unit (BEU). The BEU has a key role to play in the management of medical devices. The BEU is responsible for establishing and implementing a biomedical technology management program for all laboratory and clinical equipment across the health sector, to ensure that medical devices are safe and reliable, and to mitigate functional failures for the benefit of patient care and avoid downtime. The goal of establishing the biomedical equipment unit is to strengthen equitable access to safe and effective medical devices in public health institutions to improve health conditions and outcomes [3]. Providing quality services to healthcare institutions requires to strengthen the pillars of health systems: • Service Delivery; • Human Resources; • Information and Communication; • Finance and Governance; • Medical technology. The currently being plan BEU will the first of its kind holistic equipment maintenance and management center of Gambia for all equipment in the public healthcare institutions from primary to tertiary level of care. The capacity of the BEU is being built for the unit to function as a center for medical device management, maintenance, advisory, regulatory support, and training to the healthcare staff. The equipment in hospitals without a maintenance unit or equipment that cannot be repaired at the hospitals can be managed at the BEU. The unit can also schedule regular preventive maintenance for all priority equipment across the country. It can support in installation or decommissioning of equipment in hospitals. The unit can also support the regulatory authorities in the implementation of medical device rules and standards in the country.
Keywords: clinical engineering, health technology management, ministry of health

D2- Health Technology Management (HTM) 1

Necessity of Project Management in Clinical Engineering

By Kallirroi Stavrianou, PhD, MS

University of Warwick, UK

Description: Clinical engineering is a rapidly evolving field, with new technologies and procedures being developed all the time. In order to keep up with the latest developments, clinical engineers need to be able to manage projects effectively. Project management is a set of processes and techniques for planning, organizing, and managing resources to achieve specific goals and objectives. There are many reasons why project management is important in clinical engineering. First, clinical engineers often work on projects that involve multiple teams and stakeholders. For example, a clinical engineer might be responsible for the installation and commissioning of a new MRI machine. This project would involve coordinating with multiple vendors, scheduling downtime, and training staff on how to use the new equipment. Project management can help to improve communication and collaboration between different stakeholders, to ensure that everyone is on the same page and that the project stays on track. Second, clinical engineers often work on projects that have tight deadlines. This is important in healthcare, where even small delays can have a significant impact on patient care. Project management can help to ensure that the project is completed on time and within budget. Third, clinical engineers often work on projects that involve complex technologies. Project management can help clinical engineers to identify and mitigate risks and therefore to ensure that the project is executed effectively and within the required quality standards.
There are many different project management methodologies that clinical engineers can use. No matter which methodology is used, project management is essential for the success of clinical engineering projects. The main benefits of using project

management in clinical engineering are listed here:• Improved efficiency and effectiveness;• Increased safety;• Improved compliance;• Increased teamwork;• Enhanced communication;• Increased customer satisfaction. If you are interested in getting started with project management in clinical engineering, you should find a project management certification program that meets your needs. Second, you can find a mentor who can help you learn the ropes of project management. Third, you can read books and articles on project management. Finally, you can practice project management by working on small projects. Project management is an essential skill for clinical engineers. By effectively managing their projects, clinical engineers can ensure that they are able to deliver the best possible care to patients.

D2- Health Technology Management (HTM) 1

Setting Up Sustainable Maintenance Departments in Some State-Owned Healthcare Facilities in Cameroon

By Djankou Tchoutat Lionel, Ouassouo Passang Saibou and Tiedjou Rodrigue

Applied Technologies 4 Ever Limited, Cameroon

Adequate healthcare provision to a vast majority of citizens in Low-and-Medium-Income Countries in the appropriate healthcare facility has always been a big challenge for diverse reasons. In Africa and most especially in Cameroon for instance, provision of quality healthcare services in a quality healthcare facility is still a far-fetched reality notwithstanding the proportion of budget allocated yearly for this sector. The role and importance of a good maintenance department in a hospital is still mitigated and under looked partly because most if not all government hospitals are managed by medical doctors. Furthermore, seasoned and experienced biomedical / clinical engineers must be part of the committee in charge of following up hospital construction projects and kick start of activities in order not to neglect the establishment of a sustainable maintenance department from the early stages of the project. Prolonged downtime, high and unnecessary running costs are just some consequences of not constituting a good maintenance department. Limitations on the part of the government towards ensuring a proper HTM upon kick off of hospital activities: Late appointment / transfer of biomedical technicians and engineer to the hospital; Appointing technical staff who all have limited experience in health technology management; Number of biomedical engineers and technicians appointed to work in the hospital was small compared to the number and complexity of medical equipment installed; Late disbursement of funds to kick start activities; Poor planning and supervision of training sessions performed by the various suppliers of medical equipment and devices. Challenges encountered while setting up the biomedical engineering department: Being a state-owned healthcare facility, there was the usual inertia towards work, as observed in most state owned institutions; Lack of funds to purchase vital working materials like tools, Computerized Maintenance Management Software (CMMS), spare parts etc;Poor and incomplete training given to biomedical engineers due to the fact that they were few in number and the training sessions were poorly planned; Late transmission of equipment manuals to the hospital; Inability to properly track, follow up and document maintenance requests due to insufficient personnel and experience. Measures taken to implement a proper health technology management system: Established a list of tools necessary to perform maintenance activities;Preparation of a job request form necessary to track and follow up job requested by the medical personnel;Established a system of reporting monthly activities to the administration and achieving job request forms;Established template for preventive maintenance follow-ups; Following several complaints to the ministry of public health about lack of staff, more biomedical technicians were posted to the hospital; Division of labour was implemented upon the arrival of more staff. Key staff were assigned to follow up key sectors or groups of equipment; Proposals submitted to the administration for the purchase of a CMMS. Upon expiration of the warranty period for all equipment installed, proposals were made to externalize the follow-up and maintenance of some equipment.
Keywords: healthcare facility, maintenance, experience, report

D2- Health Technology Management (HTM) 1

Importance and Challenges of Medical Imaging in Africa

By Mario Forjaz Secca

ISUTC, Maputo, Universidade Nova de Lisboa, Lisboa

Diagnostics has been recognized as a very important part of modern Medicine. However, it has not been given its proper importance in planning and funding, and in many hospitals and medical facilities in Africa these are services that are not

adequately supplied. A very important branch of medical diagnostics is medical imaging, and this is one of the areas of medicine that is more technologically dependent, with a large range of sophisticated equipment. Hence clinical engineering has a major role to play in it. For a good health delivery to the general population, medical imaging services should be available in a widespread way across Africa, and with a good variety of modalities, from the more basic ultrasound and x-rays to the more advanced CT and MRI. For that to be a reality, many issues should be addressed. There are many challenges for medical imaging in Africa because of issues of cost, funding, safety, technical expertise, maintenance, installation conditions, operating staff and accessibility. We analyze all these main issues, detailing their main problems and present some suggestions to deal with them. We focus, in particular, in the situation of MRI in Africa. We believe it is crucial to put some energy and effort into these issues to make sure that a wide range medical imaging services is availability with equity and good quality to people across Africa.
Keywords: diagnostics, medical imaging, MRI, Africa, HTM

D2- Health Technology Management (HTM) 1

Implementation of a Decentralized Maintenance Model with Measurable Impact on Functionality and Availability of Medical Equipment in Health Care Facilities in Burundi

By Farah Beniacoub, Marc Myszkowski, Fabrice Ntwari, Emery-Christian Arakaza and Stefaan Van Bastelaere

Enabel, Burundi

Description: On average 38.3% of equipment is out of order in developing countries. This is no different in Burundi. To address this, the Ministry of Public Health has developed a maintenance model, operationalized with the support of Enabel, the Belgian Development Agency. This study analyses the effects of the implementation of a decentralized maintenance model in Burundi's resource constrained healthcare system between October 2020 and February 2022 with hypothesis that the model has a measurable impact. **Methods:** The initial model was tested in 2 pilot provinces in Kirundo and Muramvya between 2017 and 2020 before being improved and extended to the provinces of Bujumbura and Rumonge from 2020. It is composed by 4 interrelated main axes: i) Human resources: capacity building, maintenance focal points, strengthening HTM; ii) Financial resources: mainly securing funds for maintenance and working on detailed financial planning; iii) Material resources: workshops, supply and maintenance of tools and ECME, logistical means; iv) Maintenance management largely digitalized with a computerized maintenance management system. The main goal is to analyse the effects of this implementation and prove that through better maintenance management, it makes possible to increase quantity and quality of care. This benefits to the population of 5 districts of the provinces of Bujumbura and Rumonge with 6 public hospitals and 97 health centers. **Results:** During the study period, concerning medical equipment family, the rate of equipment functional in service has increased substantially, respectively +8% in province of Bujumbura and 2% in Rumonge, and the rate of equipment requiring maintenance has fallen by 9.7% in Bujumbura and 2% in Rumonge. If we compare data extracted from the national computerized maintenance management system, we realise that the 4 provinces supported by Enabel have convincing results in terms of equipment functionality with scores of at least 80%, while national average for other provinces is 64%. The study showed a decrease in response time for corrective maintenance requests. We have also clear correlations between increased preventive maintenance and reduced equipment failure rates. **Conclusions:** There is a notable and significant positive change between 2020 and 2022 in the functionality of medical equipment and a significant decrease in equipment awaiting maintenance, and therefore in its availability. This study proves that a sustainable implementation of a decentralized maintenance model is feasible and highly useful in low-resource settings due to its affordability. The development of local skills remains a constraint, as there is no dedicated biomedical engineering program in Burundi to meet existing needs, in line with the WHO global strategy on human resources for health. The context of a low-resource country is a challenge, but the model developed shows that by tackling the low-resource levels of preventive maintenance, we can already have some impact on functionality of the equipment and therefore on the quality of care.
Keywords: maintenance, management information systems, biomedical technology, health technology management

D3 - Health Technology Assessment & Innovation 1

Design and Manufacture of Healthcare Devices in LMICS – Necessity, Challenges and Way Out

By K Siddique-E Rabbani

University of Dhaka, Bangladesh

X-ray and ECG, two vital devices for healthcare, were invented more than one hundred years back and yet a great majority of the global population living in the Low-and-Medium-Income Countries (LMIC) do not have easy access to these two devices. One can easily imagine the situation with other later developments. The main cause behind this global failure is the thinking that LMICs cannot catch up with the modern technology developed and manufactured in high income countries (HIC) and therefore it will be better if these are all shipped from the HIC worldwide. This equipment, designed in the HICs cannot stand the extremes of weather and power line abnormalities in the LMICs. Secondly, the infrastructure, supply chain and expertise for the maintenance and repair of these devices cannot be established easily in remote LMICs, however optimistic policies one may formulate. The only pragmatic solution is the design, development, improvisation and manufacture of essential medical devices in each country by their own innovative manpower through optimal use of existing technological infrastructure. In almost all LMICs there is no industry which has the capability to develop a locally developed medical device into a commercial product and so would not invest in such ventures. There are capable innovators in many LMICs but they need to have their devices go through an experimental marketing in small scale which would give them the necessary feedback for improvement till it may reach a stage for large scale production. The following may be suggested as a way out in the LMICs for the innovators to become entrepreneurs but ensuring a minimum acceptable quality. 1. National regulatory bodies will only take care of imported devices and for large scale production of medical devices in the country. Their scope should not cover medical devices made by local innovators for small scale experimental production and sales. 2. For experimental manufacture and sale, the innovating team should have a university graduate in a related field who would take responsibility for its technical compliance. Again, a qualified medical doctor should be involved in the buying process who understands the medical aspects of the device being purchased. 3. The LMICs should have a 'Medical Device Promotion and Quality Assurance body' which will promote the manufacture of devices by local engineering innovators, support them if there is some weaknesses, and organize evaluation of the final products to see if all technical specifications follow a minimum acceptable quality. Since many LMICs do not have required experts for such evaluation, WHO should provide for a set of minimum technical specifications for essential medical devices and establish regional and international panels of experts to help innovators in the LMICs, if needed. **Conclusion:** For LMICs, regulatory policies need to be modified for experimental small scale manufacture and sale by an innovator with university degree in a related field and with the presence of a qualified doctor in the buying group. WHO should organize international or regional panels of experts for guidance and help.

Keywords: medical devices, LMIC, indigenous design & development, regulatory policies for medical devices, innovators of medical devices, WHO support to innovation of medical devices in LMICS

D3 - Health Technology Assessment & Innovation 1

Real World Evaluation of the NGPOD Device

By Prof. Chris Hopkins and Dr Matthew Lawrence

Tritech Institute, Hywel Dda University Health Board Nasogastric tube (NGT) management, UK

Nasogastric feeding tubes are used when patients cannot swallow food, liquids, or medication safely After insertion, national guidance requires that clinicians confirm that the nasogastric tube is correctly placed before each time they are used The current test that confirms correct placement relies upon obtaining fluid (known as aspirate) from the tube and tested using pH test strips Testing is vital as an incorrectly placed tube (most common misplacements are curled up inside the upper airway or placed into the main bronchus in the lung) can have immediate and serious consequences including severe injury or death. The current pH testing regime can be unreliable, time consuming, and often still requires an X Ray to confirm pH results Such testing methods often delay feeding treatment or the ability to give medications in a timely way There are also well documented human and technical factors associated with the current confirmation methods, leading to errors, delays, and increased risk. To address this clinical dilemma NGPOD Global have developed a new device, NGPOD® The NGPOD®

device can be attached to a one use fiber optic flexible sensor (coated at the distal end with a hydrophilic pH indicator compound), that can slide down and reach the distal end of the NG tube The NGPOD® device can then be used to determine the pH of the environment at the end of the NG tube and will indicate whether the pH 5.5 and that the tube is placed correctly. **Findings**: 21 patients had NGT's placed on the Stroke ward at Morriston Hospital and 8 on the Stroke Ward at Glangwili Hospital Data was collected on the use of NGPOD, including pH test results, x ray requests and delays to feeding/ medication Staff were engaged through interviews and surveys. The main findings of the evaluation have been divided into three key themes, Technology, Infrastructure & People and these are summarised below: 1) The Technology Evaluation: We found that the technology worked well; it was accurate with no major errors and when used appropriately the technology was safe and effective. We did find several cases of technology not being used correctly through human error. 2) The Infrastructure Evaluation: The main barriers found were around the current infrastructure at both sites, including lack of time, difficulties in finding the key people to talk to, difficulties in sign off, variability on service design and service oversight/management. 3) Staff Evaluation (People): Feedback around the device was predominately positive, however, they still advocated for pH strips to remain as a backup or alternative method. The main recurring barriers were the perceived lack of understanding and a need for more training and experience. **Conclusion:** NGPOD was found to be effective when using the device for the intended purpose and using it as per the manufacturer's specified conditions and instructions for use. It takes as long as standard aspirate testing and reduces the need for x rays in a real-world setting.
Keywords: technology evaluation, safety and risk, patient safety

D3 - Health Technology Assessment & Innovation 1

Design and Development of a Sensory Feedback System for Transradial Amputees Using Body Powered Prostheses

By Michael Awood, Catherine Gordon Grant and Sudesh Sivarasu

University of Cape Town, South Africa

The rejection of prostheses by amputees due to the lack of sensory feedback remains a significant challenge. The study aimed at developing a non-invasive sensory feedback system to augment existing body-powered prostheses. The system incorporates tactile and proprioceptive feedback, resulting in improved performance in object identification and size discrimination tests, increased perceived confidence, and quicker response times. A sensory feedback system was created, employing capacitive sensors for proximity and touch detection, and a flex sensor to capture finger digit position and motion. Sensory information was conveyed to the user through a vibrotactile armband on the upper arm. A preliminary study involving four able-bodied participants confirmed the efficacy of the sensor-vibrating motor combination. Subsequently, a study was conducted at the Medical Devices Lab, University of Cape Town, involving five able-bodied volunteers. The objective was to assess the impact of the designed sensory feedback system in conjunction with a body-powered prosthesis on the participants' ability to locate and discriminate the size of spheres while visually and aurally restricted. Results from the preliminary study demonstrated participants' ability to differentiate between different touch intensities and locate the position of stimuli accurately. Object identification test results revealed a significant improvement in accuracy when sensory feedback was provided, reaching an average of 100%. Likewise, object discrimination accuracy increased from 58.33% without sensory feedback to 85% with sensory feedback. Response times for both tasks also improved, indicating a positive learning curve with the device. Participants' confidence levels in size discrimination were significantly higher when sensory feedback was active, with a positive correlation between accuracy and confidence. Confidence increased from an average of 70% without sensory feedback to 84% with sensory feedback. This study successfully developed a non-invasive sensory feedback system that met the desired design requirements. Future recommendations include optimizing the design for enhanced capabilities and validating it with transradial amputees. Further work entails usability studies with amputee subjects, revalidating the design through bench testing and with amputee participants, and assessing scalability and manufacturability with commercially available body-powered prostheses. The findings of this study pave the way for improved prosthetic functionality and user experience, addressing the critical need for sensory feedback in prosthesis design. Ultimately, this research contributes to enhancing the quality of life and integration of amputees into society.
Keywords: prosthetic devices, inclusive innovations, rehabilitation engineering

D3 - Health Technology Assessment & Innovation 1

3D Printing in Healthcare: 25 Years of Development in Iceland

By Paolo Gargiulo

Landspitali University Hospital, Reykjavik, Iceland

3D Printing (3DP) is a well-known process and an established technology. Applications in health care are among the most intriguing and challenging, gaining attention and value in the past years. 3DP in healthcare have gained a solid position as a potential solution and support to numerous clinical problems. The process is based on the acquisition of medical images (MRI and CT) with the specific scanning protocol, the segmentation of the region of interest and the use of specific technology to 3DP the selected anatomy. Clinicians can use these models to visualize and prepare surgical procedures, to improve communication with patients and among doctors, or for educational purposes by displaying complex, pathological anatomies in a novel way.In Iceland we have been pioneers using 3DP in healthcare. Indeed, we started supporting surgical planning with 3DP in early 2005, already in 2009, we integrated 3DP as service within the Icelandic healthcare system. The use of 3DP technology to support surgery started in the Clinical Engineering department, Landspitali University Hospital (LSH) which is the only one of its kind the Icelandic Healthcare system. LSH is responsible for subspecialty service in the Healthcare system in Iceland and has a comprehensive research and development program. The CE unit is involved in routine consultation, service and research and development projects. In the frame of the RD activities, first we investigated the development and application of 3DP technologies as support in visualizing and handle anatomy in complex surgeries. Second, on defining and testing optimal imaging and scanning protocols and also software tools for medical image segmentation. In 2005, the CE unit started an official collaboration with the Department of Surgery and the first study cases were in made in Maxillo-facial and heart surgery. The number of surgical treatments requesting 3D printed models was 8 in 2005 but increased to 13 in 2006 and 24 in 2007. As the number of models increased, it was realised that outsourcing the 3DP was not effective economically, and organisationally due to the time of delivery. This led, on establishing the whole 3DP process internally. Starting from the data acquisition, based on a 3DP protocol for CT and MRI scans, accessing the DICOM from the hospital PACS, segmenting and 3D model the region of interest, 3DP and delivery to the surgeon. The entire process was completed within 48 hours. To facilitate access to the 3DP service, a special request form was provided in the Clinical portal system on the hospital intranet. Here the Physicians can order a model easily, providing information on the patient and operation, time priority, region of interest and DICOM data. Today, there are under development new applications such as Virtual reality and augmented reality showing their great potential for improving planning and clinical training. The model has been inspiring several institutions in Europe and in collaboration with over 40-word wide professionals we recently edited a book entitled Handbook of Surgical Planning and 3D Printing to establish a point of reference for 3D printing practice in healthcare.
Keywords: 3D printing, clinical engineering, surgery

D3 - Health Technology Assessment & Innovation 1

Biomedical Engineering and the Innovation Landscape in Africa: An Exploratory Study of Five Anglophone West African Countries

By Elsie Effah Kaufmann, Akofa Bart Plange, Robert Ssekitoleko, Benedict Mulindwa and Mike Raxworthy

Biomedical Engineering Department, University of Ghana

This was an exploratory study to map translational capacity for Biomedical Engineering (BME) and Medical Technology (MedTech) in anglophone West Africa. A systematic review was conducted to determine the strengths and opportunities for BME to drive healthcare improvements. The training of biomedical engineers and technicians, their professional qualification and technical competence, and how these might present opportunities for meeting the needs of local healthcare providers through local sourcing and the supply of appropriate MedTech products, were studied. A similar study was recently conducted in East Africa to which findings from West Africa will be compared for lessons to be drawn. This report presents the data from Ghana, Nigeria, Liberia, Sierra Leone and the Gambia. Eight survey instruments were adapted from the East African study for BME training institutions, researchers and innovators, professional biomedical engineers, health facilities, private companies, technology incubator hubs, regulatory bodies, and development agencies with partnerships in BME. A workshop was organised with stakeholders from the 5 countries to validate the preliminary data collected. All quantitative and qualitative data were collated and analysed. Of the N=112 responses received, n=57 were from professional engineers (80.7% of which were male), n=12 from private BME companies, n=18 from researchers and innovators (94.4% male), n=12

from health facilities, n=3 from tertiary training institutions, n=5 from development agencies, n=2 from regulatory agencies, and n=1 from an incubator hub. n=3 was rejected due to incomplete submission. All groups considered their conditions to be suboptimal for effective innovation. Training institutions highlighted lack of teaching facilities and insufficient teaching staff as challenges; researchers, and innovators cited lack of funding, collaborators, and mentors. Most professional engineers work in clinical settings and identify a paucity of career development programs as a significant challenge. Data also revealed that the discipline is still male dominated. 50% of respondents from the professional biomedical engineer group belonged to a professional biomedical engineering association and expressed that the association had had a positive impact on their career paths.This pilot study highlights some challenges in the BME discipline in Anglophone West Africa that were broadly similar to East Africa. These ranged from training to career development and opportunities for innovation, and their impact on healthcare delivery and patient care. The role of support institutions such as the biomedical engineering associations, regulatory bodies and incubator hubs were explored. The study also identified themes that could bring synergies between academia, industry, and government regarding MedTech innovation. Steps that might facilitate these in West and in East Africa will be reviewed in this presentation.
Keywords: biomedical engineering, medical technology, innovation, healthcare, Africa, technology

D3 - Health Technology Assessment & Innovation 1

Evaluation and Implementation of an On-Site 3D Laboratory to Support the Planification and Development of Highly Complex Surgical Services

By Paula Andrea Berrio Molina, Tomas Gonzalez Cano

Clinical engineering department chief, Colombia

3D printing is a rapid modeling and prototyping technique that is currently applied to the production of a wide range of shapes which has revolutionized the field of health, especially in the surgical field, allowing the creation of anatomical models that support the surgical planning and personalized surgical guides to reduce OR times and improve patient safety. The Pablo Tobón Hospital is a reference and highly complex institution, which has used 3D printing in maxillofacial and orthopedic surgery procedures through the purchase of planning services from third parties. However, these services are limited (just 2 companies available), expensive and with delayed delivery times. This made it an inaccessible technology and did not allow its use in urgent procedures. To address this problem, a comprehensive review on the 3D printing in surgery usage was done, finding the financial, location and staff resources necessary for the implementation of the on-site laboratory and the operating room time savings was identified as the most relevant benefit. A biomedical engineer dedicated to the laboratory was hired and a clinical leader was appointed, facilities adaptation was carried out, Colombian regulations related to medical devices were reviewed and the necessary equipment and resources were acquired for the implementation, among these, an Ultimaker S5 Pro Bundle printer. To guarantee compliance with the current regulations for medical devices in relation to the printing and use of surgical guides (as medical devices) in real patients, a non-required certificate was obtained from the National Institute of Food and Drug Surveillance. (INVIMA).The laboratory began to provide its services in October 2021 and to date, a total of 38 cases have been performed by using physical and digital anatomical models, from different specialties such as Orthopedic, Thoracic, Oncology Pediatric and Cardiology Surgery. 55% (21) of these cases were urgent, in which the requested anatomical model was delivered in less than 72 hours. The results obtained demonstrate the effectiveness and successful implementation of the 3D on-site laboratory, showing a reduction in delivery times of 80%, an average cost saving of 78% compared to the commercial offer on the market and the impact on the attention to priority cases that previously could not be addressed within this technology. Due to the variability in the complexity of procedures of the same type, there have been difficulties in comparing the operating times of the surgeries planned with 3D models versus the average time by procedure type, and therefore, it has not been possible to statistically demonstrate a reduction in operating time. However, surgeons have noticed a reduction in time in high complexity cases approached with this technology. In conclusion, the on-site 3D laboratory has become a high-impact and low-cost service for the Pablo Tobón Hospital, being a fundamental tool in the flow of care for trauma surgical patients. The implementation of 3D printing in surgery has proven its worth and opens up new possibilities in other clinical specialties, manufacturing of clinical training tools and support in the management of the Hospital's medical equipment.
Keywords: 3D Printing, onsite 3D laboratory, surgical planning, anatomical models, surgical guides

D3 - Health Technology Assessment & Innovation 1

Clinical Engineering Innovations for Health Equity in a Global Environment of Polycrisis

By Fred Hosea III and Jans Aasman

Ecuador

Abstract: Health Equity is a groundbreaking international endeavor in healthcare research, planning, and change-management. Its primary objective is to identify and rectify historical disparities in healthcare services provided to large populations. These disparities, stemming from systemic biases in both healthcare and Social Determinants of Health, have resulted in massive denials of care and misdiagnoses, leading to increased rates of morbidity and mortality among marginalized populations across a wide range of medical conditions. To frame these Equity challenges properly, we add an overview of global "polycrisis" theory as a complicating context for understanding how we can best promote responsible clinical research and innovation under adverse circumstances, in service of health equity goals. Traditional models of innovation may become rapidly obsolete in the face of mounting polycritical instabilities. We will argue that to address this polycrisis, a new alliance between Clinical Engineers, nurses, and physicians, empowered by new informatics tools, will be pivotal for future success. Background: "Polycrisis" has been characterized as a looming "seismic shift" in environmental, economic, political, and civilizational risk by numerous international bodies (World Bank, IMF, World Economic Forum, UNICEF, European Union, WTO, OECD, UNIDO, the United Nations, Accenture, McKinsey Global Institute, et al.) They generally agree that past global, national and corporate systems of speculative finance, debt overload, volatile markets, unsustainable resource exploitation, wealth inequality, envirocidal energy dependence on oil and coal, species extinction, habitat destruction, supply-chain fragility, short-term investments that destroy long term needs, climate disruption, etc. amount to possibly irreversible catastrophes.https://www.dropbox.com/s/fae6rpkce7fyppq/Diimensions%20of%20the%20polycrisis%20that%20will%20affect%20healthcare%20worldwide%20include.docx?dl=0 Proposal: This analysis proposes the use of Semantic Web data science and Graph Knowledge-Base tools as a transformational, transdisciplinary solution for improved data navigation and timely use in healthcare systems for normal healthcare functions, as well as to support innovations needed to achieve Health Equity goals in a hyperturbulent global environment. These tools are based on standardized taxonomies, ontologies, processes, and data governance policies that will underlie the multiple, intersecting institutional functions that are essential to coherent and convergent healthcare research, innovation, and improved, more equitable service models. Typically, these multiple functions are organized under separate professional, organizational, and market domains, resulting in a systematic disjointedness of the resulting subsystems that under-deliver services in the aggregate, despite elevated cost structures.We present an exploratory conceptual and practical framework to guide the staged adoption of convergent knowledge-graph science and related tools as foundational solutions for aligning healthcare informatics, clinical research, clinical technologies and strategies in the interest of more enlightened healthcare service design. This toolset will be a vital foundation for radical transformation of the collective knowledge resources needed to support research and innovation at global and local levels.We seek to build multidisciplinary bridges between healthcare stakeholders and informatics experts that will enable a qualitative leap in institutional capacities to study and remedy past inequities and to insure future equity in healthcare services, even under forecasted conditions of austerity and institutional challenge. Gains from this initiative should be substantially transferable through global Health Equity partnerships to leverage the outcomes on a global scale.
Keywords: health equity, polycrisis, knowledge-graph data science, semantic web, clinical systems engineering, professional development, complex systems engineering, decentralized care services, service engineering

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D3 - Health Technology Assessment & Innovation 1

Validation of a New Device for Distal Upper Extremity Rehabilitation: A Feasibility Randomized Controlled Trial

By Antonio Miguel Cruz

Department of Occupational Therapy, Faculty of Rehabilitation, Canada

Introduction: Distal upper extremity (UE) impairments have been found to impact everyday functioning and are associated with reduced quality of life, as well as increased levels of anxiety and depression. The FEPSim device (Karma Machining & Manufacturing Ltd., Edmonton, Canada) was developed for distal UE rehabilitation. The FEPSim (Flexion, Extension, Pronation and Supination simulator) was designed for these wrist movements, and it allows therapists to grade activities in terms of resistance and repetitions, as well as to ascertain patients' strength and range of motion during active movements of the hand, wrist, or forearm. This device has the potential to improve outcomes in patients with impairments of the distal

UE; however, the FEPSim's effect on hand therapy outcomes was unknown. **Purpose:** The primary purpose of this study was to assess the feasibility of conducting a definitive trial investigating the effectiveness of adding a new device for hand therapy, the FEPSim, to standard care for patients with impairments of the distal upper extremity. This study also aimed to gather clinical and statistical information, as well as information related to the cost and adoption which allows for an economic evaluation of the device. **Methods:** Thirty-eight patients with impairments of distal upper extremity were randomly assigned to either the intervention group (FEPSim and standard care, n = 19) or to the control group (standard care, n = 19). Therapeutic activities to increase strength, range of motion, resistance, and dexterity were delivered using the FEPSim device for the intervention group. Outcome measures included wrist passive and active range of motion, grip strength, pinch grip force, and Patient Rated Wrist Evaluation. **Results:** The trial retention rate and compliance were high (94.73% and 94.96%, respectively). The comparisons between groups of the change-from-baseline revealed that in 63.2% (12/19) of the outcome variables, the change was in favor of the FEPSim, with statistically significant differences in passive wrist flexion ($t(34)=-0.335$, $p=0.008$) and grip strength ($t(34)=-1.841$, $p=0.037$). In terms of technology adoption, overall, our findings suggest that the FEPSim device was widely accepted by therapists. Finally, in terms of cost, to include the FEPSim to the standard care, would result in an extra cost of CAD 48.35 per patient and the FEPSim saved cost in sanitization procedures. That is, the FEPSim saved CAD 21.87 per sanitization per patient. **Conclusion:** The use of the FEPSim device was a feasible alternative for supporting hand therapy. The trial design was feasible for hand intervention using the FEPSim device. The FEPSim positively affected grip strength, an objective measure of hand functioning.
Keywords: rehabilitation, clinical outcomes, innovation

D4 - Health Technology Quality & Risk 1

Implementing a Web Application for Medical Devices Classification

By Athanasia Kalouptsoglou, Aris Dermitzakis, Nicolas Pallikarakis

Biomedical Technology Unit, Greece

Medical devices safety is directly expressed by the classification according to the risks associated with their use for the patients and users. This paper proposes a web application that assist medical devices risk classification according to the European Medical Device Regulation (MDR 2017/745). Invasiveness, anatomical impact, duration of use, and device characteristics influence the classification assigned. Medical terminology competency, delicate rules handling, regulatory adaption, and user interface design aspects are addressed in the application. Rule analysis, constraint propagation, and targeted query correlation optimize the process. The study focuses on the importance of accurate medical device risk classification and the user-friendly application design developed to facilitate correct regulatory compliance. With an estimated number of over 1 million medical devices available on the global market, correct classification according to the risk they present for the patients and users, is crucial to guarantee safety and regulatory compliance. The European Medical Device Regulation (MDR) adopts four risk categories for medical devices based on their invasiveness, the anatomical area affected, the duration of use, and active or passive properties. Namely: Class I, IIa, IIb and III. In the context of this work, a web application for MDs classification has been designed, developed and implemented. The aim of this application is to facilitate correct classification of medical devices into these four risk categories. Developing a device classification application requires: • medical terminology proficiency used in the MDR; • understanding of the classification rules as in MDR 2017/745, considering also the MDCG 2021-24 Guidance on classification of medical devices; • Adaptability for regulatory changes. The program should adapt to changing regulatory environments to allow rule modifications without substantial disruptions; • UI/UX design elements that affect app usability and comprehension. To help users grasp device categorization, apps must use a user-friendly layout. Addressing these key features allowed the design of a medical device classification application that meets regulatory requirements and is user-friendly. The interface of the application is responsive to different display screens. The methodology followed during the development phase of the application used a scientifically popularized medical language without however oversimplifying medical device classification terms for non-specialists. Name, number, rule type, category classification (invasive, non-invasive, implantable, active), connections with other rules or conditions, description, and the applicable class described by each rule were analyzed. This analysis increased software usability and solved rule-based approach difficulties, simplifying the use of the 22-rules, of the MDR document. Usability, speed, and performance were addressed with targeted queries for optimal classification. Following code principles, JavaScript, HTML, and CSS were used to develop the app. Elegant, minimalist UI improved legibility. The app's simplicity and homogeneity make answering questions uncomplicated. Optimizing devices display and usability improves user experience. In conclusion, medical device classification ensures compliance with European regulatory framework to protect patients. The proposed web application allows correct classification in a user-friendly environment. Technological advances and data analysis can drive application feature additions to increase usability, functionality, and easy incorporation of future changes in the rules.
Keywords: clinical engineering, web application, medical device classification

D4 - Health Technology Quality & Risk 1

Medical Ceramic Oxygen Generator (M-COG)

By John Graf

NASA, USA

M-COG technology
M-COG oxygen is always >99.0% pure
M-COG can generate and store at 150-200 psig, for nominal hospital delivery at 50-75 psig
M-COG operations are insensitive to humidity, temperature of air
M-COG oxygen engine is solid state – no moving parts
M-COG process operates at extremely high temperatures: 700-800C
M-COG power consumption is similar to PSA systems now – can be more efficient than PSAs in the future

Readiness
M-COG full-scale cell stacks have been built and demonstrated
Meets design specifications for oxygen purity
Meets design specifications for delivery pressure
Meets design specifications for power use
Meets design specifications for oxygen production rate
Small, medium, or large systems can be built using different amounts of cell stacks
Small-scale demonstration facilities can be built using hand-crafted, small-batch cell stacks
Cost-effective systems need to be built at scale

Key Requirements for a Medical Oxygen Generator:
Purity: Always >99.0%
Pressure: Supplies ventilators >50 psig
Production: small, medium, and large
Power: <100 Watts per lpm (goal <50 Watts / lpm)
Insensitivity to heat and humidity (0-50C, 0-100%RH)
Endure grid power voltage surges
Endure loss of grid power / solar power
Maintenance: <2 hours every 5 years
Operator Training: <2 hours
Service Life: >10 years (goal of >20 years)
Total cost of oxygen: lower than SOA systems

Proposal
We should work together to design, build, and demonstrate an “Oxygen Shed” that uses M-COG technology and an air-gravel heat exchanger.
Build Health International can build the structure, manage the project
AmOx can supply the oxygen engine
Public Invention can provide the control software
Global Clinical Engineering Alliance can make sure the system meets the code
NASA can collect operational data, and issue a report on system performance

Keywords: medical oxygen, cost-effectiveness, stakeholder partnership

D4 - Health Technology Quality & Risk 1

Reuse of Medical Devices with Patient Safety Responsibility, Imbanaco Clinic, Cali, Colombia

By Karent Eliana Muñoz and Margarita Maria Sarmiento Montoya

Clínica Imabanaco, Colombia

Description: For the development of the management of medical device reuse with regards to patient safety, the Failure Mode and Effect Analysis (FMEA) methodology was adopted to identify potential problems or errors, and the possible effects of reprocessed medical devices, in order to proactively evaluate processes related to the use of medical devices and identify potential failures in the patient care process. The following were developed for the implementation of FMEA: Formation of the evaluation team: The team was formed by Operations Management, Financial Planning Coordinator, Quality and Patient Safety Department, Infection Prevention Committee Coordinator, Head of Pharmaceutical Service, Lead Biomedical Engineer of the Technovigilance Program, Procurement Manager, Central Sterilization Unit Manager, Health Accreditation System Leader, Clinical Engineering Manager, and technical experts in the use of the medical device. Description of the medical device: The medical device is selected, and its description is prepared focusing on the function of each medical device. The level of criticality is included according to the classification system proposed by Spaulding, categorizing the medical devices into categories based on risk. Additionally, verification is done with the manufacturer to determine if reuse is authorized. The condition and integrity of the device are assessed based on the technical-scientific criteria of the user, the epidemiological surveillance coordinator, and the central sterilization coordinator. Identification of potential failures and their effects: To establish the potential failure of the medical device, technical experts are questioned to share the most frequent failures that may occur with the use of each evaluated medical device based on their experiences. Similarly, the epidemiological surveillance coordinator provides insight into the risk of infection that the reprocessed medical device may pose. Failure mode rating: Three (3) items are used to evaluate severity, occurrence, and detectability on a scale from 1 to 5, with 5 being the highest rating. The following table details the rating criteria for severity, occurrence, and detectability.
Conclusions: Technical considerations for implementing the reprocessing and reuse of single-use medical devices are related to device design, material, cost-effectiveness, functionality, compatibility with sterilizing agents, availability of the manufacturer-recommended sterilization method, and ease of disassembling device components. By adopting the FMEA methodology, significant changes in the reprocessing of medical devices are achieved. This contributes to the identification of reprocessing failures, prioritization and mitigation of infection risks associated with medical devices, strengthening the intensive surveillance of reused medical devices, and optimizing resources for patient care.
Keywords: medical devices, patient safety, failures

D4 - Health Technology Quality & Risk 1

Current Status of Breast Cancer Prevalence & Futuristic Solution Through Telehealth & AI Based Approaches to Combat Breast Cancer in Bangladesh

By Jahin Ahmed, Md. Ushama Shafoyat, Shahin Mahmud, Md. Faizul Hakim, Dr. M Jahangir Alam and Md. Ashrafuzzaman

Military Institute of Science and Technology (MIST), Bangladesh

Breast cancer rates are rising at an unacceptably high rate in low- and middle-income nations like Bangladesh. Breast cancer death rates are usually higher in our country than those in prosperous nations because younger women are rarely diagnosed with the disease in an advanced state and other psychological, social and cultural factors are responsible for this. In this paper, we systematically analyze the overall risk factors, screening, treatment and consequences of breast cancer in Bangladeshi women. A thorough literature search in PubMed, Mendeley, and Google Scholar to find all English language research (quantitative, qualitative, and mixed-methods) and also hospital-based survey which involved 3 best hospitals of Bangladesh -Dhaka Medical College Hospital, Ahsania Mission Cancer Hospital and National Institute of Cancer Research & Hospital (NICRH) are done to collect the data about breast cancer in Bangladesh. The findings from these surveys or studies are used as reference to portray the current scenario of Breast cancer patients in Bangladesh.
Keywords: breast cancer, treatment, cancer screening, national cancer registry, artificial intelligence

D4 - Health Technology Quality & Risk 1

Addressing The Biggest Challenge Faced by Biomedical Personnel in East African Health Facilities, Accepting the Status Quo

By Deborah Aloyo

Gould Family Foundation, Uganda

Introduction: The Covid 19 pandemic exposed African governments and healthcare providers to the critical gaps and In East Africa, many started the journey to address these gaps by recruiting biomedical engineers (BME), technicians (BMET) and apprentices or creating opportunities for biomedical personnel to act. 14 biomedical staff supported and or funded by the Gould Family Foundation encountered a similar struggle throughout their career. The notion that biomedical personnel will magically repair medical equipment and ensure that all equipment in the health facility is functional once hired is the accepted norm. Surprisingly 12 out of the 14 weren't cognizant of this and were comfortable contributing towards this way of thinking. As a result, biomedical personnel couldn't influence medical equipment technology management at a strategic level that would result in sustainable positive change. Eventually biomedical staff defaulted to a firefighting mentality; troubleshooting and restoring one broken piece of equipment after another leading to a never-ending cycle of repair, demotivated biomedical personnel and a health facility management that fails to acknowledge the true importance of biomedical personnel. **Methodology;** Gaps sustaining the status quo. Biomedical Engineers and technicians do not typically track, measure, and report their performance and or the impact of the work implemented. 5% reported that they met with managers to discuss; essential equipment servicing, preventive maintenance, user training gaps and medical equipment challenges. Furthermore, 8 of the 14 biomedical engineers and technicians were managed by administrators who are not knowledgeable of how quality health care and health outcomes are directly related to biomedical support. To put it bluntly, the majority of biomedical employees are inadequately managed and health facilities don't have biomedical plans. The steps taken to change the status quo were threefold; first, advocating for health technology management through promoting evidence-based management decision-making on medical equipment. Program reporting was streamlined to top management for review of key priorities, indicators for progress and showcasing achievements of the department. Approval of basic spares and service budgets by management during annual budgeting was continuously advocated for using documentation. Secondly, developed a biomedical program based on a facility and equipment assessment done to determine health care service priorities and gaps. Thirdly, continuously mentored biomedical staff on relationships between critical health indicators and how medical equipment support affects them.
Results: User training increased from less than once in a year to at least 5 monthly with 30% reduction in the number of faults reported. Recurring medical equipment purchases lowered by 20% saving funds, and the number of critical equipment serviced increased to 70% of the monthly schedule. In Uganda, 100% of the facilities supported have a budget of $500 monthly for spares allocated. In conclusion, hospitals and their management are in desperate need of biomedical personnel who are willing to disrupt the status quo to improve the health outcomes of patients through appropriate biomedical support.
Keywords: eminent failures of a health system without biomedical support, the notion that biomedical personnel will magically repair medical equipment, fire fighting mentality, demotivated biomedical personnel, the status quo, majority of biomedical employees are inadequately managed, health facilities don't have biomedical plans

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D4 - Health Technology Quality & Risk 1

Comparison of the Performance Test of Reusable Patient Circuit and Disposable Patient Circuit of Ventilator

By Bao Li, Yun-Ming Shen, Si-Wei Xiang and Kun Zheng

Children's Hospital of Zhejiang University School of Medicine, China

Two kinds of ventilator patient circuits are used widely in clinical routine, namely reusable patient circuits and disposable patient circuits. Are they providing the same performance in clinical applications? A comparison of the performance test of these two kinds of ventilator circuits with a ventilator gas flow analyzer is given in this paper. Thirty ventilators were randomly selected to test their performance with these two types of circuits. Then paired t-test method was used to analyze whether the difference in performance test between the two circuits was significant. For respiratory rate, tidal volume and end airway pressure, there were no significant differences between these two circuits (P >0.05). For the airway peak pressure,

the reusable patient circuit was significantly higher than the disposable patient circuit (P <0.05), but the difference in actual value was very small, only about 0.2 mbar which did not yield significant clinical meaning. Therefore, the performance test results show these two patient circuits can be used interchangeably.
Keywords: ventilator, reusable patient circuit, disposable patient circuit, performance test

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D4 - Health Technology Quality & Risk 1

Potential Roles of Medical Physicists and Biomedical/Clinical Engineers in Radiotheranostics

By Cari Borrás

Radiological Physics and Health Services, Spain

Medical physicists (MPs) and biomedical/clinical engineers (BM/CEs) can have a significant role in the discovery, promotion, and implementation of emergent technologies. Yet, their involvement in the evolving field of radiotheranostics is minimal. Why? There are a lot of areas in which their collaboration could have a significant impact in patient care, especially in cancer treatments. The purpose of this presentation is to identify some of the areas of collaboration between MPs and BM/CEs in the field of radiotheranostics; understanding that the work involves other professionals as well, such as radiochemists, radiopharmacists and nuclear medicine physicians, with whom effective interactions are essential at the clinical level. The goal is to develop individualized patient-specific imaging and therapy protocols that will eventually result in improved patient outcome. Among the potential roles of collaboration between MPs and BMCEs are: searching for new radiotheranostic agents, assessing methodologies of radionuclide cyclotron production, designing new radionuclide generators, suggesting and testing biomolecules' radiolabelling techniques, developing new radionuclide detectors and imagers, calibrating SPECT/CT and PET/CT scanners, standardizing activity measurements, evaluating radiopharmaceutical biokinetic distributions, examining clinical diagnostic and therapeutic radiopharmaceutical protocols, determining individualized doses to tumors and organs at risk, combining radiopharmaceutical therapy with external beam and brachytherapy, and optimizing radiation protection. Examples of what these tasks entail will be illustrated. The scientific, technical, educational, and professional challenges faced by MPs and BM/CEs working in basic or applied research, industry, or clinical practice in this emergent field will be presented and discussed; among them, the need for additional training and potential certification changes.
Keywords: theranostics, radionuclides, dosimetry

D4 - Health Technology Quality & Risk 1

Development of Evaluation and Quality Control Protocols for Mammography

By César Yegros, Luciano Benjamín Recalde Carballo and Eladio Quintana

Biomedical Engineering Research Group - National University of Asunción, Paraguay

Mammography is a medical diagnostic study performed by taking a radiographic image directly on the breasts, at low doses of radiation, with specialized ionizing radiation-emitting equipment called a Mammograph. It's the main one for the early detection of diseases of breast origin, which is why it's essential to guarantee the operability and correct functioning of the equipment that performs this study; particularly in low-income countries, such as Paraguay, where at the state level there is 1 mammographer for every 50,000 women, which implies low-quality control of radiation emissions, low access to this health system, and in special to preventive medical check-ups. To guarantee this safety in the mammographic area, it's necessary to establish verification programs and quality controls. To carry it out, this project evaluates its operation and the quality of its ray emission, through controls of physical parameters in its radiation generators, through the measurement of its main parameters and the elaboration of a checklist based on the technical standards established by the local regulatory authority and international standard (IAEA); and the implementation of these techniques and quality protocols for mammographers, in different imaging services, in order to evaluate the control program and the meters to guarantee radiological safety and dose levels for operators, technical service personnel, and patientsThe project is based on the experimental study, through the development, verification and testing with equipment that measures physical parameters (dose, dose rate, KVp, HVL) for mammographers, through the adaptation and implementation of the international standard IAEA

-TECDOC- 1517, for mammography quality control and advice from the local Radiological Regulatory Authority (ARRN). The measurement equipment used was the black RTI PIRANHA® and an own design for measurement of pressure, height and position, for the benefit of users of this equipment in public health in Paraguay. Verifications and controls were carried out on 8 mammographers with the instruments acquired and designed, in public and private institutions in Asunción and the Central Department. 62.5% of them have their parameters within the tolerance ranges. 37.5% worked, but with values above expectations. Its calibration was suggested. It was demonstrated that it is possible to obtain information on the situational status of the mammographs, verify the quality of the image, the dose rate to determine the level of radiation emitted by the equipment and guarantee the radiological protection of technical personnel and users, as well as the scopes of dose adjustments and dose rate, if necessary. With these data it's possible to foresee solutions to avoid unnecessary stops of operation, all with the aim of guaranteeing radiological safety and facilitating decision-makers with the tasks of planning, justifying the renewal or maintenance of mammographs, in a country with scarce and deficient infrastructure and biomedical equipment.
Keywords: breast cancer, mammography, ionizing radiation, quality control

E1 -Digital Health 2

Power of Digital Bridges: Case Studies on Improving Access and Health Equity

By Manish Kohli

Beyond Horizon Health, USA

Despite known, cost-effective interventions to address NCDs, there are significant gaps in access to key programs and services, particularly in vulnerable population groups globally. The current healthcare system is currently unable to efficiently and effectively bridge these gaps due to structural, financial, operational and human resource constraints. Moreover, modern technologies, despite its potential to transform how care is delivered, is underutilized. Ironically, more people in rural areas and in vulnerable groups have access to a mobile connection than they do to healthcare, clean water and a toothbrush. Digital health technology and telemedicine can have a demonstrable impact in improving health inequity and disparities. However, even with pandemic era policy and payor reforms that have now, in many regions, formalized the role of telemedicine in many countries, the pace of technology adoption, especially in rural and remote areas, is slow. Even in the urban slum areas its use is far below the projected potential. Adequate access to a doctor or healthcare facility, insufficient awareness or challenges in accessing telemedicine services due to literacy, language or technological barriers, and lack of availability/access of basic equipment, diagnostics and therapeutics, data and modern decision support systems that can aid in evidence-based clinical decision- making among physicians. With strategic initiatives, such as the Global Humanitarian Network, built on public, private and NGO partnerships, use of digital technology and telemedicine can be accelerated to improve the access to health services, impact outcomes and reduce the burden on tertiary healthcare facilities. There exists a unique opportunity to transform health and access to basic quality, timely care. Using case study examples from around the world including India, Lebanon, Colombia and Ecuador, this presentation will discuss how technology has improved access, and can further improve access, to primary and specialty health services and deliver better patient outcomes and experience. The presentation will also highlight successful results that exemplify public-private-non-profit partnerships to bridge health inequities and disparities. Overall impact areas that will be discussed: ·Better access to primary care and specialty care through assisted telemedicine; ·Improved detection, treatment and control of NCDs; ·Improved awareness, early detection and treatment, and timely referral; Bridging gaps between community, technology and digital healthcare through trained personnel.;Continuity of care and longitudinal health data using electronic health records; Generation of and access to previously unavailable, data to inform development of suitable models for underprivileged, vulnerable and rural communities; Creation of livelihood opportunities through the hiring of field staff from the local community; Reduction of indirect healthcare costs related to travel and loss of daily wages; Decreased need for visits to hospitals due to better, coordinated primary care.
Keywords: case studies, digital health, health technology, vulnerable populations, LMIC, NCDs, outcomes

E1 -Digital Health 2

The Importance of Digital Transformation in Clinical Engineering: Bosnia and Herzegovina Case Study

By Aldin Pirić, Lejla Gurbeta Pokvić and Almir Badnjević

Medical Device Verification Laboratory Verlab Ltd., B&H

Description: The importance of digital transformation (DT) in clinical engineering has become increasingly evident in recent years. Strategic directions towards DT in clinical engineering align with the objectives of UN Sustainable Development Goal (SDG) 3, which calls for accessible, affordable, and quality healthcare services. DT in clinical engineering refers to the integration of technology-driven solutions into the management and maintenance of medical devices. This involves leveraging digital tools such as electronic health records, telemedicine, health information exchange, and the integration of medical devices with data analytics platforms. By embracing DT, clinical engineering can enhance healthcare delivery, optimize patient outcomes, and improve the overall efficiency of medical systems. A culture of innovation and continual improvement is fostered by DT in clinical engineering. Emerging technologies like machine learning and artificial intelligence (AI) can be used to analyze data from medical devices to find patterns, improve performance, and enable preventive maintenance. DT empowers clinical engineers to collect and analyze extensive data from medical devices, enabling them to predict failures, optimize workflows, and make informed decisions. Accurate patient identification and remote monitoring improve safety and reduce unnecessary hospital visits. The integration of AI-based maintenance of medical devices through DT in clinical engineering has the potential to revolutionize healthcare delivery, improve patient outcomes, and create a more efficient and accessible healthcare system. By leveraging historical data and machine learning algorithms, the system can develop predictive models that help clinical engineering departments allocate their resources efficiently, ensuring that the most critical devices receive timely attention while optimizing the utilization of personnel and materials. The successful implementation of DT in clinical engineering in Bosnia and Herzegovina requires a collaborative effort among various stakeholders, including healthcare providers, clinical engineers, technology vendors, and policymakers. Bosnia and Herzegovina has taken steps to support DT in clinical engineering through the establishment of Digital Innovation Hub (DIH) - Its4Health. In line with the United Nations 2030 Agenda for Sustainable Development, which emphasizes the potential of technology to accelerate progress, bridge economic and social divides and build knowledge societies where everyone can enjoy high-quality public services, Its4Health HUB's vision is to support the DT of healthcare and clinical engineering in Bosnia and Herzegovina leading to a system that provides medical services in a way that is safe, transparent and efficient. Its4Health plays a vital role in promoting DT in clinical engineering by providing a supportive ecosystem for the adoption of digital technologies and fostering partnerships among stakeholders. **Conclusion:** In conclusion, DT in clinical engineering, particularly with a focus on AI-based maintenance of medical devices, holds significant importance for improving healthcare services. Collaboration among stakeholders is crucial for successful implementation, and initiatives like the Its4Health HUB in Bosnia and Herzegovina play a vital role in supporting DT by fostering partnerships and providing a supportive ecosystem. Embracing DT in clinical engineering is crucial for advancing healthcare towards safer, more efficient, and patient-centric care.
Keywords: Clinical engineering, Data analytics, Safety, Digital transformation, Medical devices, Artificial intelligence

E1 -Digital Health 2

Optimal Medical Equipment Maintenance System

By Yi-Chieh Lin

China Medical University Hospital, Taiwan

Description: The Clinical Engineering team at China Medical University Hospital and within its Healthcare System considered how to optimize their hospital equipment management system using digital tools, such as AI, to assess History, Maintenance, Risk, and Recall factors. Goal:The CE team expects a more comprehensive and improved equipment management solution with this digital upgrade, benefiting the hospitals, its workers, and its patients. **Results:** Several graphics are provided to demonstrate how the range of factors improves the equipment management system, using automation and intelligence.
Keywords: clinical engineering, equipment management, digital health tools

E1 -Digital Health 2

The Pathomorphology of an Arthritic Hip Joint with Femoroacetabular Impingement – Bone to Bone Contact Predictive Analysis Using a Numerical Method

By Radhakrishna Suppanee, Prudence Wong, Mahmoud Chizari, Ibrahim Esat, Karthig Rajakulendran, Nikolaos Bardakos and Richard Field MD

AMIMechE (UK), Brunel University West London, Uxbridge, UK

Nikolaos Bardakos and Richard Field MD/ The South West London Elective Orthopaedic Centre, Epsom General Hospital, Epsom, UKAim: No optimal therapy is established heretofore for femoroacetabular impingement. The consequence of reducing the alpha angle through surgery towards the progression of hip osteoarthritis (OA) is still unknown (Fairley J et al., 2016). It was reported that 22% of young patients undergoing hip arthroscopy had an onset of osteoarthritis barely in 2 years (Rhon, D.I et al., 2019). The current study is aiming to examine the structural progression of a pre-operative patient specific motion-induced degeneration hip bone (cam-type FAI femoral head) as a function of joint space (gap) and bone to bone contact using a computational and finite element (FE) method. **Methodology:**A three-dimensional (3D) model of the left hip joint of a 41 years old male patient diagnosed with FAI was obtained from pre-operative Computerised Tomography (GE Medical systems/Light speed VCT) data using density segmentation techniques in Mimics 13.1 (Materialise NV). The predictive morphological and physiological contact kinematics resulting from FAI was analysed in Abaqus 6.9 (Simulia Dassault Systems) using a finite element method. IR 90 provocation test (hip flexion to 90°, maximum internal rotation) and FADIR (Flexion, Adduction and Internal Rotation) test were simulated in this study (Thomas Ward et al. 2022) (Lars Hansen et al. 2022). The center of rotation of the femur was translated to 2 mm and 4 mm in order to reproduce the thinning of the articular cartilage that resulted in narrowing the joint space. **Results:**The results of the analysis show that in the presence of osteoarthritis and loss of concavity of the femoral head, the pathomorphology of the cam lesion likely determines the magnitude of damage resulting from abnormal contact stress on the rim of the acetabulum. The femur for the healthy articular cartilage was able to be flexed till 100 degree with an internal rotation of 40 degree until bone to bone impingement happened due to a mild pistol grip deformity. But, it can be observed that with thinning of the articular cartilages, the joint became more and more hypomobile. **Conclusion:**The numerical analysis showed that the loss of concavity of the femoral head not only affected the kinematic of impingement in the presence of osteoarthritis but also determined the extent of damage at the site of impingement. This method may enable surgeons to have a patient specific surgical planning and optimize the osteotomy procedures for cam-type FAI femoral head. **References**:1. Fairley J, Wang Y, et al. Management options for femoroacetabular impingement: a systematic review of symptom and structural outcomes. Osteoarthr Cartil. 2016;24:1682–96; 2. Lars Hansen, et al., Hip joint motion does not change one year after arthroscopic osteochondroplasty in patients with femoroacetabular impingement evaluated with dynamic radiostereometry, Journal of Experimental Orthopaedics, 9, 4(2022); 3. Rhon, D.I et al. The two-year incidence of hip osteoarthritis after arthroscopic hip surgery for femoroacetabular impingement syndrome. BMC Musculoskelet Disord 20, 266(2019); 4. Thomas Ward M.B.B.S. (Hons), D.Phil (Oxon) et al., Arthroscopic Femoral and Acetabular Osteoplasties Alter the In Vivo Hip Kinematics of Patients With Femoroacetabular Impingement, Arthroscopy, Sports Medecine, and Rehabilitation,2022; 4:1961-68
Keywords:bone to bone contact analysis,hip impingement,finite element modeling,osteoarthritic joint

E1 -Digital Health 2

Development and Evaluation of a Virtual Reality Game for Upper-Limb Rehabilitation

By Harsha Bodla

The University of Queensland, Australia

Description: This abstract presents a case study on the development and evaluation of a Virtual Reality Rehabilitation (VRR) game aimed at enhancing traditional rehabilitation therapy for patients with upper-limb injuries. The study focuses on leveraging the Oculus Hand Tracking Software Development Kit (SDK) to create an immersive and interactive VRR experience without the need for VR controllers. The developed VRR game, named “Handy Juice Bar V.2,” replicating a real-life environment underwent a preliminary usability study due to time constraints. **Methods:**Various game development techniques

were used in accordance with Unity 3D that helped formed the base foundation for Augmented Reality (AR) tracking. This included software skills to code specific motions used for hand-tracking capabilities by the patient. The usability cohort study was conducted at the University of Queensland, involving patients with upper-limb injuries such as burns and strokes. Participants engaged in various tasks within the VRR game, including pinching, pulling handles, making hand gestures, and grabbing objects. Performance metrics were collected to assess user engagement and measure the effectiveness of the VRR game. Primary objectives were accomplished through: Evaluate the game's functionality and effectiveness on patient engagement and satisfaction through a usability study of who is suitable for and interested in trying the VRR game; Design and implement Visual Interactions for Hand Grabbing techniques in a VR game configuration; Identify and test substitute methods that diagnose and assess hand rehabilitation within the virtual environment; Initialise a height prompt in the menu stage with options that are inclusive to a wide range of users undergoing upper limb rehabilitation; Implement HF when user is grabbing objects with the incorrect configuration of hands. **Results:**A preliminary study indicated with N = 5 participants, completing a series of tasks by the developed VRR game: 95% of the participants agreed that the VR rehabilitation tasks were fun and engaging; 85% of the patients agreed that their hand movements were represented correctly in the VR environment and 80% agreed that VR tasks will be helpful to their rehabilitation plan; The study findings revealed that lighting conditions significantly influenced VR hand-tracking accuracy. The average completion time for the VRR game ranged from 8 to 12 minutes, indicating an appropriate duration for a rehabilitation session. **Conclusions:**The hand-tracking-based VRR game proved to be a valuable supplement to traditional rehabilitation therapy for upper-limb injuries, providing increased engagement and higher patient satisfaction. While Haptic Feedback (HF) was implemented for VR controllers, further investigation is recommended to explore the implementation of haptic feedback exclusively for hands within the VRR environment, aiming to enhance the immersive nature of the VRR game. Digital Health Topic: This study aligns with the theme of Digital Health, showcasing the application of virtual reality technology in the context of rehabilitation therapy. By leveraging advanced software development kits and hand-tracking capabilities, the VRR game offers a promising avenue for enhancing clinical engineering and health technology management in rehabilitation settings.
Keywords: virtual reality, upper-limb rehabilitation, augmented reality, digital health, virtual reality rehabilitation

E1 -Digital Health 2

PACS System Implementation on Distributed Infrastructure During First Steps of Health Organization Digitalization

By Alessandra Casaroli, Gianluca Rocchi and Davide Cecchetto

Fondazione Don Carlo Gnocchi Onlus, Italy

The interaction between clinical engineering and information systems is becoming extremely important to support the digitalization of the healthcare sector. This work discusses the way to implement a PACS system on a distributed infrastructure. Project scope is represented by eight healthcare facilities located in five Italian regions. Firstly, different workflows have been analysed; this requirement is important to evaluate some parameters: applications status, volumes produced and the integrations between systems. This result underlines an uneven situation in which a centralized RIS system communicates with multiple local instances of PACS applications. At this point, the infrastructure of new PACS system can be defined, in which: redundant central server will be implemented into the CED of star center and server caches, a sort of 'mini-PACS', will be located within each individual other health facilities. Connectivity tests were implemented during the second analysis phase but to proceed from an operational point of view it was necessary to identify the star point and size, in term of byte, the studies produced during clinical activity. Connectivity evaluation between centers both in upload phase and download phase has paid attention to the bandwidth upgrade for some structures. The other result obtained, made it possible, to evaluate the installations of two central server on cloud so, to support this hypothesis has been started a new connectivity test phase between FDG structures and FDG cloud, at the end it is possible to say that the two central servers will be implemented on cloud. Last phase of the analysis was focused on evaluating the consistency of the data archived on the current production systems to understand their quality, basic requirement for planning their import into the new system. The result revealed critical issues present on current systems, remediation that will be performed and the necessity of revisions about integrations especially when RIS system and PACS system aren't product to a single supplier. Conclusion of analysis phase and consolidation of produced documentation guided the software selection with six actors. Preliminary meetings and sharing materials have allowed FDG to incorporate draft offers on which to start working and evaluate a project in which timeline is not less than five years. Three potential partners were selected, invited to create a demo of their product on an appropriate mapping realized by FDG both in the clinical and research fields. The opinion of doctors during the demo phase allowed the final choice of the project partner. The start of works, preceded by the segmentation of dedicated VLANs and

implementation of reservation rules, was preceded by the contractual phase, managed in parallel with the renewal of a part of radiological fleet, this non-trivial aspect has allowed the perfect synergy between the two parts of FDG that optimizing times and costs as much as possible and leading to a synergistic approach between the IT area and clinical engineering that isn't so widespread and obvious yet.
Keywords: PACS, infrastructure, digitalization, cloud, synergy

E1 -Digital Health 2

GreenChain – A Solana Blockchain-based Management Platform for Bioengineering Academic Areas

By Oana Geman

Stefan cel Mare University and Greensoft, Romania

We propose a management platform solution based on Solana blockchain and Agile software methodologies, for academic areas (for example, for the dissemination of doctoral theses in biomedical field). Solana is a web-scale distributed blockchain that provides fast, secure, scalable data transactions and development environment for decentralized applications. It uses specific algorithms which allow transaction transfer to scale efficiently with the bandwidth of the supporting network, and excels in all areas of blockchain: security, scalability, and decentralization. Technically and infrastructurally, the system can support an upper limit of 710000 TPS over a standard Gb network and 28.4 million TPS over a 40 Gb network. A technical diagram of GreenChain is provided; a management platform solution for doctoral theses and contracts based on the Solana blockchain. An overview of the the general stages in the development process of GreenChain is provided. From Planning, Control, Construction to Transition, with major stages in the testing process described. Also, the GreenChain software development flux is shown. We gracefully thank for the provided financial support through the project "Center for the transfer of knowledge to enterprises in the ICT field – CENTRIC", a project co-financed from the European Regional Development Fund through the Competitiveness Operational Program 2014-2020, competition code POC-A1-A1.2.3-G-2015, SMIS 2014+ ID 119722, contract no. 5/AXA 1/1.2.3/G/13.06.2018, Subsidiary contract no. 18633/05.09.2022 GreenChain GS/GREENSOFT.
Keywords: blockchain, doctoral theses, biomedical engineering field

E1 -Digital Health 2

Medical Devices Nomenclature Systems: Challenges and Considerations in Health-Care Equipment Inventory Management

By Anastasia Daskalaki, Mary Marinou and Aris Dermitzakis

Institute of Biomedical Technology (INBIT), Greece

Equipment inventory is a crucial component of an efficient Health-care Technology Management (HTM) system. To establish an effective management system for monitoring and controlling Medical Equipment (ME), it is necessary to maintain an accurate and continuously updated inventory. The successful implementation of these management systems heavily relies on the use of a clear and consistent nomenclature and codification system. Europe's official nomenclature system for medical devices according to 2017/745 regulation is the European Medical Device Nomenclature (EMDN). However, Global Medical Device Nomenclature (GMDN) continues to be used in the healthcare units, since a reliable mapping between these two systems is not yet available. This study is focusing on challenges associated with maintaining the GMDN nomenclature system and being ready to align it with the EMDN, as an integral part of an HTM system. As Biomedical and Clinical Engineers, our primary focus lies in ME, which accounts for approximately 20% of the total volume of nomenclature codes. The use of GMDN over the past two decades has revealed several difficulties. Access to GMDN is not freely available to all stakeholders. Non-paying users are only able to search and access individual codes on the GMDN Agency website. The structure, hierarchy, and relationships within the system are not openly accessible for consultation and download, preventing the public from using the GMDN hierarchy for further analysis. Updates occur dynamically without a predetermined schedule or notice. Furthermore, there is a lack of briefing on the changes accompanying these updates. In order to assess the difficulties on passing from GMDN to EMDN we conducted a trial on different ME categories, with a particular emphasis on core ME used in the case of COVID-19, such as ventilators, oximeters, patient monitors, defibrillators, infusion pumps, ECGs, and ultrasound imaging systems and compared these categories in terms of GMDN and EMDN terminology.

Our attempt to correlate terms between the two systems yielded several observations:• In certain cases, matching was not feasible due to missing terms or ambiguous definitions in both systems.• Some terms that are not widely used at the international level, pose terminology challenges within the EMDN.• The two systems employ different grouping features, making it difficult to match terms. For instance, defibrillators and electrocardiographs are categorized differently in EMDN and GMDN.• Most of the ME we examined falls within EMDN' Z category of "Medical Equipment and Related Accessories and Materials," which comprises 1,137 bottom-level terms out of the total 5,508 terms.• The lack of detailed descriptions for bottom-level terms in the EMDN system complicates the process of achieving accurate matching.• GMDN system utilizes a greater number of specialized categories compared to EMDN, resulting in multiple GMDN codes often corresponding to a single code in EMDN.These observations underscore the complexity associated with the transitions from GMDN to EMDN, highlighting the necessity of mapping effort that WHO has been engaged to provide, towards a universal coding system.
Keywords: medical devices nomenclature systems, healthcare technology management, GMDN, EMDN

E2 - Health Technology Management (HTM) 2

Best Practices in Medical Equipment Purchasing

By Mery Vidal, Joe Mochcco, Jesica Coronado and Maria del Rosario

AUNA, Peru

AUNA is a Peruvian group of private hospitals and medical centers founded in 2008, which mission is to transform the healthcare experience and vision, to be the leader and referent in Latin America with a people-centered care. Currently, AUNA has more than 25 facilities in Perú, Colombia and México, more than 2000 beds, 15,000 employees and it is one of the top healthcare operators in Latin America. The Clinical Engineering (CE) Department was created in 2010 to manage the medical equipment from all AUNA´s facilities. In 2019, the Medical Equipment Purchasing area was created in Peru with the objective of: Promote AUNA's technological leadership through the incorporation of new technologies aligned with the future vision of each business unit. In almost five years the area has bought more than USD$ 40M medical equipment, 1320 and has saved more than $2.5M primarily in Peru, since 2021 in Colombia and since 2023 in Mexico.As part of our 2023 Plan, this year we performed a Global Benchmarking to validare and to update our purchasing strategies and service level agreements. We interviewed 77 participants from 21 countries and 04 continents around the world. Participants were hospitals, medical equipment suppliers, leaders in clinical engineering areas and referent organizations. The main purchasing strategies opportunities were: Seeking strategic alliances with the main suppliers (15%); standardizing technologies by type of center (9%); group needs to buy by volume (7%); actively exploring the market (6%). On the other hand, the ones related to service level agreements were: Negotiating after-hours service (30%); Establishing non-compliance penalties with the evaluation of future purchases (12%);Ensuring spare parts delivery times (6%). Besides the benefits that we obtain for AUNA company as part of this Benchmarking exercise, it is important to highlight the importance of being connected with our peers around the world, knowing their strengths and opportunities, and maintaining active communication that allows us to continue growing not only as a company itself but also as a community and country. These results will be also presented in one of Peruvian Association of Clinical Engineers (ASPIC) webinars.
Keywords: purchasing, networking, HTM

E2 - Health Technology Management (HTM) 2

Healthcare Technology Management in Anguilla

By Kenichia Charles

Health Authority of Anguilla, Anguilla

The Health Authority of Anguilla has a main hospital – the Princess Alexandra Hospital, three district health facilities as well as a senior citizen's home. The organization recently invested in the procurement of much needed medical equipment and facilities for improved patient care and healthcare delivery for the citizens and visitors on the small island of Anguilla. Up until only about two years ago; a preventative maintenance program initiated when the organization recruited a biomedical engineer for the proper maintenance of its healthcare devices. An inventory was initially created of all equipment found within all the health facilities of the organization. The medical devices found underwent initial evaluation to determine their current relevance and operation. Subsequent to the identification of the types of equipment, the institution was encouraged

to invest in a variety of test equipment. This test equipment was used to check and verify that current equipment was within their tolerances. End of life devices were decommissioned, and a significant portion of equipment underwent repairs through the replacement of parts and accessories. Other factors which determined whether equipment continued to be used included: accessibility to spare parts and consumables. A major breakthrough was the identification of the ongoing risks associated with the use of infusion pumps – air embolism, near misses, over infusion and under infusion. Resultantly, an infusion device policy was developed, and all stakeholders were sensitized during its implementation. The outcome of this resulted in the removal of some models of infusion pumps which were deemed unsafe for use and the purchase of global market approval infusion devices safe for patient use. The facility saw a reduction in the reported incidents associated with infusion pumps usage hazards and risks. The role of biomedical engineer entailed a lot of end user training of the new equipment procured as well as retraining as staff changed over time. This was done periodically to ensure patient and end user safety with the usage of new and continuing medical devices. There was also an investment in the proper labelling for devices so that end users as well as technical staff were aware of the current status of equipment. There was also oversight of ongoing contracts for major assets within the facility which included imaging, dialysis and laboratory equipment. Contractors were notified as soon as possible where equipment may have failed as well as when another preventative maintenance was due. **Conclusion:** The institution currently continues to undergo the standardization of equipment for interoperability where possible as well as the financial benefits for the health facility. The implementation of the preventative maintenance program allowed for the significant reduction in equipment downtime. As a result, more medical devices, although limited in quantity, were available for use by clinicians when needed. Another major outcome was also the encouragement of staff to stay abreast of the developing trends in healthcare technology and to play a pivotal role in the integration of those technologies into our health facilities on island.
Keywords: health technology management, preventive maintenance, infusion device policy

E2 - Health Technology Management (HTM) 2

Identifying the Strategic Management Issues that Impact Preventative and Corrective Medical Equipment Maintenance Practices at the Eric Williams Medical Sciences Complex of the North Central Regional Health Authority in Trinidad and Tobago

By Paul Taylor

Health Sciences Faculty, University of Trinidad and Tobago

Background:The objectives of the research were two-fold; firstly, to identify the strategic management issues impacting medical equipment preventative and corrective maintenance practices at the Eric Williams Medical Sciences Complex (EWMSC) and secondly to provide recommendations to strengthen medical equipment maintenance practices at the EWMSC. **Method:**A qualitative, retrospective, exploratory survey design approach was used. The qualitative research approach is used when the subject to be investigated requires in-depth analysis that would not be revealed in a quantitative study. In order to obtain the information for analysis two data collection methods were employed; face-to-face interviews with key informants and review of documents of the organisation relevant to the subject being researched. **Results / Findings:** Having gathered data from both the face-to-face interviews as well as the secondary data sources, there were connecting themes emanating from the results. The information in the secondary data sources generally supported the information gathered during the face-to-face interviews. Additionally, the secondary data sources provided deeper exposure and insight into the issues uncovered during the interviews. The emerging themes: A. Staffing and staff development issues; B. Lack of spare parts and associated issues; C. Performance and execution of preventative and corrective maintenance; D. Outsourcing and In-house dilemma. **Conclusions:**The study fulfilled its primary goal of providing an understanding on how maintenance practices were impacted by strategic management issues. It provided the connectivity between policy and practice or lack thereof through the identification of actions or inactions throughout the organisation. The study also served to sensitise senior management of the challenges affecting maintenance.
Keywords: clinical engineering, equipment maintenance, capacity building

E2 - Health Technology Management (HTM) 2

Methodology to Define the Period of Test Performs in Medical Equipment Using Control Chart Method for Metrology Standards

By Juliano Martins and Renato Garcia

Instituto de Engenharia Biomedica UFSC, Brazil

In the last decade, there has been a worldwide trend toward the prevention of adverse events in order to increase patient safety in healthcare facilities. In Brazil we can cite the National Program for Patient Safety, which proposes a set of measures to prevent and reduce the occurrence of incidents in Health Care Establishments. Therefore, the Ministry of Health - MoH published the RDC No. 36, which establishes actions for patient safety in health services. The Clinical Engineering - CE has its role to perform in this scenario, developing and/or suggesting improvements in standard operating procedures - SOP; conducting training for users of Health Technology; inspecting the infrastructure and management and quality control of the Health Technology used. One of the quality indicators of Health Technology used by the CE is the performance test. The validity period of the Health Technology test has always been a matter of doubt, even after the publication of IEC 62353 - Recurring Test. Even following the deadlines determined by the standard or by the Technology manufacturer, it can still be susceptible to hidden flaws in the time between tests. In the laboratory of Metrology in Health of the Biomedical Engineering Institute of the Federal University of Santa Catarina, Brazil-IEB-UFSC, to meet the requirements of ISO/IEC 17025 (item 7.7.1.d "use of check standards or working standards with control charts, where applicable"), the methodology of periodic verification (control chart) is applied in the patterns used for testing. It consists in recording values of signals simulated by these laboratory standards and comparing them with the values read by some verification control instrument. Example: You simulate values, defined in SOP, in the Pulse Oximetry standard - OXP compare it with the value read in a pulse oximetry monitor. In the SOP, the error limit is defined; if the reading exceeds the limits, an investigation is started to verify where the failure is. This is not a test or calibration, but a simple monthly verification of the laboratory standard, where the standard's performance between calibrations and during its useful life is quickly registered and monitored. This same methodology the CE can use in the Health Technological Management - HTM, in Health Care Facilities. For example, the CE team, during their monthly preventive maintenance activities on pulse oximeters, can also register the oximetry measurements presented in the equipment that are generated by the OXP simulator. With the implementation of this methodology, the EC, in addition to improving HTM traceability, allows, after a period (suggested 1 year, or the current limit between tests), to analyze the history of recorded measurements and adjust the period between tests. Helping to predict occurrences of failures to better define the moment of intervention in the HTM, either in maintenance or in the definition of obsolescence. This methodology improves POPs in the management of HTM and may allow the reduction of adverse events and contribute to patient safety.
Keywords: calibration, verification, traceability, reliability

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E2 - Health Technology Management (HTM) 2

Reinforcing MoH and Private sector BMET Capacity in Difficult Conditions Set Up: Case of HAITI

By Emmanuel Kouemo Tchokodjeu, Ziad Hamze and Clerve Ovil

United Nations Office for Projects Services, Haiti

Context: During the last 2 years Haiti has been facing multiples crises (political, economic, social, educational, natural, sanitary) leading to the country isolation 'de facto' as many developed country for security reasons emitted notices to warn, to prevent their citizens and obviously their experts/ engineers from travelling to HAITI. Our experience and other Project lessons learnt indicate that 70% of BMET in public and private hospital have not received proper BMET training and there are very few initiatives for BMET proper training. As the country context becomes increasingly difficult the few local BME experts are leaving the country thus creating a huge void with significant impact/ delay in MoH activities, health related Projects. We faced such situation in several Project these last two years, and we had to be very agile in order to achieve projects objectives and accelerate the local BMET replacement process in order to fill the void created by the departure of many local experts. **Objectives**: Providing BME services (installations Works, Medical staff capacity building…) to empower beneficiaries hospital staff and increase the quality/quantity of cares production. **Strategies**: Reinforcing the local company's capacity by involving our team in capacity building / Redaction of quick user guide in creole / Facilitating through our Project the link between manufacturer and local companies. **Results:**Health facilities: Medical equipment properly installed,Locals companies: Enhanced expertise in specific technologies such as sterilization, lab analyzers, ICU monitoring devices , direct access to manufacturer and field services level training for local technician Capacity building: Medical staff

and BMET. Success factors:UNOPS Technical team Involvement in quick user guide redaction/ Link between manufacturer and local companies team/ Capacity building for all medical staff / intensive Capacity building for BMET.Next steps: • Develop through our projects more collaboration with manufacturer of Respirators, Digital Imaging, Oxygen Plants, Dialysis… in order to have regular training sessions for BMET • Designing an Academic BME curriculum with local engineering school and medical school to train future clinical engineers.
Keywords: BMET, capacity building, local companies

E2 - Health Technology Management (HTM) 2

iSUB: A Proposal of an Indicator for Use in Medical Equipment Replacement Planning

By Gustavo De Castro Vivas and Fernanda De Carvalho Vieira

EBSERH, Brazil

Introduction: Currently, one of the greatest challenges in the management of medical equipment is making decisions regarding the replacement of these devices, due to the limited financial resources available. Often, replacement decisions are made reactively, considering only factors such as the age of the equipment, malfunctions, or subjective criteria. This can result in acquisitions that do not adequately meet the actual needs of healthcare delivery organizations (HDOs). It is essential to look for tools capable of facilitating and systematizing the process of equipment replacement selection and prioritization, taking into account other existing demands. **Objective:** In this context, a model called "iSUB indicator" (Replacement Index) has been suggested, which consists of using objective variables extracted from most asset management software and based on available technical literature. **Methodology:** A case study was carried out to describe the tool used in the evaluation of the replacement of medical equipment in a teaching hospital. Secondary data were used, with specific coding to categorize corrective maintenance (failure cause codes - FCCs), extracted from the computerized maintenance management system (CMMS) adopted by the hospital, with data up to December 2022. The parameters selected for the model were age, failure rate, maintenance accumulated costs, and severity of harm by equipment. These parameters were evaluated using a matrix scoring system, generating results on a scale of 0 to 10 after necessary normalization. The following intervals were adopted: equipment with iSUB < 4 (green group), at first glance, do not indicate the need for replacement; equipment with iSUB ≥ 5 (red group) there is strong evidence that may indicate the need for replacement. The intermediate range (yellow group) may require a more detailed analysis to determine whether the equipment should be part of the short or medium-term replacement plan. Results and Discussions: The iSUB methodology was applied to an inventory of 2,229 pieces of medical equipments. The result was an ordered, non-exhaustive list of devices that need to be replaced. Approximately 90% of the equipment obtained iSUB < 4, indicating no need for replacement, while only 5% showed a strong recommendation for replacement (iSUB ≥ 5). The quality of maintenance work order data is a crucial factor for the model. Therefore, a CMMS is a prerequisite for both creating this indicator and other types of studies. **Conclusion:** The iSUB methodology can be adopted by any HDOs that manages medical equipments through a computerized system and has access to the data of the variables used in the proposed model. This model allows clinical engineers and health technology managers to make more accurate decisions regarding the renewal of medical equipment based on clear and objective evidence, classifying and identifying technologies with the greatest potential for replacement.
Keywords: clinical engineering, medical equipment replacement, medical equipment management, objective decision-making

E2 - Health Technology Management (HTM) 2

Monitoring the Rate of Decay of the Level of Liquid Helium in an MRI

By Bruno Roma

Associação Brasileira de Engenharia Clínica, Brazil

Magnetic resonance imaging (MRI) equipment uses liquid helium to keep its superconductors at very low temperatures, so that it is possible to generate a strong magnetic field, necessary for the signal acquisition system. To keep liquid helium at a very low temperature, an advanced cryogenic cooling system is required. These systems may present some expected loss of liquid helium, this loss needs to be monitored to ensure the proper functioning of the equipment. The equipment in this case study has a maximum expected loss of 1% every 15 days, according to the manufacturer's information. This article aims

to present a case study of the monitoring of the rate of decay of the level of Liquid Helium (RDLLH) of an MRI equipment installed in a hospital in Brazil. **Methodology:** Several liquid helium level measurements were performed during the period from October 2017 to June 2023. RDLLH was calculated between measurements for comparison with the expected rate of 1% every 15 days. **Results:** at the beginning it was possible to identify that the equipment presented an average loss of 0.68% in the level of liquid helium every 15 days. In 2018, 26 measurements were performed, with an average RDLLH of -0.65% every 15 days. During the 2018 measurements, we noticed 7 measurements in which the RDLLH was equal to or greater than 1% every 15 days, which represents 26.9% of the samples. However, it was found that 5 of the 7 measurements that presented a rate equal to or greater than -1% were performed with an interval of less than 7 days. It is possible the shorter the measurement range, the greater the inaccuracy of the measurement of the helium level by the equipment. This led to disregarding measurements with an interval of less than 7 and recalculating some points. In 2019, 19 measurements were performed, with an average RDLLH of -0.71% every 15 days. Only one measurement had RDLLH equal to or greater than -1%. In 2020 we had 31 measurements, mean RDLLH of -0.81% every 15 days. There were 2 measurements with RDLLH greater than -1%. In 2021, 15 measurements were performed, with an average RDLLH of -1.19% every 15 days. There were 7 measurements with RDLLH equal to or greater than -1% every 15 days. Over the course of the 2021 measurements it was found that RDLLH was higher than expected. The manufacturer's technical assistance was triggered by the Clinical Engineer who evaluated and indicated the replacement of the coldhead. The coldhead was replaced in January 2022. In 2022, 11 measurements were performed, with an average RDLLH of -0.68% every 15 days. Only one measurement had RDLLH equal to or greater than -1%. **Conclusion:** It is possible to verify that the monitoring of TDNHL was effective and ensured the rapid detection and consequent resolution of the failure, as verified in 2021. Without correct monitoring of the RDLLH, it is not possible to certify whether the loss of liquid helium is in accordance with the manufacturer's recommendations.
Keywords: Monitoring the rate of decay of the level of Liquid Helium, MRI, magnetic resonance imaging

E2 - Health Technology Management (HTM) 2

Ensuring Electrical Safety Systems in an MOH Hospital in Mali

By Kelly Aldjouma

Ministry of Health, Mali

Description: The interest and importance of electrical safety is based on the prevention of electrical risks and particular attention must be paid to protection against electric shocks in a hospital environment, the protective measures must be closely linked to the premises and the setting. earthing, especially the earthing of the masses (safety measures specific to hospitals) and that the standards relating to this are observed: Level of criticality of activities according to the services; Classification of premises; Electrical class of appliances; Permissible leakage currents. The objective of this study was to take stock of the electrical installations of the Bamako Dermatology Hospital in order to determine the various anomalies and failures and to propose the necessary solutions to ensure and maintain hospital-wide electrical systems safety. The BME (CE) Department within MOH Mali was asked to both verify the electrical safety at the MOH Dermatology Hospital and to recommend how electrical systems could be improved to assure overall hospital performance. Goals and those that will benefit: Dermatology Hospital staff, patients, and equipment **Results:** 1. Create a General low voltage distribution panel (TGBT) which is the central distribution point composed of:boxes and cabinets; protection organs; measuring and monitoring devices;control and communication modules; low voltage surge arrester; differential circuit breakers; protection of distribution boards; special differential protections of fire safety equipment; the fuses; Emergency stop box located outside. 2. Create Compacts and distribution boards at the level of the various buildings. 3. Earth rods. 4. Lightning rods.
Keywords: electrical safety, medical equipment, MOH hospitals

E3-Health Technology Assessment & Innovation 2

Barriers and Facilitators in Regulatory Processes: Improving Health Innovation in Peru and European Union

By Rossana Rivas, Luis Vilcahuaman, Andres Diaz Lantada and Carmelo De Maria

Universidad Peruana Cayetano Heredia, Peru

Sharing of best practices in the Biomedical Engineering field as well as harmonization of medical device regulations are two actions which can foster universal health coverage and increase the access healthcare technologies [1]. "Public Health

Emergency of International Concerns", such as the recently formally ended COVID-19 pandemic, have demonstrated the importance of harmonization, and coordinated actions, because even high resource settings can be found unprepared due to lack plans, resources, competences. Furthermore, differences in regulations can hinder the spread of innovations among different countries. In this paper we analyze barriers and facilitators in regulatory processes, through a comparison between Peru and European Union. As a specific case of study, we will present NATBRE, an innovative mechanical ventilation device, developed in Peru after the impulse of COVID-19.Indeed, Peru is the country with the highest number of COVID-19 deaths per 100,000 population (Johns Hopkins University, 2021). In other side, the country is among the 40 countries with the highest burden of tuberculosis and multidrug-resistant tuberculosis globally (D. Dilas et. al, 2023). Some characteristics of Peruvian healthcare system are limited infrastructure capacity, limited number of intensive care unit (ICU) beds for emergency preparedness, lack of oxygen in case of emergency pandemics, etc. (M. Ramirez et. al, 2021). NATBRE is a negative pressure mechanical ventilation device applied to the user's chest. It is easy to use, low cost, portable and non-invasive, it's aimed to care for patients between 35 and 50 years of age with COPD caused by Covid-19 or tuberculosis. The design is based on computer-simulated mathematical models and aligned with electrical safety, ventilatory therapy, ergonomics, materials, and biosafety standards. Next steps include strengthening the tests aligned to international standards and regulations and incorporating clinical tests. The comparison between EU and Peru will be carried out by exploiting the functionalities provided by the UBORA platform, a unique framework for designing Open-Source Medical Devices, according to European Union (EU) Medical Device Regulation 2017/745 [2].

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Keywords: health technology innovation, regulation, clinical engineering

E3-Health Technology Assessment & Innovation 2

Design a Mobile Application for Maintenance of Hemodialysis Machines using Flutter Framework

By Badria Ibrahim Eisa Idris and Dr. Mohammed Yagoub Ismail

Sudan University of Science and Technology, Sudan

The hemodialysis machine is used as an artificial kidney to perform the hemodialysis process; and it is considered as one of the life-supporting devices. There are many biomedical engineers in Khartoum state (Sudan) work in dialysis centers with various years of experiences starting from 6 months to a year up to more than 10 years, training workshops are for one engineer from the hospital to each, and it does not cover all engineers or all types of different machines, so we found them resorting to consulting with each other about the problems and the common daily malfunctions that are repeated usually, and there is suffering in using the service manuals due to the difficulty of the language in some of them and the abundance of information in it and the importance of time for the patient who is waiting for his machine to be processed as soon as possible, it was necessary to find a solution to facilitate this matter for the engineers. Mobile applications had recently spread for their usefulness in several aspects especially in healthcare, so the aim of this project is to use one platform of the frameworks and developed to design mobile application for the maintenance of hemodialysis machines that help biomedical engineers, especially juniors in their daily work, using flutter frameworks and dart language; which is a hybrid language that has one single code for Android, desktops and iOS. Using flutter framework here gave the app simple UI with single code for multi-platform. "HDservice App" was designed and built with information about machines' malfunction and how to solve them, it works without access to the Internet access. As the development of technology especially mobile application in healthcare; here in this article mobile applications proposed to give and provide a huge services to support training programs and maintenance information for biomedical engineers about hemodialysis machines and water treatment system. Flutter with its classes that made addition of new information easy and that was the starting point of knowledge and exchange of experiences. The real needs of traditional training program have decreased, the way of receiving information here was more efficient and that caused the experiences increased between engineers. In addition, the app was a guideline as the same as service manuals and more so that reduced faulty steps in maintenance and reduced the wasted time during looking for solution. As for this application, we are now in the process of adding other services to it, such as the ability to download service manuals from a direct link saved in it, and also a channel containing additional explanation videos can be added to increase knowledge. The last step is to upload it to the Google store so that it is available to all engineers inside and outside Sudan.

Keywords: hemodialysis machine, maintenance, mobile application, flutter framework

E3-Health Technology Assessment & Innovation 2

Contrast-Enhanced Mammography in the Early Diagnosis and Screening Of Breast Cancer

By Greta Puleo, Greta Bortolaso, Umberto Nocco, Roberta Pavesi and Poala Colombo

ASST GOM Niguarda - Lombardy Region, Italy

Objectives: Breast cancer is a widely diffused disease – the most diagnosed cancer in women in accordance with "the number of cancer 2002" national report, with 55.700 new diagnosis in 2022 in Italy. MRI imaging is at this very moment considered the golden standard for such diagnosis, but its use in breast cancer screening will result in a shortage of scanner availability for other major diseases. A new method to detect breast cancer is to be found, and CEM (Contrast Enhanced Mammography) is remarkably promising as an alternative to MRI with contrast agent. Such being the context, a Health Technology Assessment evaluation was conducted in 2023 with the aim to evaluate the potential impact of the introduction of CEM (Contrast-enhanced mammography) in clinical practice, assuming the institutional perspective. Moreover, since no fare is available in the Italian health care price list at the moment, the HTA evaluation can help in defining the correct pricing for such procedure. **Methods:** The EUnetHTA Core Model and additional specific criteria from the HTA program of the Lombardy Region were used to conduct this evaluation. The EUnetHTA Core Model dimensions were deployed considering: i) literature evidence, to define efficacy and efficiency indicators; ii) consultation of experts from areas concerned by the subject iii) quantitative tools useful for the clinical pathway economic evaluation, and the definition of the organizational and accessibility advantages, in terms of time and procedures savings. MRI was used as a comparator for this evaluation. **Results**: Literature reviews showed that CEM presents indications similar to those of the comparator, with which it also shares the high sensitivity and specificity. CEM can combine digital mammography with the intravenous injection of contrast agent using the dual-energy technique and allows breast evaluation with diagnostic performance similar to MRI. Additionally, CEM is characterized by higher patient acceptance and shorter exam time; thanks to the greater availability of devices in the area and lower contraindications, CEM ensures greater equity of access. From the organizational point of view, results showed that use of CEM for identified indications would allow the release of an important asset used in different medical fields such as MRI, currently subject to long waiting lists. From an economic perspective, compared to the gold standard, the CEM has lower acquisition, installation and maintenance costs. **Conclusion**: Given the above, the use of the CEM for the eligible population and the identification of a correct reimbursement rate would allow the RHS (Regional Health System) to make savings compared to the use of the RM with comparable detection rate for breast cancer to that now possible.
Keywords: health technology assessment, multidisciplinary approach, breast cancer, contrast-enhanced mammography, CEM, MRI

E3-Health Technology Assessment & Innovation 2

Breaking the Diagnostic Barrier in Tuberculosis Diagnosis Using an Innovative Cough Aerosol Sampling Device for Individuals with Minimal Sputum Yield

By Ra'Eesah Ismail, Keertan Dheda and Sudesh Sivarasu

University of Cape Town, South Africa

Tuberculosis (TB) disease resulted in the one of the highest number of deaths due to infectious disease in 2021, second only to COVID-19. Pulmonary disease is caused by infection with aerosolised Mycobacterium tuberculosis, which enters the respiratory tract and travels into the lungs. Bacteria are aerosolised by infected people by coughing or sneezing. If left untreated 50% of TB cases result in fatalities. With approximately 10.6 million cases and 1.6 million fatalities the TB endemic remains the subject of constant research. This includes developing methods to intercept transmission pathways via testing and preventing infection of highly communicable diseases. Identifying and treating people spreading the disease via respiratory droplets is crucial to infection prevention. TB diagnosis is via sputum smear microscopy and culture confirmation. This requires patients to produce sputum samples by coughing from deeper parts of the lung. Sputum samples are widely used, but producing the required sample quantity can be difficult for 15% of patients. Since other diagnostic methods are costly/ time consuming many cases go undiagnosed in under resourced settings. Consequently, developing countries like South Africa have the highest disease burden. A solution for sampling sputum-scarce patients in these settings is a step in the direction to end the TB endemic where it is most prevalent. Current solutions include cough aerosol sampling systems (CASS), typically used more as research tools than mass screening devices. While these devices are effective in capturing

cough aerosols, they require bulky equipment and difficult setup. This study aimed to design and develop a novel device for mass cough aerosol sampling in low resource settings. The CASS device design constituted three main components: the physical form of the device, a substrate on which to collect the aerosolized bacteria on and a means by which to induce a continuous airflow. Design included CAD modelling and 3D printing of the physical shape to produce a wearable device to be worn for the sampling time. Comfort, transportability and disposability were important considerations in this part of the design. The catchment substrate had to be non-toxic and compliant with diagnostics such as Nucleic Acid Amplification Testing (NAAT)/ culture confirmation. Properties like hydrophilicity & biocompatibility were prioritized to increase surface adhesion by bacteria. Continuous airflow induction in the device was a means to ensure maximum contact with the substrate by cough jet streams to maximize bacterial capture. This attachment had to be lightweight, and battery operated to meet setting constraints. The final design took the form of a mask, fully 3D printed in Poly Lactic Acid. Within the mask was a Poly Vinyl Alcohol substrate with confirmed ability to collect Mtb. aerosols from real patients by NAAT. The mechanism to induce continuous airflow was an extractor fan placed in the mask housing, with an exterior battery pack connection to mitigate the need for a continuous power supply during sampling.
Keywords: TB diagnosis, medical device innovation, increased access

E3-Health Technology Assessment & Innovation 2

Clinical Effect Analysis of Different Absorbable Hemostatic Material Usage in Laparoscopic Resection of Lung Cancer: A Propensity Score Matching, Retrospective Real-World Study

By Yanjun Pan, Jing Sun and Jingyi Feng

Zhejiang University School of Medicine, Hangzhou, Zhejiang, P.R. China

Background: There are various types of absorbable hemostatic materials, and they are suitable for a wide range of surgical procedures. How to properly evaluate their use effects and benefits is a challenging problem. This study evaluates the safety, efficacy and economic outcome of using different methods of hemostatic materials in laparoscopic resection of lung cancer. **Methods:** This was a propensity score-matched, retrospective real-world study using clinical information system data from a tertiary hospital in Hangzhou, Zhejiang, P.R. China. The data of inpatients from July to December 2019 and July to December 2020 were retrospectively analyzed. The patients were divided into two groups according to the use of hemostatic materials: ① combined use group (regenerated oxidized cellulose hemostatic gauze and gelatin sponge), ② single use group (regenerated oxidized cellulose hemostatic gauze). The safety, efficacy, and economic outcome of the two groups were compared. **Results:** In the propensity score-matched cohort, a total of 1038 patients were included, of which 519 patients used two kinds of hemostatic materials during operation, and 519 patients used a single hemostatic material during operation. Compared with the combined use group, the mean cost of hemostatic materials in the single group was reduced (MD = -322, 95%CI [-383, -260], P<0.001), and the median cost of total hospitalization was reduced (MD = -2213, 95%CI [-3324, -1101], P<0.001), median length of stay increased (MD = 1, 95%CI [0, 1], P<0.001) , the proportion of patients using hemostatic drugs decreased (RD= -0.054, 95%CI [-0.098, -0.009], P=0.019), and the drainage volume in 48 hours after operation increased (MD = 30, 95%CI [0, 60], P =0.040); no statistical differences were found between the two groups in the median operation time, intraoperative blood loss, major blood loss (>500ml) ratio, intraoperative blood transfusion ratio, bloody drainage fluid ratio, secondary operation ratio, and postoperative inspection indicators. **Conclusions:** The use of hemostatic gauze alone in laparoscopic resection of lung cancer can reduce hospital costs, with no significant differences in performance in terms of safety and efficacy. Therefore, on the premise of ensuring the therapeutic effect, it may be a more economical choice to only use hemostatic gauze in laparoscopic resection of lung cancer.
Keywords: absorbable hemostatic material, laparoscopic resection of lung cancer, real-world study, propensity score matching

E3-Health Technology Assessment & Innovation 2

A Bariatric Clinic Development at a High Specialty Hospital in Mexico

By Stephanie Y Durán-Negrete, Lizbeth Guzmán-Canizales and Martha R Ortiz-Posadas

Universidad Autónoma Metropolitana Iztapalapa, Mexico

In Mexico, obesity affects more than 75% of adults, and 36% of the child population. It has the first place worldwide in childhood obesity, and the second in adults. About 34% of obese people are morbidly obese, the highest degree of obesity. The High Specialty Regional Hospital of Ixtapaluca (HRAEI, its Spanish Acronym), is a tertiary care public institution with 348 hospital beds, 20 surgical specialties and 21 clinical specialties. The Hospital attends population from four states at the East of the Mexican Republic: Mexico, Hidalgo, Puebla, Tlaxcala, and the East of Mexico City. In this geographical region, there is no specialized clinic to treat obesity, and therefore the HRAEI is interested in having a bariatric clinic among the medical services it offers. A bariatric clinic provides a comprehensive treatment by assessing and managing patients who have morbid obesity through both surgical and non-surgical interventions. In this sense, the objective of this work was to define the technical, operational, and economical criteria to develop a bariatric clinic, and provide comprehensive care to the population of the HRAEI's geographical region of influence. For developing this project, we initially made an epidemiological analysis of type II and type III obesity in adolescents and adults, who present one or more comorbidities (heart disease, diabetes, hypertension, gallbladder disease, osteoarthritis, sleep apnea, among others) in the region of influence of the Hospital. Then, we did a SWOT strategic analysis (Strengths - Weaknesses - Opportunities - Threats), to identify internal and external factors that would influence the implementation of a bariatric clinic. Finally, to assess the possible implementation of a bariatric clinic in the HRAEI, operational and technical studies were done. Medical devices and supplies required by a bariatric clinic according to national and international regulations were identified. The infrastructure and the professional staff profile for the bariatric clinic were defined. It is important to say that the Hospital already has these medical specialties for attending obese patients: bariatric surgery, anesthesiology, cardiology, nutrition, and psychology (among others). This implies that Hospital has the medical staff for working in a bariatric clinic. Finally, we generated the guidelines for health-care facilities and professional staff requirements for developing the bariatric clinic at the High Specialty Regional Hospital of Ixtapaluca. It is important to say that this manual can be used by other health institutions interested in a bariatric clinic.
Keywords: bariatric clinic, SWOT strategic analysis, guidelines for developing a bariatric clinic

E3-Health Technology Assessment & Innovation 2

An Investigative Study into the Morphological, Physical and Biocompatibility Properties of Medical Grade UHMWPE Rods for Orthopaedic Implants

By Chelsea Johnson,Santosh Kumar Balivada,Divya Patil

AMTZ, India

Abstract: Ultra-high molecular weight polyethylene (UHMWPE) has garnered significant attention as a highly promising biomaterial for a range of medical applications. This presents a comprehensive investigation into the morphology, physical properties, composition, and biocompatibility of UHMWPE rods. The study aims to provide a deeper understanding of the structural characteristics and mechanical performance of UHMWPE, as well as its compatibility with living tissues. The analysis of UHMWPE rod morphology entails a meticulous examination of its microstructure using scanning electron microscopy (SEM). This thorough evaluation encompasses an assessment of the surface topography and grain size distribution, enabling elucidation of their impact on the overall properties of the material. The size of each granule is about 100 µm and polyhedral in shape. To assess the mechanical strength of UHMWPE rods, accurate tensile strength testing is of crucial parameters such as tensile strength at yield is 24.1 MPa, the ultimate tensile strength is 49.5 MPa, and the elongation at break is 429.4 %. Furthermore, density measurements are performed to quantitatively determine the material's mass per unit volume, which is 934.8 kg/m3 providing essential insights into its lightweight nature and potential applications. Through the use of Fourier-transform infrared spectroscopy (FTIR), melting analysis, and DSC (Differential Scanning Calorimetry), the chemical morphology of UHMWPE is examined. The effects of these elements on the characteristics and biocompatibility of the material have been rigorously investigated. The evaluation of UHMWPE rod biocompatibility involves comprehensive small animal implant testing. Rods of various dimensions are implanted in animal models, and their biological responses are precisely monitored over a defined period. According to ISO 10993, Biological Evaluation of Medical Devices Part-11 Test for Systemic Toxicity, the UHMWPE rod was tested on mice for systemic toxicity. According to ISO 10993, Biological Evaluation of Medical Devices, Part 4, another test is reviewed for the hemocompatibility test of UHMWPE rod on rabbits. In accordance with IOS 10993-10: Biological Evaluation of Medical Devices Part-10 and 10993-06, the UHMWPE rod's

intracutaneous reactivity and intramuscular implantation are carried out on New Zealand white rabbits. According to ISO 10993-3: Biological Evaluation of Medical Devices, Part 3: Test for Genotoxicity, Carcinogenicity, and Reproductive Toxicity, the chromosomal aberration test of the UHMWPE rod was conducted in mice. The results of this study significantly contribute to the fundamental understanding of the morphology, physical properties, and intricate interactions of biological tissues. These findings offer invaluable insights that can drive advances in the design and development of UHMWPE-based implants, thereby facilitating remarkable progress in the field of medical devices and ultimately leading to improved patient outcomes.
Keywords: UHMWPE,tensile strength,biocompatibility

E3-Health Technology Assessment & Innovation 2

Resource Allocation of Medical Devices Strategies for Breast Cancer Screening

By Fabiola Martinez-Licona

Universidad Autonoma Metropolitana, Mexico

Medical devices are critical in diagnosing, monitoring, and treating medical conditions in healthcare. However, their availability and allocation can be a complex challenge, particularly in resource-constrained settings. Effective resource allocation is essential to ensure equitable access to medical devices, optimize their utilization, and ultimately improve patient outcomes. Maximizing medical devices' impact by ensuring their availability where they are most needed so they can deliver the most significant benefit must be the objective of any allocation strategy. Factors such as disease prevalence, patient needs, and cost-effectiveness are determinants in the prioritization of resources. This work aimed to analyze a method for resource allocation based on the analytic hierarchy process (AHP) and applied to a high morbidity non-communicable disease in Mexico: breast cancer. The epidemiological, infrastructure, and socioeconomic factors are included in a prioritized way allowed to identify their impact on determining the number of mammography machines for screening in Mexico'states with the three highest female indigenous populations (Guerrero, Oaxaca, Chiapas). The socioeconomic and demographic determinants, the screening mammography demand, and the available mammography machines were used, under the author's heuristic assumptions, as variables for the categories of the target population, epidemiological indicators, and infrastructure. The AHP determines the specific weight of each factor based on the relations between the considered variables. In this case, the variables included female population over 50 years old, women's age who underwent mammography, origin municipality from women who underwent the mammography, mammogram outcomes, mammogram locations, number of mammography machines, breast cancer mortality, breast cancer mortality municipalities, and breast cancer morbidity rate. From them, only those that scored the highest were used in the model. The AHP determined the weights for the categories of target population, epidemiological indicators, and infrastructure (0.473, 0.156, and 0.370 on average); the process also calculated the specific weight from each selected variable, and these values were integrated into the model. Two approaches were used for the model: the accumulative contribution of the three categories and their product. Finally, the number of mammography machines for screening purposes was calculated for each approach. The data came from the National Institute of Statistics and Geography (INEGI), the National Council for the Evaluation of Social Development Policy (CONEVAL), and the Mexican Ministry of Health for 2020. The results for the additional and product approaches show that Chiapas requires 1070-48 machines, Guerrero 1071-35, and Oaxaca 1087-32, respectively. The results differ from the model considerations and are strongly linked to the reported data. Some external factors are not included, such as the physical conditions of the mammography machines and whether the mammography studies performed per state corresponded to its female citizens or belonged to neighboring territories. Another consideration is that more than the number of machines is needed to guarantee better coverage for screening mammography. Compared with previous results from an adaptation of the resource allocation working party, the product approach seems to provide feasible information for the decision-making process regarding technological infrastructure for breast cancer screening.
Keywords: mammography machines, breast cancer, infrastructure resource allocation

E4 - Health Technology Quality & Risk 2

Exploring the Use of ChatGPT in the Creation of Technical Documentation for Medical Device Certification

By Stefano Bergamasco, Luigi Cuorvo, Roberto Belliato, Ilaria Sirotich, Eliana Monaco and Federica Miola

MedTech Projects Srl, Italy

Artificial intelligence has paved the way for many transformative changes across different industries. This paper explores the use of artificial intelligence, particularly focusing on the system known as ChatGPT, as a supportive tool for drafting the technical documentation required for the certification of medical devices according to the European Union Regulation 2017/745.Medical device certification is a complex process involving several critical steps such as risk analysis and clinical evaluation. These are essential regulatory activities that demand accurate, coherent, and comprehensive documentation. Given the scale and complexity of this process, leveraging AI technology like ChatGPT can bring about substantial efficiency and precision. ChatGPT, based on OpenAI's GPT-4.0 architecture, has exhibited impressive capabilities in processing and interpreting large amounts of text, subsequently producing coherent and relevant synthetic outputs. This intelligent system, enhanced by automatic learning abilities and natural language processing algorithms, can serve as a potent virtual assistant in technical document drafting. It can streamline the process, improve the quality of content, and significantly reduce the time and effort required for document creation. In the realm of risk analysis, we have applied ChatGPT to identify potential risks associated with device usage. The system proved to be adept at providing a comprehensive list of possible risk sources, their corresponding consequences, and potential mitigation strategies. Furthermore, in terms of clinical evaluation, ChatGPT showed promising results by offering valuable insights into possible indications, contraindications, and side effects of the device under examination. Our initial practical experiences saw the utilization of ChatGPT in brainstorming safety features and clinical efficacy aspects of a diverse range of devices. These included dermatoscopes, gynecological examination tables, cardiac needles for cardiopulmonary bypass (CPB) procedures, and critical components of medical gas installations. These trials yielded extremely beneficial starting points for subsequent analysis phases, while notably reducing the time required for the initial overview. Moreover, ChatGPT demonstrated remarkable coverage of various relevant aspects, suggesting its robust applicability in this field. Despite the many advantages, it is vital to note some limitations of the technology. Currently, ChatGPT is unable to provide reliable bibliographic references and occasionally "invents" such references. This aspect (that is a well-known "side effect" of artificial intelligence systems, known under the name of "allucinations") necessitates the user's utmost attention and careful evaluation of the content proposed by the AI.In conclusion, the preliminary experiences with the application of ChatGPT in the field of medical device certification are extremely promising. It is becoming increasingly clear that AI tools like ChatGPT can provide valuable assistance in drafting complex technical documentation in the regulatory landscape. These experiences highlight the exciting potential for technology to streamline, expedite, and improve processes within the medical field, pointing towards a future where AI integration becomes the norm rather than the exception.
Note: This abstract was prepared by the authors with the support of ChatGPT itself.
Keywords: artificial intelligence, medical device certification, clinical evaluation, risk assessment

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E4 - Health Technology Quality & Risk 2

Equipment Decontamination: A Missed Opportunity in Healthcare Equipment Maintenance in LMICs

By Martha Tusabe and Brian Matovu

WHO AFRO, Congo RD

Background: Globally, more than 50,000 different kinds of medical equipment are estimated to be used on patients every day in health facilities. Despite their importance in supporting healthcare service delivery, maintenance and appropriate management of medical equipment in LMICs remains a widely recognized challenge. Medical equipment in African countries are poorly maintained and many often neglected. The poor medical equipment maintenance in the region is partly due to a lack of trained clinical engineering staff trained to effectively manage and maintain available equipment. This has been further combined with the fact that the available equipment is shared among hundreds of patients which increases the risk of spread of nosocomial infections or hospital acquired infections among the patients. The spread of these nosocomial infections is worsened by the emerging anti-microbial resistant strains of bacterial organisms which significantly increase the mortality and morbidity rates as well as the cost of healthcare treatment. A study was done to investigate the role of medical equipment in the spread of nosocomial infections in public hospitals in Uganda. This study included equipment that was in good working condition in the operation theatre, imaging and neonatal departments where most equipment

is deployed in the health facilities in LMICs. The medical equipment in the study was prior disinfected using 70% alcohol within 24hrs before collecting samples using sterile swabs. The samples were then subjected to a microbiology lab for analysis. **Results:** Nearly 9 out of 10 of the equipment (57/65) had bacterial isolates identified from samples taken in at least one of the three points tested, 2 out of 3 equipment (67.7%) tested positive in two or more locations and 27.7% (18/65) of the equipment had bacteria isolated from samples taken at all three points While the user and patient contacted locations showed relatively high percentages of contamination (60 and 66%, respectively). The observation that over half of the remote locations were also contaminated (55%) suggests that this equipment were not properly disinfected equipment or the microorganisms are resistant to the current disinfectants used in these health facilities. The percentage of samples that were found to have bacterial isolates from each department were: 73% (77/105) in the Neonatal Department, 60% (9/15) in the Imaging Department and 42% (30/72) in the Surgery Theatre Department. This represents the level of risk to patients, health workers and biomedical engineers in each department. **Conclusion:** Understanding the role medical equipment in the spread of hospital acquired infections is extremely important in Healthcare Technology Management since patients, health workers and BMEs encounter this equipment very frequently. Further, the bacterial organisms identified were resistant to multiple antibiotics which indicates a greater risk of spread of Multi-Drug Resistant bacterial strains in the community. These results provide strong support for strengthening overall disinfection/sterilization practices around medical equipment use in public health facilities in LMICs. There's also a need for further research to make a direct link to the bacterial isolates identified and their resistance to some disinfectants used in the health facilities.
Keywords: hospital acquired infections, bacterial organisms, medical equipment disinfection

E4 - Health Technology Quality & Risk 2

The Practice of Implementing Smart Delivery in a Supply-Process-Delivery System in Large Hospitals

By Jin Pan, Xueting Qu, Yinxue Wang, Shuping Chen, Tao Wu and Jingyi Feng

First Affiliated Hospital of Zhejiang University School of Medicine, China

Description: To resolve burden of managing storage for nurses and enhance the delivery efficiency of consumable medical supplies, a customized supply-process-delivery (SPD) system is designed and deployed in a tertiary hospital in China. The biggest difference between the new SPD system and the order-delivery system is automatic supplying after use, repackaging according to usage and all trackable online. The system is composed of an online platform and a hierarchical delivery system. The platform is mainly used to assign deliveries, maintain storages, and record payment. The delivery system is divided into central warehouse, as the main package processing and distribution center, the subordinate campus's warehouse, as the secondary distribution center, and the department storage as the terminal. Packages are reassembled, registered online, and relabeled with a unique ID, recent address and destination in central warehouse. The secondary center categorized packages from central warehouse and arranged delivery task for robots to terminal storages once there is order or alarm. Nurses or clinicians access the terminal storage using their ID cards, take out what they need and register user by scanning label on patient and the package, while the smart storage or cabinet recognize storage change by RFID and weight sensors. From secondary center to terminal there are two modes of delivery, which are regular delivery and special delivery. When some common medical supplies in terminal storage went lower than a setting number, an alarm will be sent to secondary distribution center for regular delivery. As for arranged surgeries, packages are wrapped based on common needs in certain types of surgery and special demands from surgeons and patients. Routine delivery is carried out by automatic guided vehicles. Some special, expensive, and urgent supplies are directly used on a specific patient, usually directly delivered to emergency, dental clinics and operation room and inspected on site. An estimate of each month's usage is obtained by survey and can be renewed by procurements based on the online records, which is a reference for setting alarm and packages. **Conclusion:** The new logistic system performed successively. In most cases, nurses are relieved from tallying and focus more on medical tasks. Routine delivery work and daily packages are compatible with both procurement procedure and automatic delivery system, which further improve efficiency. Besides, irregular usage will be quickly found out once the frequency of alarm gets higher. Still, there is an argument about the list of special supplies and solution to sudden circumstances such as pandemics.
Keywords: supply-process-delivery system, RFID, automatic guided vehicle, smart cabinet

E4 - Health Technology Quality & Risk 2

The Emergence of Cervical Cancer in Bangladesh and The Necessity of Introducing Low Ultrasound & AI-based Portable System to Ensure Early Detection of Cervical Cancer in Lower Middle-Income Countries (98)

By Md.Faizul Hakim, Jahin Ahmed, Rezwan-Ul Quadir, Md. Ashrafuzzaman, Dr. M Jahangir Alam and Md.Asadur Rahman

Military Institute of Science and Technology (MIST), Bangladesh

Cervical cancer is one of the leading causes of cancer among the females in lower middle-income countries like Bangladesh. It showed an increasing trend over the past 10 years. Health facilities in Bangladesh (except for some tertiary level hospitals) lack readiness in cervical cancer management in terms of guidelines on diagnosis and treatment. From our study, we found that Bangladesh has a high burden of cervical cancer due to the lack of screening, high prevalence of risk factors like early marriage, early initiation of sexual activity, multiparity, sexually transmitted diseases (STDs), and low socio-economic condition. A low ultrasound based portable & artificial intelligence-based decision support system (AI-DSS) in the gynecological examination for early detection of cervical cancer must be established for high-quality diagnosis in resource-poor settings where inter-observer variation in VIA will be reduced.
Keywords: cervical cancer, national cancer registry, artificial intelligence, cancer screening, decision support system

E4 - Health Technology Quality & Risk 2

A Multi-Leaf Collimator Continuous Quality Improvement Project for Medical Linear Accelerators

By Qipeng Lu, Yong Wu, Jian Shao and Xiaodong Mao

The Cancer Hospital of the University of Chinese Academy of Science (Zhejiang Cancer Hospital), China
Medical linear accelerator is an important means to treat cancer. The safety of patients has always been the most insisted and valued tenet of Zhejiang Cancer Hospital, and it is also the primary responsibility of clinical medical engineers. We found some problems in the maintenance process of medical linear accelerator equipment, which will lead to the increase of equipment maintenance cost and equipment back repair frequency. Based on the analysis and discussion of the failure maintenance review and maintenance cost management of medical linear accelerator proposed in 2019, we established a quality improvement group, formulated project quality scoring standards, and applied PDCA management mode to carry out continuous quality improvement work on the operation of multi-leaf linear accelerator used in the whole life cycle management of large medical equipment. Mainly through the investigation and analysis of 349 maintenance reports of 9 medical linear accelerators in our hospital from January 2019 to December 2019, the equipment operation, fault source, downtime and other aspects were investigated and analyzed. According to three kinds of fault importance degree and three kinds of fault diagnosis methods, seven kinds of fault classification were obtained. The quality improvement team further studied the operation of three Varian medical linear accelerators with MLC. Fifty reports completed from January to December 2019 were set as the PDCA control group, and 33 reports from January to December 2020 were set as the PDCA improvement group. The problems in the process of quality improvement were discussed, analyzed and summarized, including the score of equipment operation, the score of external factors and internal factors, and the cycle was repeated to achieve continuous quality improvement. **Conclusions:** According to the study of fault classification, there are two types of faults with high frequency in the seven types of fault classification, one with medium frequency, and the rest with low frequency. The top two faults were functional faults (43%) and parametric faults (31%). The results showed that the quality score of the PDCA improvement group was significantly higher than that of the control group. The running condition of physical parts, logic parts, transmission parts, control and circuit parts were significantly improved, and the failure rate of transmission parts decreased by 19.69%. In addition, the reason that the average score of each factor of the control circuit operation was higher than that of the PDCA improvement group was the increase in the frequency of external power supply instability and the abnormality of air conditioning. This project confirmed that the measures taken by the quality improvement team of the hospital in this project are feasible and effective, and can be applied to the whole life cycle management of other large medical equipment.
Keywords: PDCA, quality improvement, Linac, MLC

E4 - Health Technology Quality & Risk 2

Definition, Implementation and Continuous Improvement of the Risk Management System for Medical Devices

By Ilaria Sirotich, Roberto Belliato, Stefano Bergamasco, Eliana Monaco, Federica Miola and Luigi Cuorvo

MedTech Projects Srl - AIIC, Italy

The new medical device regulation (EU) 2017/745 (hereafter MDR) establishes in article 10 General obligations of manufacturers that all manufacturers of medical devices must "establish, document, implement and maintain" a risk management system compliant with the requirements of Annex I, and that this risk management system is an integral part of the company's quality management system. The request by the legislator to apply a risk-based approach focused not only on the product, but also on all the processes related to it, is therefore evident. First, Annex I, pt.3 of the MDR establishes the minimum requirements of the risk management system, which are congruent with the philosophy of continuous improvement that emerges from EN ISO 14971 together with the order of priority imposed by the MDR as regards the solutions to be adopted for risk mitigation (annex I, pt.4). However, the manufacturer must pay attention that standard and MDR are not congruent in defining the risk reduction criteria: the standard, in fact, leaves free choice, while the regulation underlines that the risk must be reduced to the lowest possible level (AFAP). Another significant difference between the requirements of the regulation and those of the standard is the fact that the former requires the analysis of the benefit-risk ratio to be carried out considering all the residual risks (Annex I, pt.8) and not just the residual risks unacceptable. The objective of our work is to provide manufacturers with a tool that allows them, first of all, to define and implement an ad hoc risk management process for products and related procedures; and that the risk-based approach is extended to clinical effectiveness assessments, in such a way as to be able to relate clinical benefit and residual risk on a normalized scale. Therefore, the IT tool that has been implemented applies the FMEA method extended to the evaluation of the benefit and its relationship with the residual risk, as specifically required by the new Regulations on medical devices. This IT tool can also find parallel application to the management procedures of biomedical technologies during their life in service, becoming a valuable risk management tool for the Clinical Engineers themselves.
Keywords: risk management, clinical benefit, benefit/risk ratio

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E4 - Health Technology Quality & Risk 2

Shared Management of Biomedical Waste in the Dassa-Glazoue Health Zone

By Pascal Soroheye, Espoir Hounsossou and François Bohounton

Ministry Of Heath, Benin

Objective: To improve biomedical waste management by pooling available resources. **Methods:** The disposal of biomedical waste produced by health facilities in the Collines department is a real problem. Only 49% of the department's health facilities have functioning Montfort-type incinerators. These incinerators, built using local materials, have a maximum lifespan of 3 years. What's more, Montfort incinerators incinerate waste at 850°C, and several health facilities in the Dassa-Glazoué health zone, one of the department's three health zones, continue to burn medical waste in the open air, which is a real health problem and a risk of environmental pollution. In a context of limited resources, the construction of new incinerators is not an effective long-term solution. To this end, and as part of the search for a sustainable solution, a modern burner was acquired through a project financed by AFD and implemented by Enabel. The burner has a daily incineration capacity of 200kg. 34 of the 46 existing health facilities were included in this phase. The waste is transported by two specially equipped tricycles. **Results:** The strategy considered 1 hospital with an average waste production capacity of 80 kg and 34 health centres, each producing an average of 4 kg of waste per day. The two tricycles will be distributed at two points so that each health facility can be visited every three days to collect waste. Between November 2021 and November 2022, 15.6 tonnes of biomedical waste were safely incinerated at a total cost of 8,400 euros. The financial contribution from each health facility is €0.18 per kg of waste incinerated. This revenue is used to purchase fuel for the burner, maintain the motorbikes and burner, and pay bonuses to motorbike drivers and incineration workers. The strategy will run for 4 years (2021-2025). The investment cost is €276,424, which is economically more advantageous than investing in the construction of Monfort-type incinerators, whose investment cost is estimated at €285,080. In order to perpetuate the strategy, the additional income is deposited in a bank account for the depreciation of the burner and the motorbikes. A joint committee made up of community representatives and administrative managers has been set up to manage the strategy. The experience of pooling resources and activities for the disposal of biomedical waste in a context of limited financial resources has enabled around thirty

structures to manage the waste produced in complete safety.Perspectives: incineration of all biomedical waste in complete safety; gradual phasing out of Montfort-type incinerators; national coverage of the strategy.
Keywords: biomedical waste, Montfort-type, incinerators, modern burner

E4 - Health Technology Quality & Risk 2

Modernization of a Patient Monitoring Critical Alarm Management System

By Amanda Hunton, Nehal Kapadia and Oliver Nigro

Massachusetts General Hospital, USA

Central monitoring using audio and visual is a crucial part of patient monitoring for a quick response to bedside monitor alarms while enabling nursing staff to care for more than one patient. Massachusetts General Hospital (MGH) is replacing its obsolete visual alarm distribution system with a new technology. The clinical units rely on LED signs for a quick visual on the alarms and the beds they come from. The original system was designed in the 1980s using an idea from a vendor's production facility to display alarm from patient monitors and other monitoring devices. It went out of support in 2006. MGH explored off-the shelf products to continue using the LED signs; however no viable and scalable solution was available at the time. The Biomedical department then built its own PC using the same application software to route alarms from patient monitors to the LED signs. The homegrown solution can no longer be supported due to lack of parts and a more modern solution is required to continue using the LED display signs. While the new technology provides an opportunity to expand the platforms for alarm notifications, the initial phase was to maintain the current alarm visual capability for a smoother clinical transition. Beginning in 2017, the process included risk assessments, product evaluations and selection, collaboration with stakeholders on the design, provisioning, configuration, and implementation of the system, as well as troubleshooting issues encountered during the process. As of now, a pilot has been completed and a full implementation is pending, following a few final design changes. Many challenges were encountered during the project, and it was realized that replacing a ~20-year-old system with current technology advancements on an enterprise IT network, while maintaining similar functionality, is challenging. Working with a vendor who has a scalable solution that can be adapted through all unforeseen roadblocks was extremely beneficial in navigating these challenges. With the next phase of the pilot in July 2023, the project aims to be fully implemented by 2024.
Keywords: alarm management,patient safety,technology replacement

F1 - Women in Clinical Engineering

Women in STEM in Clinical Engineering Departments: A Survey Analysis in Canada

By Marie-Ange Janvier and Ishtar Al-Tahi

Children's Hospital of Eastern Ontario, University of Ottawa, Carleton University, Canada

The representation of women in Science, Technology, Engineering, and Mathematics (STEM) fields, particularly in clinical engineering departments, varies across different provinces in Canada. This abstract presents a survey-based analysis that focuses on women's participation and representation in STEM roles within clinical engineering departments, with an emphasis on data collected from each province. By examining survey responses, this study aims to provide valuable insights into the current state of gender diversity in clinical engineering across Canada, identify regional variations, and propose targeted strategies to address gender disparities. The survey data collection process involved administering structured questionnaires to clinical engineering professionals across various provinces in Canada. The questionnaires captured information on demographics, educational backgrounds, career progression, workplace dynamics, and perceived barriers faced by women in the field. The collected data was analyzed using percentages and proportions to assess the representation of women in clinical engineering departments and compare it across provinces. The analysis of the survey data explores regional variations in women's participation in clinical engineering departments, shedding light on potential factors contributing to the observed differences. These factors may include provincial policies, cultural norms, educational resources, and networking opportunities. The findings of this survey-based analysis provide province-specific insights into the challenges faced by women in clinical engineering within Canada. This is a planned STEM study just getting underway where a comprehensive dataset will be valuable information for STEM fields. The study aims to highlight areas of improvement

and suggest evidence-based strategies to promote gender diversity in each province's clinical engineering departments. By recognizing the regional variations and proposing targeted solutions, this research aims to foster inclusivity, equality, and enhanced career opportunities for women in STEM, particularly within clinical engineering, across Canada.
Keywords: Women in STEM, clinical engineering, gender diversity, survey data, Canada

F1 - Women in Clinical Engineering

Women in Clinical Engineering in Brazil

By Tatiane Dantas, Alexandre Ferreli Souza

E-CLASS Institute Brazil

Female participation in technology and engineering has increased globally and this includes clinical engineering in Brazil. To discuss the topic, a survey was carried out using an electronic form with 23 questions addressed to working clinical engineers. The results showed that being a female professional in clinical engineering means overcoming more obstacles than those presented to male professionals. The objective of the study was to know, describe and understand the participation of women in the areas of technology and health, with a focus on clinical engineering. The study reinforces the relevance of addressing the theme "women in clinical engineering", since it is necessary to encourage the work of these professionals in the area, as well as the importance of fostering the debate about greater female representation. Main difficulties reported by Clinical Engineering professionals: Harrassment in the Work Environment; Balancing career and motherhood; Restricted opportunities and career advancement; Payment difference. The results of the work corroborate the hypothesis that women face more difficulties in the Clinical Engineering career than men. In view of the above, it is very important to form support groups and debates such as Women in Engineering and the women's committee of ABEClin (Brazilian Association of Clinical Engineering).
Keywords: women in CE, clinical engineering, national CE society

F1 - Women in Clinical Engineering

Women's Unique Aptitudes Support Clinical Engineering Development

By Ewa Zalewska

Clinical Engineering Association of Poland

The position of women in clinical engineering (CE) is significant and stands out for being much more represented compared to other engineering fields, supported by visible contributions. This is an achievement that highlights the importance of women's contribution in this field. When considering the development of women's activities in clinical engineering, it is important to determine what is the essence of the topic of women in clinical engineering. What is special about this profession and what makes it possible for women to play a special role in this profession, and how this special role should develop in the future. The most significant contribution of women is the new perspective and some kind of new values that have come with women to the field of clinical engineering and practice. The female perspective takes into account the idea of helping others and the humanitarian aspect of this profession. Women's contributions also raise awareness of ethical issues in clinical engineering. These, along with the creativity of women in any activity, enrich the CE profession and help in making important achievements. The use of women's outstanding aptitudes such as communication skills relevant in an interdisciplinary collaboration, empathy, holistic thinking, a deeper understanding of the human aspect of healthcare technology is essential to empower women and stimulate progress in this field. The challenge is to find areas of activity where women's aptitudes will be particularly useful. It can be a comprehensive analysis of the safety of medical devices, not only in the technical aspect, but also considering environmental factors, human factors, psychology. Another relevant area for women's activities is the role of the creative partner of the medical team in everyday practice, which involves participating in the application of medical equipment by bringing interdisciplinary knowledge and a holistic approach to performing patient examinations and interpreting results. Women's aptitudes in this aspect requiring a holistic and creative approach are valuable and desirable. Therefore, thinking about the future, it would be worth changing the perspective. This implies that instead of viewing the context of women and men as competitors, it is important to consider it as an advantage and adopt a cooperative perspective. The way to increase the empowerment of women in clinical engineering lies not in the pursuit of equality in obtaining the same achievements as men, but, on the contrary, in the use of individuality. The roles of

women and men could complement each other. Women bring diversity to clinical engineering, which is a source of inspiration and innovation, simply progress. In conclusion, the challenge is to find areas suitable for women's ability to enhance women's unique contributions to CE. The future is about maintaining gender balance and good cooperation. Then diversity will stimulate complementary development.
Keywords: clinical engineering, women in CE, CE development

F1 - Women in Clinical Engineering

Knowledge, Attitudes and Challenges of Female Biomedical Engineers in LMICs: A Case Study of Uganda

By Shalom Katusiime, Elizabeth Nakuya and Priscilla Kemigisha

Ernest Cook Ultrasound Research and Education Institute, Uganda

Women remain a minority in engineering. Gender disparity is seen in all pathways in engineering as there are low rates of female students in STEM in Uganda. Undergraduate education is a critical time when peer influence may alter choice of majors and careers for young girls interested in science. 40% of women engineers leave or never enter the field for a variety of reasons that are poorly documented. There are unconscious biases in society like women are less technically competent; mothers are not as committed to their positions compared to their male counterparts. Gender stereotypes and roles of women confine them to the kitchen and taking care of homesteads. Family responsibilities; often women and girls are confined to fulfilling roles as mothers, wives and caretakers. Gender norms position girls as caretakers which leads to gender inequality in how roles are distributed at the household level. Engineering is a demanding career. There are also low rates of retention in female engineers, about 20% of them work in engineering occupations and this is because there is minimal mentorship to empower women at every stage of their careers; minimal meaningful connections and support systems that may be caused by a lack or low education levels due to the restriction of outside opportunities. Survey **Results:** A study was carried out among biomedical engineering women in Uganda and data was collected from 35 participants. This was an online survey done using Google forms and the data collected is explained below: 80% of the respondents were aged between 18 -25years and 51.4% of the respondents were bachelor's holders while only 3% had master's degrees. Concerning employment, 53% of women volunteer in their fields of work, 21% are employed and 26% are unemployed. Of these, 83% of women have a working experience of 0-5yrs. This is explained by the fact the biomedical engineering is about 13 years old in Uganda. The respondents have also had achievements in their careers like exposure, experience, skills, promising innovations, and respect. Some of the remarkable achievements mentioned were, "I was the best female innovator of the year in a renewable energy challenge" Another mentioned that "I have been able to learn from the people around me, to work on the things that I can do and also accept when I can't do something and ask for help". Majority of our respondents cited their challenges as undermining women in regard to technicality, exploitation of female engineers, uncomfortable sexist jokes in workplaces and the field, preference of male counterparts, less physical strength as compared to males, minimal meaningful connections and exposure and inferiority complex. Sensitization of girls and women about STEM, inclusion of women in STEM, educating men on the importance of women in STEM were some of the solutions given by the respondents to solve some of the challenges mentioned. In conclusion, 97.1% of the respondents would encourage women to choose a career in biomedical engineering.
Keywords: gender diversity, gender stereotypes, STEM, inequality, norms, disparity

F1 - Women in Clinical Engineering

BMWEB: Empowering the Biomedical Women Engineers in Bangladesh

By Tasnuba Tabassum Mourin, Rayesa Haque Rupanti, Nawrin Tasnim and Md. Ashrafuzzaman

Biomedical Women Engineers in Bangladesh (BMWEB)

In Bangladesh, Biomedical Engineering (BME) is a comparatively new and emerging field. The healthcare system is still in its infancy, resulting in an increasing need for biomedical engineers to provide solutions to ongoing health problems. The very reason that the country is unable to address the healthcare issues is because of not properly utilizing women's contributions to society. With the aim to mitigate the challenges of women biomedical engineers in various healthcare facilities and biomedical industries, Bio-Medical Women Engineers in Bangladesh (BMWEB) has established on September 2022.

The ultimate objective of BMWEB is to give these engineers an omnipresent platform where they can come together to solve problems, strengthen themselves, and play a significant role through their active services while also advancing their technical careers. A recent national survey tells that over 53% of biomedical engineers are under 25, and over 98% are under 29, enabling them to design advanced healthcare solutions (fig 1 and 2). BMWEB offers specialized courses and opportunities to train future leaders supporting Women in Clinical Engineering. There are many challenges for a woman pursuing a career in a male-dominated field. For starters, every woman in positions of power still contends with gender-based harassment. One of the biggest hurdles that female engineers have to face is an unconscious bias which can manifest as preferences for women that speak and dress in certain ways. Moreover, the prevalence of sexual hostility and unwelcome physical actions towards women is quite common in the workplace these days. Such actions impede their career advancement and may force them to pass up important opportunities. Besides, women engineers with high qualifications are not taken seriously for authoritative roles in many places like hospitals, pharmaceutical industries, or even in educational sectors since they might not tolerate gender discrimination or are unobligated to act in certain ways. Being raised in a patriarchal society, the stigma associated with social and cultural rituals makes women inappropriate to work in a place with men. This is exactly how the potential of female engineers is underrated which ultimately results in the underdevelopment of the healthcare system. Taking account of the prevailing circumstances, BMWEB aims to break down constraints around female biomedical engineers to help them flounder against the stereotyped mindset in everyday life. Last, but not the least, BMWEB wants their voices to be heard and the values of women engineers to be recognized.

Keywords: BMWEB, women in engineering, bangladesh, biomedical women engineer

F1 - Women in Clinical Engineering

Experience in the Implementation of the Medical Technology Model for a High-Complexity Clinic, Cali, Colombia

By Margarita Maria Sarmiento Montoya and Karent Eliana Muñoz Salazar

Clínica Imabanaco, Colombia

Description: The Imbanaco´s Clinic implemented the clinical engineering model for the management of medical equipment throughout its lifecycle, serving as a fundamental axis to guarantee patient safety. In 2017, as an organizational strategy, the Clinical Engineering Department was formed under the leadership of a biomedical engineer with the aim of designing and implementing a standardized clinical engineering model in accordance with national and international accreditation standards, such as the Joint Commission International (JCI). This management model consists of six phases that relate to the lifecycle of medical equipment: Phase 1: Acquisition: planning and evaluation activities; Phase 2: Incorporation: technical and legal management activities; Phase 3: Commissioning—knowledge management; Phase 4: Operation—activities for safe use; Phase 5: Risk Management and Quality Control Activities; Phase 6: Renewal and Disposal Activities The model also incorporates research and development, establishing guidelines for the planning, evaluation, and management of medical technology projects aligned with the organization's strategic objectives. **Conclusions:**The participation of women in clinical engineering leadership has been transformative in the management model of medical equipment at the Imbanaco´s Clinic. Projects like "Implementation of an Intelligent Infusion System in a High-Complexity Clinic" have gained recognition despite numerous barriers to the adoption of intelligent infusion technologies in Colombia. This project was honored with the Emergency Care Research Institute (ECRI) Excellence in Health Technology Awards in 2021, gaining recognition among healthcare professionals and organizations worldwide. Additionally, our management model promotes the integration of universities and the industry through involvement in academic events where students, clinical engineers, and healthcare professionals come together to share and discuss ideas and advancements in medical technologies within a hospital setting. One such annual academic event is the "International Clinical Engineering Symposium," which has been held since 2019. These events facilitate the dissemination of new ideas, the identification of opportunities in medical technologies, and constructive debates to contribute to patient safety. Another notable aspect of women's leadership in clinical engineering is the implementation of the metrological assurance project, which led to the accreditation of the metrology laboratory in 2021. This accreditation allows for internal calibrations following the guidelines of the International Electrotechnical Commission/ International Organization for Standardization (IEC/ISO) 17025:2017: General requirements for the competence of testing and calibration laboratories. As a result, we have become one of the three healthcare institutions accredited by the National Accreditation Body of Colombia (ONAC). The lessons learned from the academic development of women's leadership in clinical engineering have strengthened the management of medical equipment, positioning this management model as a national reference to highlight the role of women in the field of clinical engineering worldwide.

Keywords: clinical engineering model, medical equipment, patient safety, accreditation standards, Lifecycle

F1 - Women in Clinical Engineering

Uplifting the Role of Women in Biomedical Engineering

By Selamawit Asfaw Abay

Founder and President, Ethiopia

The continuous developments in science and technology are increasing the availability of thousands of medical devices all of which should be of good quality and used appropriately to address global health challenges. It is recognized that medical devices are becoming ever more indispensable in healthcare provision and among the key specialists responsible for their design, development, regulation, evaluation, and training in their use are biomedical engineers. Biomedical engineering professionals are key players in developing and advancing the usage of medical devices and clinical services. Depending on their training and sector of employment, the responsibilities of biomedical engineering professionals can include overseeing the research and development, design, safety, and effectiveness of medical devices/systems; selection and procurement, installation, integration with electronic medical records systems, daily operations monitoring, managing maintenance and repairs, training for safe use and upgrading of medical devices available to health-care stakeholders. Biomedical engineering professionals are employed widely throughout the health technology and health-care industries, in the research and development (R&D) of new technologies, devices and treatment modalities, in delivery of healthcare in hospitals and other institutions, in academia, government institutions and in national regulatory agencies. According to the survey of WHO on 2016, Biomedical engineering professionals can be found in 129 of 194 Member States of WHO. Among those three times greater proportion of male biomedical engineers (77%) compared with female (23%). Nevertheless, five countries (Argentina, Ukraine, Macedonia, Malaysia and Sudan) reported more women than men. In contrast, countries like Lao People's Democratic Republic, Micronesia, Rwanda, Sierra Leone, United Republic of Tanzania and Vanuatu reported no female biomedical engineers at all.When we come to Ethiopia, biomedical engineering as an education is started in one of the prestigious university, Jimma Institute of Technology (JIT) in a degree level graduated the first batch in 2013 G.C. JIT's first batch were 28 biomedical engineering degree graduates in which 27 of them was males. Fortunately, I am the first female biomedical engineering graduate in Ethiopia. However, as a first batch and being the one and only lady female student in the class brought me through challenges and obstacles. Throughout my work experience, I have witnessed the most governmental and private hospitals are using medical devices and capital equipment even without verification and calibration. Additionally, our education standard and working environment has its own limitation on personnel, facilities, and research funds. These all things inspire my female fellows and me to create a Society of Ethiopian Women Biomedical Engineering Professionals on 2020 G.C. by having the objective of creating advocacies and awareness in the usage of biomedical engineering field, preparing trainings and on job/ hands on trainings on maintenance, calibration, and installation of medical devices, organizing bench markings on the other country medical devices regulatory systems, Building the capacity of women professionals, Creating women expertise in biomedical engineering, Promoting the highest medical device standards in biomedical engineering education and ensuring the rights and benefits of women biomedical engineers, technicians and technologists.

Keywords: BE-Biomedical Engineer, CE-Clinical Engineer, SEWBEP-society of Ethiopian women biomedical engineering Professionals, WHO- world health organization, JIT-Jimma institute of technology, G.C.-Gregorian calendar

F1 - Women in Clinical Engineering

Women's Resilience in Fighting Against Covid19 Pandemic – Women in Clinical Engineering and Technology in Rwanda

By Umutesi Francine

Rwanda Biomedical Centre, Rwanda

During covid19 pandemic, 30 volunteer biomedical technicians applied to support the GoR efforts in the fight against the pandemic. There was a huge need for technical support to run oxygen production, distribution, and safe delivery to patients, in addition to other technical support in other clinical activities. 4 young women stood out from the beginning. They volunteered right after they got married, gave their all and spent days and night at one of the major national treatment centres called sent up in Nyarugenge District Hospital. They gave birth while supporting oxygen distribution activities in the National c19 treatment centre, in Kigali City. One of them, named Nyirangeri Diane, whom we see on the below pictures, was among technicians assigned to fill the oxygen cylinders at the PSA plant and filling station. She was moving bottles and sitting only once the job was done. Despite having aids, she made sure that oxygen was properly filled and safely connected to the piping system. She gave birth to a healthy baby, and was back to work only after a few weeks, until the closing of the

treatment centre. Foto: Nyirangeri Diane, pictures taken in 2021, she gave birth on 10/08/2021.3 more young women gave birth between 2021 and 2022, but at the time, they continued to support taking a leave of 4 to 6 weeks each. Engineer Peruth joined the Medical Technology Division for an internship, which was extended due to the high need of support. She has since benefited and learned about oxygen production and distribution systems, epidemic awareness and decontamination technologies using robots, acquisition and general HTM best practices, and more..Foto: Eng. Peruth. **Conclusion:**Since December 2020, the Medical Technology Division of Rwanda Biomedical Centre is led by a woman. Before 2020, less than 10% of biomedical engineers and technicians were counted among the health sector engineering and technology teams. During covid19 pandemic response, they showed their worth and the situation has tremendously changed ever since, about 47% are women as of today, hospitals appreciate the contribution of young, graduated ladies who are making a difference in the healthcare facilities and asset management while contributing to the improvement of the overall service delivery outcomes. More fotos:Credit: pictures by Andre, RBC Photographer

Keywords: clinical engineers, biomedical technicians, women in clinical engineering

F2- Health Technology Management (HTM) 3

Healthcare System and Clinical Engineering Program in Afghanistan

By Huma Abdul Rauf

IFMBE Afghanistan

Clinical Engineering plays a crucial role in a healthcare system and support of clinical operations. In Afghanistan, lack of clinical engineers and healthcare technology management is causing strain on an already crippling healthcare system. This paper will explore the current state of healthcare system in Afghanistan and key areas that the global clinical engineering community can partake in.Prior to Taliban seizing power, Afghanistan had made significant improvements in their healthcare sector. It was reported in 2004 that there was an estimate of 117 private and government run hospitals in the country. Since then, the number had significantly increased to over 3,000 with each district having at least one facility/ hospital. The most advanced and leading children's hospital in the country are The French Medical Institute for Children and Indira Gandhi Children's Hospital in Kabul. Some of the major hospitals are in Kabul area – The Daoud Khan Military Hospital, Jamhuriat Hospital, and Jinnah Hospital. In addition, Maiwand Teaching Hospital is in Kabul and has been reported to be linked with Kabul University. Lastly, the 350-bed Aino Mina Hospital and the 50-bed Mohmand Hospital in Kandahar were reported as two of the most modern hospitals in the southern part of the country. After the withdrawal of U.S troops from Afghanistan and Taliban's swift return to power left Afghanistan with a collapsing economy. Afghanistan's collapsing economy has crippled the healthcare system that has endangered millions of lives and causing further strain on the existing humanitarian crisis. Taliban seizing power in 2021 has caused many international organizations to pull back and healthcare aids/funds to be frozen. In January 2022, WHO reported Afghanistan's healthcare system was on the "brink of collapse". Sehatmandi program has been essential to Afghanistan's healthcare system and provided healthcare to millions of Afghans and to over 2000 hospital facilities across the country. However, due to the lack of funding it has had a devastating effect on the Sehtmandi program and hospital facilities with shortage of medicine, equipment, and staff. In recent conversations with Dr. Wahid Majrooh, former health minister of Afghanistan, there is an increasing need for clinical engineering program and healthcare technology management. Key areas that have been thus far identified for immediate needs are as follows: 1. Education and Training – Providing access to educational webinars and trainings, both English and Farsi, on various topics such as medical device maintenance, medical devices such as: XRAY, CT, etc., and overall clinical engineering program. 2. Collaborative network and partnerships – Creating an open network with engineers and clinicians in Afghanistan with the global community to share practices and policies surrounding clinical engineering, medical device maintenance, and healthcare technology management.3. Policy and Procedures – Sharing and applying global clinical engineering policies and procedures with Afghanistan to start building a clinical engineering and healthcare technology management program.

Keywords: healthcare system, clinical engineering, Afghanistan, impact measurement

F2- Health Technology Management (HTM) 3

Optimisation of medical equipment replacement strategies, National Heart Institute Malaysia

By Maizatul Akmal

Malaysia Society of Medical and Biological Engineering (MSMBE) and National Heart Institute, Malaysia

Description: Decision making process concerning the equipment replacement conventionally takes place when the equipment reaches obsolescence, end-of-support, beyond economic repair, technology deterioration, excessive downtime or based on budget availability. It is more of an ad-hoc and reactive approach rather than structured replacement, depending on the situation or condition of the equipment as well as the judgement made by the clinical user and higher management. This approach often leads to a premature decision in prioritising the replacement, hence creating a scenario that is not cost effective to the organisation while putting risk to the patient's safety. In a standard healthcare setting, the lifespan of medical equipment is estimated to be between four to ten years before they are being replaced with a new technology. In the case study selected, the hospital has about 3000 medical equipment worth RM200 million currently being used to support the hospital operation. Out of 3000 medical equipment, about 50 percent of them are10 years of age with a total purchase value of about RM100 Million and 26 percent of the equipment is currently aged between five to nine years. Unbalanced equipment age distribution shows that there is no proper medical equipment replacement planning in placed within the hospital, hence causing half of the equipment to be stretched for operation beyond their expected useful life. **Goals:**The inability of the hospital to strategically plan its medical equipment capital allocation will also cause them to be drown in a huge amount of capital every year due to immediate, unplanned, and unbudgeted replacement. This project is principally focused on assessing the current capital allocation process implemented by the hospital to replace its medical equipment. Based on the assessment, the project focuses on developing and implementing optimization tools to improve the present medical equipment replacement approach practiced by the hospital based on several identified criteria. **Results:**The identified criteria are divided into four main aspects that are technical (age, equipment function, service support), safety (risk, adverse incidents), clinical (user preference, impact to operation, standardization) and economics (cost involved, utilization) aspects in making the decision to prioritize or select medical equipment. With the criteria identified as vital in deciding the replacement plan, a strong case can be built alongside with rational plan that will further guide the hospital management to make better and just decision in the capital allocation thus facilitating a better investment planning.
Keywords: equipment replacement, investment planning, clinical engineering

F2- Health Technology Management (HTM) 3

Empowering Excellence: A Comprehensive Overview of the Competency Program for Medical Device Management in Healthcare Delivery Organizations

By Thangavelu Sasikala

Policy, Code & Standard Division, Medical Device Authority, Malaysia

This article provides a comprehensive outline of the Competency Program developed for technical personnel engaged in the installation, commissioning, testing and maintenance of medical devices within Healthcare Delivery Organizations. The program furnishes insights into the competency framework, encompassing four main categories of medical devices, along with corresponding proficiency levels for each device listed in the category and product specialist. Furthermore, it delineates potential career trajectories for biomedical engineers and technologists within the healthcare sector. Additionally, the program extends its reach to non-biomedical engineers aspiring to specialize in the installation, commissioning, testing, maintenance, and disposal of medical devices within Healthcare Delivery Organizations, outlining their career pathways and prerequisites. A notable aspect of the program is the establishment of a special grandparenting initiative, tailored to assess and certify existing technical personnel engaged in medical device management and related activities. The article underscores the meticulous structure of the training regimen, incorporating compulsory modules, medical technology training, assessment and certification, and Continuing Professional Development (CPD) endeavors. The versatility of this competency program enables its seamless integration and customization, aligning with the policies and specific needs of medical device regulatory requirements, Healthcare Delivery Organizations and Health Ministries.
Keywords: medical devices, competency, biomedical engineers, technologist, medical device management

F2- Health Technology Management (HTM) 3

International CE in Portugal: Hospital Case Study

By Pedro de Britto Moreira Neto

HWMed, Portugal

Description: In addition to the typical role of the Clinical Engineering professional in equipment maintenance, company members actively participate in technology assessment and technology transfer as managers of these activities. The management of health technologies, with engineering knowledge and management techniques use, enables healthcare facilities to provide conditions that ensure better treatment for patients. A case study methodology was chosen here, with qualitative and quantitative analysis techniques, focused on the implementation of a Clinical Engineering service at Hospital da Senhora da Oliveira - Guimarães, Portugal, throughout the year 2021. **Goals:** This study aims to contribute scientifically to this field of knowledge through the analysis of the implementation of Clinical Engineering in a Portuguese public hospital. **Results:**The cost reduction achieved in 2021 through the work of Clinical Engineering constituted €333,790.63, shown in the table, with the reduction distributed across the quarters.
Keywords: clinical engineering, health technology management, cost-saving

F2- Health Technology Management (HTM) 3

Enhancing Medical Equipment Management and Performance Metrics in a Regional Healthcare Authority

By Mary Marinou, Anastasia Daskalaki and Aris Dermitzakis

Institute of Biomedical Technology (INBIT), Greece

Medical Equipment Management Systems (MEMS) are a fundamental part of managing and maintaining medical equipment in a healthcare setting, from a local health center on a distant island to a metropolitan hospital. These systems have evolved over the years to streamline processes, enhance efficiency and ensure regulatory compliance. The Institute of Biomedical Technology in Greece (INBIT) has developed such a system, called Web-Praxis, with emphasis on safety, efficiency and effectiveness of Medical Equipment (ME). Web-Praxis is a web-based system that keeps track, assists and facilitates all the ME related actions a Clinical Engineering Department has to perform during the whole life cycle of ME in a healthcare unit. Some of the main features and functionalities of Web-Praxis include inventory management, tracking repairs and maintenance scheduling, vendor and contract management, reporting, analytics and integration with other systems. The use of such a system installed in every healthcare unit under a Health District, allows supervision of equipment and actions that take place on a daily basis and enables the utilization of the ME by knowing the devices distribution within the district area, and allowing their allocation based on the needs of each unit. Web-Praxis is currently installed in more than 10 Greek hospitals and about 100 health centers. This study will present the results of a 10-month tracked use of this system in the 2nd Greek Health District of Piraeus and Aegean consisting of 86 health units. More specifically, analytics focused on the ME entries over this 10-month period, usage of the system per separate health unit along with statistics for the condition and status of each medical device registered in the system are presented. In more detail, 542 ME new entries were added, increasing the total number of ME inventory by 11%, resulting in a total of 5426 devices. Moreover, reporting regarding the number of failures and repairs compared to the total number of devices are also included along with data about the origin of the repairs. A total of 484 failures were reported, with the majority of them being repaired by external agencies. Less than 5% of the failures were unrepairable. Additionally, different types of analysis, like the most frequent ME types and groups that were malfunctioning, may be performed. Such a system introduces a new line of communication between the central administration and each individual health unit offering direct communication regarding medical equipment. Finally, data-driven decision making based on performance metrics provided by a system is also an important part of what can be achieved and contributes to a safer and more efficient healthcare environment.
Keywords: medical equipment management systems (MEMS), medical equipment inventory, performance metrics

F2- Health Technology Management (HTM) 3

Survey on the Biomedical Cooperation Practices of French International Hospital Cooperation Actors and their Partners, and their Needs for Support

By Cathy Blanc-Gonnet, Emilie Durand, Benoît-Pierre Ligot and Clarisse Delaspre

Humatem (NGO), France

The Covid-19 pandemic highlighted the weaknesses of low-and middle-income countries' (LMICs) healthcare systems and the lack of sufficient qualitative equipment essential to care for patients. In France, many hospitals are involved in international hospital cooperation (IHC) partnerships with other hospitals in the world, still, few of these projects currently include clinical engineering (CE) aspects. Yet, the absence of biomedical cooperation activities can considerably reduce the impact of IHC projects. To understand this gap, the NGO Humatem along with the French association of biomedical engineers (AFIB) and the French Hospital Federation (FHF) conducted a survey among French IHC actors and their partners in LMICs with 3 objectives: take stock of current practices regarding biomedical activities in IHC projects, assess their potential needs for support, while raising their awareness on this area of cooperation. An online survey was sent by 2 IHC financial backers to 34 French IHC focal points (representing 46 partnership projects), asking them to forward it to their partners : the FHF targeted 22 « PRPH » grant recipients, and the Ministry of Health to 11 « APCHI » grant recipients. Humatem carried out email and telephone reminders until August. Amongst the 20 respondents, 16 were representatives of French hospitals, 2 of French associations, 2 of partner healthcare facilities in the « South ». 10 projects include biomedical cooperation activities (WBC) and 9 do not (NBC). Where 92-100% of the projects involve doctors, only 14% of the NBC projects include CE professionals versus 100% of WBC projects, however, these were not systematically invited to on-site diagnostic missions. The major difficulties encountered by the « Southern » healthcare facilities are 1) acquisition of medical devices (MD) and management of MD (mentioned by 15 out of 20 respondents), 2) training of CE professionals (14/20 including 100% of WBC actors). On average, WBC actors identified 2,3 times more difficulties than NBC actors and mentioned more technical issues. Activities led by the partners included 1) procurement of MD (early on in the projects), 2) training of medical/nursing staff on the use of MD, 3) training of CE professionals (carried out by the longest-running projects or programmed later on in the course of the project as IHC actors have difficulty finding in-house or external experts to implement it). If WBC actors witness positive changes thanks to IHC projects, many obstacles remain: human resources (turn-over, insufficient staffing or competencies), infrastructures and means, limits of partitioned or small-scale projects... but they also shared solutions. 90% of the respondents would find relevant to develop (furthermore) biomedical cooperation in their projects (with 14/17 prioritizing the training of CE professionals): 100% of them express a wish for support. Finally, 61% of respondents did not have any information about the biomedical department of the « Southern » partner hospital (3/11 WBC actors, 8/9 NBC actors).To sustainably improve the quality of care in LMICs' partner hospitals, IHC projects need to adopt an integrated approach, starting with addressing the means and needs of biomedical departments during the diagnostics.
Keywords: LMICs, international hospital cooperation, biomedical cooperation, procurement of medical equipment, management of medical devices, clinical engineering training, equipment user training, biomedical department, integrated approach, maintenance, donations, biomedical / clinical technicians

F2- Health Technology Management (HTM) 3

Central Equipment Library

By Rebecca Bailey

Royal Melbourne Hospital, Australia

Hospitals frequently have a large inventory of medical devices with a mixed ownership model of pooled medical equipment and locally acquired and managed devices. The inconsistency of this ownership model creates an environment where equipment is hoarded, hidden, misplaced or Marked as "Ward Y'; this has made a surplus of underutilized devices that are difficult to find for routine maintenance when required for clinical care. Equipment can have negotiated maintenance agreements with various owners and no overarching visibility or operational and maintenance status individually. The variations between maintenance strategies make it difficult to manage assets consistently across both fleets and appropriately manage their lifespan by tracking common points of failure and managing service costs. The following are frequent consequences of the current disaggregation model. 1. Medical devices are frequently unavailable when urgently needed leading to delayed patient care with the potential for indirect poor patient outcomes.2. Unnecessary capital investment in additional (often cited as replacement devices).3. Increased staff injury and worker compensation premiums because of the inability of nurses, Allied Health and Clinical Assistants to locate the required patient transfer equipment to support comfortable and safe movement

and transport.4. Inaccessible equipment is not proactively maintained within recommended thresholds leading to unplanned failures and increased downtime. The clinical engineering department established a dedicated central equipment library that was customized to address these ongoing organizational challenges. The space includes powered areas for loan equipment, imprest equipment, electric beds (standard, low and bariatric), technician benches and a large workspace to facilitate annual preventative inspections. The Central Equipment Library will ensure: 1. Commonly used equipment is available through a Local Equipment Area replenishment service or by contacting the CEL directly.2. Established processes for sourcing and hiring equipment.3. Supply of essential manual handling equipment to prevent user injury.4. Better tracking of equipment used to enable further investment.5. Reduction in time spent by clinical staff on sourcing equipment and reporting on faulty equipment. The benefits of hospital-wide shared/pooled equipment have been demonstrated, improved patient safety, and show financial advantages compared to a department or ward-level ownership system. Establishing the central equipment library has uncovered unexpected benefits, including identifying equipment with old software versions and drug libraries. The central equipment library has improved equipment availability for patients and clinical users, managing recurring clinical and manual handling risks reducing equipment diversity and improving equipment management. We uncovered the high bariatric bed hire costs, first taking on the hire of these beds to capture and track expenses transparently and then moving to procure and purchase additional hospital-owned bariatric beds. The increased oversight has allowed the hospital to make smarter decisions about procurement versus equipment hire and the placement of bariatric meds. The central equipment library centralized an existing bed bureau with clinical manual handling equipment and progressively transitioned to pooled clinical equipment, including infusion pumps, syringe drivers, enteral feed pumps, patient warmers and peripheral circulatory compression assist units.

Keywords: central equipment library, capital investment, opportunities, manual handling equipment, beds, pooled medical equipment

F2- Health Technology Management (HTM) 3

Use of Business Intelligence Software for Monitoring Key Performance Indicators (KPI) for Computerized Maintenance Management System (CMMS) Evaluation

By Adriana De Cosmo Andrea Pezzillo

Politecnico di Milano, ASST G.O.M. Niguarda, Italy

In the area of Technology Management, there is an increasing need to analyze the complex world of healthcare assets using performance indicators (KPIs) and dashboards to strategically support health technology managers. In particular, the use of electromedical equipment for the delivery of hospital care services requires increasingly advanced technology governance, which is often not adequately supported by current management and analysis tools. The task of a Clinical Engineering Department (CE), such as that of ASST Grande Ospedale Metropolitano Niguarda, is the management and maintenance of all this equipment to deliver a high clinical service. Maintenance, a combination of all the technical, administrative, and managerial actions aimed at maintaining or restoring the functionality of the equipment, is an activity of great technical/economic importance and as such it should be subjected to performance measurement to assess and improve its efficiency and effectiveness. The use of KPIs allows the in-depth analysis of the entire electromedical equipment pool, a greater awareness of the economic value managed by the facility, and a better understanding and evaluation of the critical issues of the various existing operating units. The objective of this work is the identification of KPIs best suited to the reality of ASST Niguarda through the literature review, with particular correspondence to the current European standard UNI EN 15341, which suggests a series of indicators designed to evaluate the performance of hospital maintenance. Moreover, the standard emphasizes the importance of adapting the indicators to the reality considered, given the complex heterogeneity of the facilities present in the European community. A further objective was to develop an interactive dashboard that, through the visualization of the time trend of the KPIs, would support the facility in managing the maintenance process of the technology pool. After a thorough literature search, more than 20 KPIs were identified and subsequently divided into 6 groups derived from those existing in ISO 9001: administrative management, logistics management, technical management, quality, staff training, and equipment management. Then, using data extrapolated from the CMMS and leveraging the potential of the Microsoft Power BI business intelligence tool, the dashboard was implemented to monitor workflows and performance in real time through graphs and reports. A dashboard was created and the real-time vision and manipulation of data through filters made the potential of the solution immediately clear. Moreover, it was possible to identify in detail the critical issues within the workflow. Further work is to be done. At the moment data input to the system is not optimally structured for the development of the KPIs that were identified. A process of CMMS reengineering has been started and the

new CMMS will be implemented with a process approach and a dataset designed on both workflow and KPIs. This process will last roughly 12 months.
Keywords: CMMS, technology management, maintenance, KPI, dashboard

F3 - National CE Societies

AIIC: The Italian Association of Clinical Engineers AIIC. Our first Thirty Years

By Umberto Nocco, Stefano Bergamasco, Lorenzo Leogrande and Paolo Lago

Italian Association of Clinical Engineers, Italy

The Italian Association of Clinical Engineers (AIIC) this year turns 30. Founded in Milan in 1993, is now a leading association in the field of Clinical Engineering. The first seed of the association was planted a couple of years before the actual founding, when it became clear among the few clinical engineers operating in Italy that an association was needed to spread and enhance the role of a rising profession, needed in the health care system to grant a correct and safe use of devices. AIIC increased in number of associates and in status within the healthcare system, and almost all the clinical engineers operating in Italy are now members. A recent survey showed some interesting results. The number of members rose from just a few in 1992 to more than 2000 in 2023; the majority of members (64%) are less than 40 years old, while 21% are 40-49 and only 15% are 50+ years old. The profession is equally distributed throughout Italy (39% in the north, 23% in the central regions and 38% in the south) and 59% of the associates work in public hospitals. Moreover, the survey showed that, although the total sums up to 50% women and 50% men, younger members are more likely women (more than 60% both in under 40 and under 30) while men are the majority among older members. AIIC has been active in many areas, providing both services for members (tutorials, workshops, etc.) and political endorsement trying to achieve a legal recognition of the profession. In 2017 a big goal was achieved: a national law established a national list of clinical and biomedical engineers, based on competencies recognition. The covid outbreak proved the Italian clinical engineering community to be vital, united and important for the health care system: relationships at a regional, national and international level were enhanced, daily work inside hospitals made it possible to help patients and many young colleagues were enrolled in hospitals increasing the overall presence. AIIC organizes a national congress every year: it is a privileged occasion to establish relationships, meet colleagues and stakeholders and meet vendors presenting their innovative devices. In ten years, it has become the bigger and most important health technology meeting in Italy. In the other hand, from 2022 a Summer School was established: dedicated to younger colleagues and taught by senior CEs only, proved to be a privileged occasion to exchange knowledge and competencies, establish close relationships – human and professional – thus enhancing skills and membership to the CE community. AIIC, a member of IFMBE and one of the first GCEA members, is very active in international relationships and started a specific action in Europe to unite all CE Associations in order to establish a new entity that could talk to European Institutions. This is an important goal not only with regards to knowledge sharing and professional exchange but also as a means to interact with EU and obtain recognition and the chance to be part in the regulatory process.
Keywords: CE, association, national activities, recognition

F3 - National CE Societies

CEASA: South Africa 2023 Global Clinical Engineering Day Competition

By Shija Daniel

Netcare Group, South Africa

This competition is open to Clinical Engineering Professionals in South Africa (CEASA members and non-members) Deadline for entries to be submitted: 15 September 2023. This year' s competition offers the following categories:CE Student of the Year Award • This category is directed at Tertiary Institutions offering the Clinical Engineering Qualification • This competition is directed at the highest performing Clinical Engineering student(s) that has completed his or her S3 (old syllabus) or S4 (new syllabus) • The Representative from the Tertiary Institution enters the student for this competition • Written permission must be obtained from the student who is to be enrolled in the competition • Prizes include: – CEASA branded jackets – Powerbanks – Guaranteed interviews with prospective organisations for the 6 – 12 month work integrated

learningMost Popular CE Award: • This category of the competition is aimed at the most popular CE Professional working in the CE field • The winner will be selected on a nomination basis • The nominator must obtain written permission from the nominee to enter him/her in the competition • Prizes include: – CEASA branded jacket – TabletProfessional of the Year Award: • Submissions are invited in any one or combination of the following themes: – CE Value Add Initiative or Project Targeting Improved Patient Lives or Patient Safety – CE Process Design or Process Improvement or Maintenance Best Practice Project Implemented • Submissions to be in the form of an essay with supporting information to substantiate the result of initiative or project implemented, ie. photos, tables, figures showing relevant data • Participant must indicate their category on submission of their entry via email • Prizes include: – Grand Prize: A weekend away for two valued at R10 000 plus a CEASA Branded Jacket – Consolation Prizes include CEASA Branded Jackets and PowerbanksCE Mentorship Award: • This category aims to recognize an impactful mentorship between a mentor and mentee • A mentee can nominate a mentor who has had a huge impact on them • Written consent must be obtained from the Mentor who will be entered into the competition • Both Mentee and Mentor win a prize • Prizes include: – CEASA branded jackets and powerbanks

Keywords: clinical engineering, awards, Global CE Day

F3 - National CE Societies

ABEClin: 20 years Promoting Clinical Engineering in Brazil

By Ricardo Sa Maranhão

Brazilian Association of Clinical Engineering, Brazil

Description: The Brazilian Association of Clinical Engineering (created in São Paulo in 2003 filling a need for clinical engineers, manufacturers and society in this period: -National Congresses were held. -Support for international events. -Increase from 60 associates 2004 to 1 000 2023. -Support for government agencies and seeking official recognition of the Clinical Engineer profession in Brazil. ABEClin carries out its work through volunteers in all states of Brazil We are present with regional offices in 6 out of 23 states and in the process of opening new regional offices In our events we seek to bring knowledge and bring together professionals and manufacturers. **Goals:** ABEClin supported and was one of the first members of the GCEA, supports the IFMBE, partnering with the ACCE and always seeks to interact with serious entities to bring solutions to its members One of ABEClin's focuses is the safe use of technology in the patient, according to our definition of a clinical engineer: "the clinical engineering professional is the one who applies engineering techniques in the management of health equipment with the objective of ensuring the traceability, usability, quality, efficiency, effectiveness, safety and performance of this equipment, with the purpose of promoting the safety of the patients." In the search for the best qualification of the clinical engineer, the Latin American seminar on clinical engineering was held in May 2023 (at the Hospitalar Fair which began studies together with representatives of Latin American countries.)**Results:** Our associates have institutional support just as we help government agencies in terms of technology management Seeking points to be improved, we founded the Feminine Committee to encourage and support women in Clinical Engineering During the pandemic period, we were able to provide information practically in real time, psychological support for technicians, technologists and engineers, as well as organize and support the ventiladores Project where more than 2000 pulmonary ventilators were recovered at no cost to public hospitals In partnership with one of our associates, we provide a course on ventilator maintenance in Portuguese, English and Spanish, free of charge. We are fighting for the recognition of the profession in Brazil, with a minimum curriculum that allows for quality assured courses.

Keywords: clinical engineering, national CE Society, definition

F3 - National CE Societies

GSBE: Towards the Recognition of Clinical Engineering as Health Profession in Ghana: The Role of the Professional Association

By George Boadu

Komfo Anokye Teaching Hospital, Ghana

Introduction: Technological advances in healthcare delivery have made clinical/biomedical engineering an indispensable role in the healthcare industry. The traditional role of the clinical engineer repairing and maintaining medical devices has progressively grown to now include the equally important role of supporting and optimizing the use of healthcare technology.

In Ghana, hospital maintenance services started in the 1950s when the Hospital Engineering Department was established in the Komfo Anokye Teaching Hospital. By 2004, clinical engineering units had been established in the then Ten Regional Health Directorates and the Teaching Hospitals, to respond to the rising need for maintenance and repairs of medical equipment. Although clinical engineering professionals advance healthcare, by ensuring that health technologies are appropriately and effectively used to improve healthcare delivery, their services were not appropriately recognized. In 2011, the government of Ghana restructured the public sector pay policy and implemented the single spine salary structure for all public sector workers. The commission that implemented this policy placed clinical engineering as administrative and support staff but not a health workforce. This paper elaborates the steps taken by the professional association that led to the recognition of clinical engineering as a health workforce. **Methods:** Petition was submitted to the various stakeholders, i.e., Fair Wages and Salaries Commission, Ministry of Health, Ghana Health Service and the Teaching Hospitals to register our grievance on the Single Spine Implementation and called for re-grading. Participated in the Single Spine Implementation Review Taskforce meetings comprising MoF, MoH, HSWU and Professional Groups in the Health Sector. Meeting with Stakeholders – Fair Wages and Salaries Commission, HSWU, MOH, Ghana Health Service and also participated in job evaluation exercise. Organized public awareness campaign all radio stations to educate the general public on the role of clinical engineering in healthcare delivery. **Results:** Clinical engineering re-graded to the 'Clinical Category' on the Single Spine Salary Structure after five years of engagement with stakeholders. Placement of clinical engineering staffs on the same salary level with nurses and allied health professionals, after series of meetings and job evaluation exercise carried out by the professional association. **Recommendation and Conclusion:** The clinical engineering struggle for recognition as a health workforce should be tackled as a collective responsibility by the professional associations at all levels. Together we can really do it better for better recognition, through advocacy and collaboration.
Keywords: clinical engineering, professional association, recognition, clinical category, fair wages and salaries commission, job evaluation, placement

F3 - National CE Societies

IFMBE: Survey on Diversity and Inclusiveness in the Membership of the Council of Societies of IFMBE

By Marie-Ange Janvier

Children's Hospital of Eastern Ontario, University of Ottawa, Carleton University, Canada

The Council of Societies of the International Federation for Medical and Biological Engineering (IFMBE) recognizes the importance of diversity and inclusivity in advancing the field of medical and biological engineering. The abstract highlights a survey to be conducted by the Council to identify and understand the diversity within the membership of his societies. The primary objective of this survey is to gather comprehensive information about the demographic characteristics of the Council's member societies, including geographical distribution, gender representation, age distribution, and cultural diversity. By obtaining this data, the Council aims to gain insights into the current state of diversity within its membership and to identify potential areas for improvement. The survey is designed to be comprehensive yet concise, taking into consideration the valuable time and resources of member societies. It will be distributed to all member societies of the Council, utilizing digital platforms and communication channels to reach a wide audience. Efforts will be made to ensure the anonymity and confidentiality of participants' responses, fostering an environment of trust and openness.The collected data will be analyzed using appropriate statistical methods to derive meaningful insights. The results of the survey will provide a snapshot of the diverse landscape within the Council, enabling a better understanding of the representation of various groups and identifying any underrepresented demographics. This information serves as a valuable baseline for future initiatives aimed at promoting diversity and inclusivity within the Council and its affiliated societies. The findings from the survey will shed light on areas where targeted efforts can be made to enhance diversity. These may include implementing outreach programs to regions with low representation, promoting leadership opportunities for underrepresented groups, and fostering a supportive environment that encourages the participation of individuals from diverse backgrounds. The Council can also use the survey results to develop strategies for improving diversity and inclusiveness in its conferences, workshops, and publications, ensuring a broad range of perspectives are represented. In conclusion, the survey conducted by the Council of Societies of IFMBE to identify diversity within its membership provides a vital starting point for promoting inclusivity and equality in the field of medical and biological engineering. By acknowledging and addressing any existing gaps in representation, the Council aims to create a more diverse and inclusive community that fosters innovation, collaboration, and excellence in advancing healthcare technology for all.
Keywords: council of societies, diversity, survey, members, demographic characteristics, geographical distribution, gender representation, inclusivity

F3 - National CE Societies

CSCE&CMD: Empowering Clinical Engineers in China

By Dong Jin, Meng Xu, Yan Wang and Hongjun Liu

Journal of China Medical Devices, China

Through global research carried out by IFMBE CED and GCEA in recent years, the needs of Clinical Engineers (CEs) around the world have become clearer. In order to provide a better communication and learning platform for CEs in China, the Journal of China Medical Devices (CMD) has been making new attempts to assist CEs, utilizing our accumulated experience and resources over the years. With the goal of helping the growth of CEs and amplifying their voice in the healthcare industry in China, we would like to share two main progressions that we have made. A) Building Unique CE Network based on the Journal: Founded in 1986, CMD is a scientific and technological journal in the field of clinical engineering. It is recognized as a core journal by Chinese Science and Technology - a statistical source for Chinese scientific and technological papers. The journal is supervised by the National Health Commission of the People's Republic of China, and has achieved a latest published core impact factor of 0.754. Till date, CMD has built a five-level structure to connect with CEs in China. B)The Launch of the Outstanding CE APP: To fully utilize the capabilities of an online platform, CMD developed and launched the Outstanding CE APP in 2019. The app solves the problem of geographical restrictions by providing information to grassroots staff in remote areas and hospital departments, breaking the bottleneck of learning and communication. This mobile platform is designed to manage, use, purchase, sell, repair medical devices. The app has several functions that allow easy access to a vast library of resources. As of June 2023, the app has been downloaded by over 2.6 million users, including 56,000 CEs. It offers more than 1,000 live streaming medical conferences and webinars annually, making it an efficient and real-time online knowledge dissemination platform for clinicians and CEs to learn about "new products, technologies, and methods" related to medical devices. Overall, CMD provides not only a platform for CEs in China to publish high-quality papers but also, with the launch of the app, it has become a convenient platform for CEs to learn and communicate anytime, anywhere. CMD continuously explores new approaches to serve CE community, such as organizing regular webinars, arranging China's Outstanding CE competition, conducting research on medical device industry data, and celebrating Global Clinical Engineering Day. By sharing CMD's two successful experiences of promoting education and communication among CEs, we hope to inspire more innovative ideas for the advancement of clinical engineering.
Keywords: education, mobile application, medical device, clinical engineer

F3 - National CE Societies

CMBES: Clinical Engineering Standards of Practice, 4th Edition

By Michael Barton

Canadian Medical and Biological Engineering Society, Canada

The Canadian Medical and Biological Engineering Society (CMBES) would like to present on the recent revision to its Clinical Engineering Standards of Practice (CESOP). As Canada's national society for research and hospital based Biomedical / Clinical Engineering (BME/CE), we have long had a standard of practice guide for hospital CE departments regarding how to set up and manage a CE program in a hospital setting. It incorporates a multiplicity of approaches and coverage options useful to hospital administrations for achieving their unique goals in their unique ways.First introduced in 1998, this 2023 is the fourth edition of the CESOP and continues to provide aspects of a model CE department and hospital organization approach to a biomedical equipment and technology management program. The very first sentence of the Introduction sets the tone for the entire CESOP: "Clinical Engineering is one of several professional disciplines contributing to patient safety and staff safety through safe, effective and economical health care Technology Management across the Hospital." As such, the ultimate goal of any CE program is to provide the best environment to support safe, effective, and affordable technology usage, which in turn supports clinicians with the best chance of positive patient outcomes. (Though formally written to address engineering aspects, the CESOP implies a sentiment common to all CE programs world-wide, regardless of jurisdiction: these are our patients, too. Everyone contributes to safe patient care and the CESOP is organized to help achieve exactly that.)This CESOP forms the basis of questions for our Peer Review program, a review service which BME/CE departments from across Canada may engage voluntarily to test their departmental policies and approaches. Though

not binding, one can truly think of this as a type of soft-credentialling for BME/CE departments and helps them to stay current and respectful of advances and developments in technology support. Accreditation Canada uses the CESOP to inform their intensive review processes, which are binding, so a CESOP Peer Review is very much a useful check to see how well a department will likely fair during their next hospital accreditation. This 2023 third edition represents a significant update. Since even the 2014 third edition, advancements in networked and/or wireless technologies have been significant, cybersecurity has (rightly) given everyone pause in all that we do, patient-owned device ownership has exploded, and quality / risk factors have never been more important to assess, track, and control. We have either amended and expanded existing sections or added sections to address all of these key factors. We have also revised and improved sections to reinforce our core business – management of technologies in health care – as well as amended sections that are used by more acadaemic institutions that participate in research / development and in-hospital assessment of health technologies. Details for all of these sections, which align with the 5th ICEHTMC Congress topics will be presented. (NB. CMBES offers the CESOP for free to under-resourced jurisdictions World-wide as part of our international outreach.)
Keywords: standards of practice, health technology management, policy

F3 - National CE Societies

TNBMEA: Collaboration & Affiliation with International Clinical Engineering Organisations by the LMIC Clinical Engineering Communities - Best Practices - A case study of Tamil Nadu Biomedical Engineers Association (TNBMEA), Tamil Nadu, India

By Jagadesh Kumar Dhayalan and Kavi Bharathi Sakthivel

Tamil Nadu Biomedical Engineers Association, India

Clinical engineering practitioners in lower-middle-income countries can greatly benefit from the work of the International CE/HTM Advocacy Organisations without having to reinvent the wheel locally in their countries. Merely imitating the work of these organizations can go a long way in improving the status of clinical engineering professionals in their respective countries. International CE organizations may already have a working solution in place for most of the pressing challenges of the LMIC clinical engineering communities and are working already for our future challenges. Most often, a minor tweak to their offered solutions to fit local conditions, situations, and adoption of the same can yield impactful results. In the process of seeking solutions to their problems, LMIC clinical engineers often end up finding opportunities to get involved, get inspired and add more value to their own community and that of the others.The submission seeks to present the success story of a Biomedical Engineer from an Indian State of Tamil Nadu finding inspiration from the global clinical engineering fraternity leading to the establishment & operation of a state-level biomedical engineering society for government clinical engineering practitioners. Also presented are the activities of the society and potential future high-impact activities planned with possible active partnerships with organizations sharing similar interests. Best practices for reaping benefits through observation, participation, affiliation, and collaboration from these organizations for LMIC clinical engineering groups looking to form a professional society are also discussed. Tamil Nadu Biomedical Engineers Association (TNBMEA) is a not-for-profit professional society for Biomedical Engineers practicing clinical engineering profession in the Government Institutions and hospitals of the State. TNBMEA was constituted in the year 2014 and allegedly is the oldest registered active clinical engineering association in India. TNBMEA & members associated with Global Clinical Engineering Alliance (GCEA), Association for the Advancement of Medical Instrumentation (AAMI), American College of Clinical Engineering (ACCE), Clinical Engineering Division (CED) of the International Federation of Medical & Biological Engineering (IFMBE) is trying to replicate the many activities of these great organizations to promote & advocate CE/HTM practice in the State. TNBMEA expresses its willingness to collaborate with more organizations in the domain of Clinical Engineering/Healthcare Technology Management across the globe to help bring best practices to our State. TNBMEA through this submission wants to place on record our gratitude to these global organizations that share our interest, for being an inspiration and leading by example.
Keywords: Clinical Engineering, Healthcare Technology Management, Clinical Engineering Society

F4-Industry

Healiom: Digital Health Access Innovation

By Carla Gallegos,Ash Damle, Sean Howse MD

Healiom Inc.

Description: Based out of the USA and India, Healiom, Inc. is a healthcare technology (HT) company dedicated to solving the medical capacity crisis. There are not enough providers to serve the massive demand of consumer health services and the gap continues to grow daily, resulting in the burnout of medical overworked professionals and an ever-increasing population of patients unable to secure care. This is happening because healthcare today is not designed nor developed in the best interests of those who deliver and receive care. The team at Healiom, impassioned by personal accounts of how the current healthcare ecosystem failed to help and save the lives of their loved ones and empowered by collective decades of practical field experience, thought enough was enough. Leveraging cutting-edge generative AI, Healiom aims to tackle the capacity crisis in three ways: unlocking unused provider availability, improving efficiency and clinical quality of a provider's workflow, and expanding the breadth of care that can be handled remotely. Core to how the team has built a new healthcare stack is user-centered design. Providers are people too and deserve tools shaped around how they best deliver care. All of this allows us to ultimately meet the patient where s/he is, especially during moments of duress and pain. Healiom's AI engine connects all facets of healthcare—patient and provider preferences, clinical history, symptoms, treatments, billing codes, and everything in between. Over a 12+ year timespan, the Healiom AI engine has learned from the experiences and outcomes from over 80M patient lives, has ingested over 500GB of MediSpan/FDB and 50M articles, and has been curated for more than 40K hours. We started applying this AI in real-world use cases. In a recent clinical study, we followed the physical exam and diagnostics process for 10,000+ consultations and found that medical providers selected one of the top 5 diagnoses that our AI engine recommended 94% of the time and the final differential that was the top differential diagnosis suggested 70% of the time. Beyond clinically proven recommendations for diagnoses and treatments, the Healiom platform is able to generate a full snapshot of a patient's medical history, facilitate remote vitals capture, support secure sharing of medical records with family and friends, activate telehealth encounters, and handle all post-consult logistics, including the automatic creation of a SOAP note and updates into a patient's EHR. As all of this happens, our AI is continuously learning to systematically improve the threshold of care quality and reduce the number of medical errors that occur. Our platform is developed in a way that allows us to easily plug in best-in-class medical tools and seamlessly integrate our components into existing health systems. All of this is wrapped around a user interface and experience that prioritizes the patients and providers and truly enables culturally competent care, 24/7, from anywhere in the world. "Healthier lives with Healiom!"
Keywords: access, digital health, AI

F4-Industry

DocBox: Integrated Clinical Environment (ICE): From Device Integration to Autonomy

By Tracy Rausch and Steven Dain

DocBox, USA/India

In 2005 at the EMBS conference in New York City, an abstract was presented on the benefits of medical device interoperability. The Integrated Clinical Environment (ICE) standard evolved (AAMI 2700). Over the past almost 20 years, the concept of simple device integration has evolved into an infrastructure and platform for autonomous medical systems. This presentation will review the base standard, and its vision and provide an overview of the most recent technical demonstrations including far Remote Control and the path forward for physiological closed-loop control applications. This presentation will provide an overview of the standard, how it has evolved, demonstration of multiple concepts which a platform based on ICE can make possible. It will also review what HTM professionals should consider as this new era of autonomy begins to emerge in medicine.
Keywords: autonomous medical systems, remote control, IOMT

F4-Industry

Siemes: Risk Management of Operating Medical Devices: An Application with a Systematic Approach

By Abdelhadi El Falaki

The Moroccan Biomedical Society, Morocco

The complexity in operating the management of medical devices, notably their risks during use, require approaches to management that consider multiple factors: organization, technical/technological, human factors, and structure. Under the foundation of applying a systematic approach to risk management of medical devices, the presented thesis proposes a methodology that integrates a variety of existing tools from different sectors. Additionally, where the system is complex and users are involved, the steps in the approach take into consideration methods to evaluate user error. The application of this approach proves that when the methodology is practiced, it has the capacity to not only effectively analyze risk but also decision-making, increase the organizational structure of identifying medical device risk and the implemented written regulations to expand research in clinical settings.
Keywords: risk management, management of risk, biomedical technologies, medical devices, clinical, systematic approach

F4-Industry

Schiller: A Collaboration Case for a New Medical Devices Factory in India During the Peak of Covid-19 Pandemic

By Germán Giles and Marcelo Lencina

Schiller, Americas/India

The COVID-19 pandemic affected in different ways to every country. As India has a very large population, the lack of enough medical devices to treat patients those days, encouraged the country to develop strategies to manufacture more devices. Committed to the country, Schiller set up a new manufacturing unit in the AMTZ area in record time, after a simple chat with AMTZ CEO.
Keywords: manufacturing, networking, pandemic, AMTZ, Schiller

F4-Industry

B. Braun: Cost Impact Analysis for Peripherally Inserted Central Catheters vs. Totally Implanted Ports in India

By Rashid Ali Khan, Ravi Valia and Pinaki Ghosh

B.Braun Medical (India) Pvt. Ltd

Introduction: Peripherally inserted central catheters (PICC) are associated with frequent adverse events such as deep vein thrombosis (DVT), exit-site or pocket infection, blood stream infections (BSI), and occlusion. The estimated incidence of all-grade adverse events is 13.1% to 22%, including 1% to 8% of CR-DVT and 0.5% to 8% of occlusion in cancer patients. Its prevalence has increased in recent years along with the growing use of PICC, particularly in critically ill and cancer patients. These events complicate treatment, interrupt care, and increase cost, morbidity, and mortality. PICCs and totally implanted ports are used to deliver systemic anticancer treatment via a central vein. However, Ports are costlier than PICC, thus necessitating a comparison of value. The objective of this study was to determine the comparative cost and consequences of chemo port versus PICC based on comparative clinical outcomes in India across different implant durations. **Methods:** A decision tree approach was conceptualized for 1000 catheter days to measure the impact of the chemo port vs PICC in India. Input parameters to populate the model were cost of one episode of all grades adverse events including DVT, BSI, adverse reaction and incidence of all grade adverse events to estimate total cost due to all grade adverse events in chemo port and PICC respectively. Input parameters such as cost of device, insertion, maintenance and removal cost of device and indwelling periods in chemo port and PICC was incorporated to perform a decision analytic comparison in costs and consequences

between two arms of the decision tree. The current study also conducted scenario analysis based on varying indwelling periods of chemo port and PICC. **Results:** The overall cost due to all grades adverse events in chemo port and PICC was INR 4,26,999 and INR 7,63,581.66 respectively with percentage saving of 44.08% in chemo port. As the budget impact was favourable thus providing an economic argument to use chemo port in clinical setting in India. The scenario analysis based on varying indwelling periods of chemo port and PICC reported that savings increase as the indwelling period of the chemo port increases. The savings were -2.91%, 44.08% and 67.84% over short term (137 days), mid-term (280 days) and long-term use (593 days) of implant respectively. **Conclusions:** Chemo port is cost effective and has a favourable budget impact for consideration in clinical use in India.
Keywords: peripherally inserted central catheters, chemo ports, cost impact analysis, deep vein thrombosis

F4-Industry

B. Braun: Comparative Analysis of Drug Coated Balloon and Drug Eluting Stent in Patients with Multivessel Coronary Artery Disease: Cost Impact Analysis

By Rashid Ali Khan, Ravi Valia and Pinaki Ghosh

B.Braun Medical (India) Pvt. Ltd

Introduction: Multivessel coronary artery disease (MVCAD) patients with multiple stenting and long stent length may experience a high stent burden. Over a period of long follow-up, the incidence of ischemic events associated with stents steadily increases without reaching a plateau. Furthermore, stent implantation may impede the restoration of vasomotion in stented segments and potentially accelerate neoatherosclerosis in MVCAD patients. As drug coated balloon (DCB) based treatment approach may safely reduce stent burden in patients with MVCAD, thus necessitating a comparison of value. The objective of this study was to determine the comparative cost and consequences of DCB versus drug eluting stent (DES) based on comparative clinical outcomes using Indian cost. **Methods:** A deterministic decision tree approach was used for one hundred hypothetical patients to measure the impact of the DCB and DES in India. The decision analytic comparison in costs and consequences between two arms of the decision tree enabled a cost benefit comparison between DCB and DES. Input parameters to populate the model were cost of one episode of Major adverse cardiovascular event (MACE) and incidence of MACE to estimate total cost due to MACE in DCB and DES respectively. Other input parameters such as cost of device and cost of dual antiplatelet therapy (DAPT), were incorporated to perform a decision analytic comparison in costs and consequences between two arms of the decision tree. Our model considered a 3-month DAPT use in DCB arms and a 12-month DAPT use in DES arm. All cost inputs for products and clinical consequences were evaluated based on the Indian healthcare system and a patient perspective was taken in the model as India is an out-of-pocket market. **Results:** The overall cost in DCB and DES was Rs. 1,44,51,810.30 and Rs. 1,52,95,697 respectively with budgetary saving of Rs. 8,43,886.7 in DCB. Even though DCB price 58% higher, 5.52% saving is calculated in DCB over DES. As the budget impact was favourable thus providing an economic argument to use DCB in clinical setting in India. Cost Per MACE avoided was computed as Rs. 1,18,857 per patient when DES was replaced by DCB. **Conclusions:** DCB is cost effective and has a favourable budget impact for consideration in clinical use in India.
Keywords: drug coated balloon, drug eluting stent, multivessel coronary artery disease, major adverse cardiovascular event

F4-Industry

B. Braun: Cost Impact Analysis for Safety Peripheral Intravenous Cannula with or without Multi-Use Blood Leakage Control Septum in India

By Rashid Ali Khan, Ravi Valia and Pinaki Ghosh

B.Braun Medical (India) Pvt. Ltd

Introduction: Conventional safety peripheral intravenous cannulas (SPIVC) reduce the risk of blood exposure during cannula insertion. However, they often fail to prevent blood leakage which poses a risk of contamination and infection from blood-borne pathogens. These complications may increase hospital stay and patient distress, often requiring cannula replacement. The objective of this decision analytic investigation was to determine the comparative costs and consequences of SPIVC with multi-use blood leakage control septum versus SPIVC without multi-use blood leakage control septum based on comparative clinical outcomes in India. The study also evaluated the nurses' time of using SPIVC with or without

multi-use blood leakage control septum. **Methods:** A deterministic decision tree approach was parameterized for 100 hypothetical patients to measure the impact of the SPIVC with or without multi-use blood leakage control septum in India. The decision analytic comparison in costs and consequences between two arms of the decision tree enabled a cost benefit comparison between SPIVC with and without blood leakage control septum. The model was based on the assumption that incidence of device related complications like blood leakage, blood spillage and contamination to the surroundings would mean a replacement of SPIVC. Input parameters were device costs and device replacement costs due to complications. All cost inputs for products and clinical consequences were considered based on the Indian healthcare system and a patient perspective was taken in the model as India is an out-of-pocket market. The time taken from skin cleansing to completion of cannulation was considered for nurses' time calculation when using SPIVC with or without multi-use blood leakage control septum. **Results:** The overall cost in SPIVC with or without multi-use blood leakage control septum was Rs.37,971.20 and Rs. 46,176 respectively with budgetary saving of Rs. 8,204.80. From a budget impact perspective savings of 17.77% was observed in SPIVC with or without multi-use blood leakage control septum respectively. Hence, the budget impact was favourable thus providing an economic argument to use an SPIVC with multi-use blood leakage control septum in clinical setting in India. The study also demonstrated that the introduction of SPIVC with a multi-use blood control septum could offer time efficiency savings equivalent to a 46.6% reduction in average cannulation time for 100 patients. The SPIVC with multi-use blood leakage control septum can save 124 seconds of nurse time per patient. **Conclusion:** SPIVC with multi-use blood leakage control septum is cost saving and has a favourable budget impact in clinical use in India. Optimizing cannula use can reduce staff time and deliver the most effective care.
Keywords: safety peripheral intravenous cannula, blood leakage, cost impact analysis, nurse time

F4-Industry

Chalapathi Institute of Pharmaceutical Sciences: Role of Clinical Pharmacist in Risk Management of Adverse Drug Events in Healthcare Technology

By Sk. Baajirahamtulla, K. Ramakrisnareddy, N. V. Rama Rao, Rama Rao Nadendla

Chalapathi institute of pharmaceutical sciences, India

Adverse drug reactions contribute significantly to the healthcare burden. However, they are largely preventable through appropriate management processes. This review aims to identify quality indicators that should be considered for routine monitoring of processes within hospital ADR management systems. It also examines the potential reasons behind variation in ADR management practices amongst HCPs, and explores possible solutions, to improve both the quality and quantity indicators of ADR management processes. Improving the quality of life of patients is a key concern in public health. In the context of improving therapeutic compliance, quality of life of patients. We conducted this review to support risk minimization actions. ADR risk increases with age-related changes in pharmacokinetics and pharmacodynamics, increasing burden of comorbidity, polypharmacy, inappropriate prescribing and suboptimal monitoring of drugs. ADRs are a preventable cause of harm to patients and an unnecessary waste of healthcare resources. Several ADR risk tools exist but none has sufficient predictive value for clinical practice. Good clinical practice for detecting and predicting ADRs in vulnerable patients includes detailed documentation and regular review of prescribed and over-the-counter medications through standardized medication reconciliation. New medications should be prescribed cautiously with clear therapeutic goals and recognition of the impact a drug can have on multiple organ systems. Prescribers should regularly review medication efficacy and be vigilant for ADRs and their contributory risk level when drugs are no longer efficacious or beneficial or when safer alternatives exist. Inappropriate prescribing and unnecessary polypharmacy should be minimized. As a result, there is now an added focus on safety and risk assessment after a product has received regulatory approval when it is placed on the market and prescribed to large populations. Although there is no international standard that dictates the components of an adequate pharmacovigilance system or the processes to be engaged in risk management, there is a consensus among the major regulators that pharmacovigilance is necessary and important in the development and commercialization of medicinal products. Therefore it is essential in building capacity for clinical trials to understand the components, the functions, and the processes required for full and effective pharmacovigilance and risk management. **CONCLUSION:** The focus of ADR management in hospitals should be to promote patient safety through comprehensive assessment, risk communication and safe prescribing. There is a need to develop a system to define, measure and monitor the quality of ADR management. With health technology. Educational strategies may help improve the quality of ADR management processes. By using strategies like ADR alert card, making patients adhere to the medication with the help of health technology tools like issuing ADR alert card, voice message systems, short message systems, and continuous follow-up to report ADR and any other complications related to drug or devices to minimize the risk of adverse drug reactions and events so that we can generate a signal to recall the medication affecting the society to recall specific medication to minimize the adverse effects.
Keywords: ADR, clinical pharmacist, risk

WICE Panel 2

WICE: The Role of Being Women and Clinical Engineer

By Fabiola Martinez and Samantha Alvarado

IFMBE CED, Mexico

Women in Clinical Engineering (WICE) bring a unique perspective, skill set, and dedication to the field, making them a valuable and strategic resource in shaping healthcare technology management, assessment, and other clinical engineering functions. Their contributions are essential in driving innovation, improving patient outcomes, and ensuring the efficient and effective use of technology in healthcare settings. WICE possess strong problem-solving skills and attention to detail, allowing them to identify and address complex challenges related to healthcare technology issues. They can also think critically and find creative solutions, ensuring that medical equipment functions optimally and prioritizing patient safety. Their communication talents promote effective collaboration with healthcare providers, patients, and other stakeholders. Their ability to listen, empathize, and convey information helps to facilitate seamless communication and understanding, leading to improved patient care and outcomes. The package completes with their high level of empathy for their work; by understanding the importance of human-centered design and the impact that medical devices and technology have on patients' lives, they contribute to developing and implementing user-friendly and patient-centric technologies. While there is no doubt that women in clinical engineering have an ideal profile for these tasks, their impact has yet to be fully acknowledged, partly because we have not taken the time to recognize ourselves. That is why the interest group of women in clinical engineering within the IFMBE CED arises to publicize their contribution to clinical engineering, analyzing their participation in the different clinical engineering functions, recognizing their trajectory, encouraging female participation in CED activities, and eventually, girls and young people to study clinical engineering. As the first step in this direction, a call was made to share the stories of women in clinical engineering. These are reports where the interest is to know what it has been like for women also to be clinical engineers. The first call received 29 contributions between stories and case studies. The stories come from Argentina, Bangladesh, China, Colombia, India, Mexico, Nigeria, Peru, Poland, Saudi Arabia, and the United States; it is worth mentioning that almost all countries contributed more than one story. Among the most relevant aspects that are addressed are the need to acquire new tools to improve medical care through technology and how to overcome it by developing specialized CE programs, the challenges for a woman in a male-dominant field, the effective communication with health stakeholders, the problem-solving urgency that seems to be a constant in the hospital, the complexity of balancing personal and professional lives, the weight of being the first in the field of clinical engineering in our regions and countries, the support for our younger sisters to join the professional area, the skills more than the strength that allows us to work in a heavy environment, and to consolidate professional groups outside the natural borders of nations, among others. The enthusiasm generated by this call has allowed the incorporation of more actions in favor of WICE's objectives. The call is permanently open to enrich a collection that inspires future clinical engineers.

Keywords: WICE, women, stories

WICE Panel 2

The Necessity to Introduce Women Clinical Engineers in the Modern Hospital of Bangladesh

By Mohiuddin Ahmad, Md. Anwar Hossain, Afrin Binte Anwar, Celia Shahnaz

Khulna University of Engineering & Technology (KUET), NEMEMW & TC, Ministry of Health & Family Welfare, Bangladesh

In Bangladesh, like many other developing countries, the healthcare system is facing a critical shortage of clinical engineers. These professionals are responsible for designing, installing, maintaining, and repairing medical equipment, which is essential for providing quality healthcare services in the public and private hospitals of Bangladesh. Despite the importance of clinical engineers, there is a significant gender gap in this field, and women are underrepresented. The purpose of this paper is to highlight the necessity of introducing women clinical engineers in hospitals in Bangladesh. Firstly, the paper will explore the current situation of the healthcare system in Bangladesh and the role of clinical engineers in improving it. Secondly, it will examine the reasons behind the gender gap in this field, including cultural and societal factors, lack of education and awareness, and discriminatory hiring practices. The paper will then argue that introducing women clinical engineers in hospitals in Bangladesh is crucial for several reasons. Firstly, women constitute a significant proportion of the healthcare workforce and can bring a unique perspective to the field of clinical engineering. Secondly, introducing more women into this field can help to address the gender gap and create a more diverse and inclusive healthcare system. Thirdly, women clinical engineers can serve as role models for young girls and inspire them to pursue careers in science, technology, engineering, and management fields. The paper will also discuss some of the challenges that may arise in introducing women clinical engineers in Bangladesh. These challenges include the need for education and training programs specifically designed for women, overcoming cultural and societal barriers, and promoting equal hiring practices. In conclusion, the introduction of women clinical engineers in hospitals in Bangladesh is essential for improving the quality of healthcare services and addressing the gender gap in this field. The paper will provide recommendations for policymakers, healthcare organizations, and educational institutions to promote the inclusion of women in clinical engineering and create a more diverse and inclusive healthcare system in Bangladesh.
Keywords: clinical engineers, healthcare system,medical equipment,gender gap, women clinical engineers, hospitals of Bangladesh, role models

WICE Panel 2

Motivating Message for Women

By Amna Elhassan

Tumor Therapy and Cancer Research Center, Sudan

I agree very much with the saying I had read before. 'What will it take to get more women in green energy jobs' sums it up for me - 'Fewer women means less diversity; less diversity means less innovation; less innovation means less economic growth; and less economic growth is a serious economic threat.' So, men you don't have a choice, we're sticking together. Over the ages, women have faced many difficulties in accessing education and employment and in obtaining credit for their work. In fact, I was afraid to write about the challenges that I face as a woman working in medical engineering, especially in radiation areas, so that you take it as grumbling or attempts to draw attention, but I cannot deny, is a challenge that I have to do more to prove myself and my ability to do my job fully and efficiently. Since my appointment, I started working hard that's why I was promoted to head the Department of Medical Engineering two years after I was appointed. Since then, I have used my knowledge and practical experience to contribute to the solution of problems and technical failures of medical devices. Consider myself lucky to work in an environment where I have to use my mind more due to a shortage of work aids and knowledge sources. Well, am going to tell you a funny story in 2018 I used my personal headphone magnet to maintain the chemistry device cover saving the hospital more than $1,000 So it's all about passion, ladies and girls, and we can do anything with determination and strong will. Eventually, my hope is that more women and little girls have the opportunity to experience an exciting and rewarding career like clinical engineering.
Keywords: women,challenge, strong will

WICE Panel 2

Empowering Women in Clinical Engineering: A Case Study of Nepal

By Prashiksha Ulak

Nepal Mediciti Hospital, Nepal

This abstract highlights the importance of empowering women in clinical engineering, focusing on a case study of Nepal. Women's empowerment and gender equality are critical in all fields, including engineering. This presentation sheds light on the challenges faced by women in clinical engineering in Nepal and highlights initiatives promoting their empowerment. It addresses the low representation of women in the field, societal norms, and gender bias that hinder their empowerment. To date, 51.02% of the total population of Nepal is occupied by women, but the literacy rate of women is just 57.7% which is lower than that of men by 20%. In the same way, the rate of labor participation of women is 26.3% while that of men is 53.8%. Among the major fields of study, the population who choose the field of Engineering, manufacture, and construction, only 12.3% is female. On the same note, only 14.4 % of professional engineers are women. According to the Nepal Engineering Association, Nepal is suffering from a shortage of skilled engineers. About 17000 engineers were registered between 2001 to 2017 but only 2645 women engineers were registered with the Nepal Engineering Council and between 2009 to 2022 only 191 women biomedical engineers were registered which is 35% of total registered biomedical engineers. Among 191 registered women biomedical engineers 70% are settled abroad and the remaining are also planning for the same. So going through the 30% of women biomedical engineers in Nepal, 59% are working as clinical engineers. But one proud moment is that 90% of big and renowned hospitals in Nepal has chief clinical engineer as women. Women are leading clinical engineering. The presentation showcases the success stories of women clinical engineers. Efforts of organizations, and government working towards gender equality. It emphasizes the benefits of women's participation in clinical engineering, such as diverse perspectives and enhanced problem-solving abilities. Strategies for empowering women in the field are discussed, including educational initiatives, mentorship programs, and supportive work environments. The case study highlights the achievements and challenges faced by a Nepalese woman in clinical engineering, serving as an inspiration to others. The presentation concludes by encouraging to support gender equality and promote it in clinical engineering and beyond.
Keywords: women empowerment in STEM, clinical engineer, gender biasness, case study of Nepal

WICE Panel 2

Women Clinical Engineers of Tamil Nadu: An Analysis of Women Clinical Engineers' Education and Career Progressions and Solution to Overcome the Social Hindrance Faced

By Kavi Bharathi

Assistant Engineer Biomedical-Tamil Nadu Medical Services Corporation, India

Clinical Engineering in Tamil Nadu has grabbed greater positive attention surpassing the other engineering domains in recent times, as it attains a commendable progression after the pandemic 2020. Tamil Nadu being a southern part of India plays a vital role in Health/medical tourism not limited to India but also to the contiguous countries. Biomedical engineering is a vibrant field with which future medical technology is being built. Many younger talents now have a passion for medical technology and clinical engineering. The field of engineering is predominantly carried over by masculinist society, of late Women had started making their presence strongly felt in all the fields of engineering and remarkably in Clinical engineering. They also shine as a star in the international societies of clinical engineering globally, motivating the Women's community by setting themselves as an example. Tamil Nadu, setting its standards high in all fields, requires special concentration in the development of career perspectives of Women clinical engineers. Over the years, major variation is noticed in the ratio of students who plump for clinical engineering/biomedical engineering as their field of study in their graduation/college and the students who pursue careers in clinical engineering. Concisely there is a huge difference in the percentage of female graduates pursuing their career in biomedical engineering. Looking forward to a woman service engineer or a woman technician is a thin on the ground scenario in the state of Tamil Nadu. This study aims to understand and analyze the gap between the academia and the health technology requirements of female clinical engineers. The survey will be conducted among the graduated students, professionals, biomedical engineers, technicians and Health technology managers in the biomedical engineering field for the past 10 years to understand the underlying reason for the shortfall in the ratio of Women clinical Engineers in the state, where we have enormous opportunity for women in various fields. To bridge the gap and improve the number of woman clinical engineers in Tamil Nadu and to motivate young women engineers to pursue their dream jobs by managing all the commitments and social responsibilities a women's clinical engineering guidance cell could be launched and can be associated with other international clinical engineering Societies. The results of the study

may have consolidated data on the number of women clinical engineers in the field as service technicians, Customer call centre executives, service managers, service coordinators, application specialists and CEOs who are very successful in their careers and ways to conquer the factors that affect their career progression in all aspects. The goal of the study is to prove women in Tamil Nadu can also be successful Clinical Engineers by overcoming all the hurdles in society that demands them to be more responsible in managing family than prioritizing their career and to encourage young female clinical engineers by motivating and appreciating their contributions.
Keywords: women clinical engineer, social hindrance, career progressions,academia

Use of a Weighted Decision Matrix to Aid in the Selection of a CMMS

By Gustavo Sosa, MBA, BE

University of the Republic, Uruguay

Description: This study shows the work done to aid in the selection of a Computerized Maintenance Management System (CMMS) and to show the thought process that went into the selection of a vendor, comparing alternatives through the use of a weighted matrix, in order to minimize subjectivity. The system will be implemented in one of the top hospitals in the Public Health System (ASSE) in Uruguay. It will be the first one actually implemented in a public hospital, and among the very few in the whole nation. The expected impact of a correct use is huge, as almost every hospital in Uruguay lacks any sort of Maintenance Management System, be it on paper or computerized, and not even Inventory is controlled beyond the most basic accounting needs. Just to give a reference, the National Direction of Medical Technology has an inventory file that dates from 2016, and another top-level hospital, with much more resources, has an inventory that dates from 2020.In the United Sates, adoption of CMMS systems in healthcare institutions is widespread, as it is a basic requirement for TJC (The Joint Commission) Accreditation. It also happens that the USA government CMS (Centers for Medicare and Medicaid Services) demands a 100% up-to-date inventory and Preventative Maintenance plans to every hospital or clinic that intends to receive their payments. TJC regulations are based partially on CMS directives, so both things reinforce each other. This situation leads to the success of CMMS adoption in the USA. In Uruguay, there is a system similar to Medicare called FONASA, but its regulations don't say anything about the inventory or the maintenance of equipment. It barely demands that equipment complies with the MSP (Ministry of Public Health) directives, but even that is not mandatory, as many equipment that is too old (over 10 years is common) or has been technically altered (bypassing controls, or using copycat spares), is simply the only option available to provide treatment. In this situation, the implementation of a CMMS is a leap of faith into the future, as it is likely that the system will expose uncomfortable failures as much as it helps with management.

Resilience, Grit, and Moving Forward Under Challenging Circumstances

By Bassam Tabshouri

Healthcare Technology Management & Advancement (HTMA), Lebanon

Description:"A pessimist sees the difficulty in every opportunity. An optimist sees the opportunity in every difficulty." Winston Churchill. The Lebanon health sector has been facing several challenges before the current crisis. The Palestinian refugees and later the Syrian refugees (since 2011) with limited access to healthcare services added a major stress factor to the Lebanese healthcare sector. This was compounded with economic and political turmoil since October 2019, and topped with the COVID-19 pandemic and the current challenging global crisis. Consequently, Lebanon's healthcare system is now suffering from lack of resources, overloaded infrastructure, and immigration of medical, nursing, paramedical, technical, and administrative professionals. In view of the forementioned challenges, Health Technology Management (HTM) professionals, clinical engineers and BMETs need to think (and move) out of the box to improve access to care and strengthen the healthcare system quality and resilience by

1.Enhancing their soft skills especially stress management, dealing with uncertainty, agility, resilience, grit, and managing upward.
2.Transmitting an atmosphere of agility, resilience, grit, and positivity around.
3.Conducting more in-house repairs, modifications, and some parts manufacturing.
4.Strengthening the existing technical education and training by supporting the development of programs as needed.
5.Providing free training lectures and webinars.
6.Enhancing the efficiency and collaboration within the institutions HTM professionals, clinical engineers, and BMETs work in by assisting in streamlining clinical workflows and reducing duplication of services.
7.Improving access to care by overcoming geographic and logistical barriers to care though facilitating telemedicine, remote patient monitoring, and other digital health solutions. This can help people in remote or underserved areas.
8.Facilitating and conducting research and innovation in HTM and clinical engineering practices under such challenging situations.
9.Acquiring solid knowledge about Crisis Management practices.
10.Supporting disaster/crisis preparedness within the healthcare institutions and on a national level by also including the lessons learned during the COVID-19 outbreak and the explosion of Beirut.

11.Introducing Hospital Based Technology Assessment.
12.Collaborating with local and international organizations and experts.
13.Enhancing the access and stocking of the needed spare parts.
14.Sharing needed highly specialized test equipment with other centres when needed.
15.Creating procedures to allow the different forms of collaboration.
16.Digging more into the medical practices and standards of care. Some of it may be surprising like Oxygen, Medical air and gases being classified by FDA and EU as a drug.
17.Establishing closer collaboration with IT and Plant Engineering.
18.Establishing closer collaboration with the Purchasing, Supply chain departments, and the suppliers and their technical staff to have a cost- effective operation.
Several of the above points look challenging under regular circumstances and more so under hard situations. Yet, as the renowned Lebanese poet Gibran Khalil Gibran said:"Out of suffering have emerged the strongest souls; the most massive characters are seared with scars."

Deep Convolutional Neural Networks for Brain Tumor Classification

By Alaka Acharya; Jackfin KC; Kishori Kunwar; Menam Pokhrel

College of Biomedical Engineering and Applied Sciences, Nepal

Description: Diagnosis of brain tumours at an early stage will allow medical professionals to initiate appropriate treatment in the least amount of time, which will ultimately help in reducing its severity. Deep learning in particular has shown considerable promise in recent years for identifying brain cancers. This project aims to create a deep-learning model that correctly categorizes three distinct malignant brain tumour types: gliomas, meningiomas, and pituitary tumours. Convolutional Neural Networks (CNNs), a family of deep learning models that are especially well-suited for image classification tasks, are the foundation of the proposed model. The feature extraction process is one of the crucial elements of the suggested CNN model. In this work, feature extraction is done with the help of CNN model using several convolutional layers. This study uses a CNN model with five convolution layers containing around 170 million parameters. In the proposed CNN model, the first convolutional layer recovers fundamental characteristics, such as edges and lines, while the successive layers extract increasingly sophisticated features, such as forms and textures. The last convolutional layer produces an array of high-level characteristics that may be utilized for categorization. The suggested CNN model's hyperparameter tuning is a crucial part as well. Hyperparameters are parameters chosen before the training process starts, significantly influencing the model's performance. The convolutional layers, the number of filters in each layer, and the optimizer's learning rate are a few examples of hyperparameters used in this project. This study used grid and random search methods to maximize the CNN model's hyperparameters. A 3264 MR brain images dataset was used to train the proposed CNN model, obtained from the Kaggle data archive. The model was trained on T1, T2, and FLAIR MR images of the brain. Images from four groups were included in the dataset: individuals with glioma tumours, meningioma tumours, pituitary tumours, and those without any malignancies. A ratio of 88:12 was used to divide the dataset into training and test sets. Accuracy measures for testing and validating the suggested CNN model were used to assess its performance.Results:The model accurately classified cancers into several classes using the MR images, with a test accuracy of 98% and a validation accuracy of 96.5%. These results outperformed the 2019 study by Abiwinanda et al., which asserted a validation accuracy of 84.19% on the same categories of malignancies. This approach's effectiveness will significantly affect how brain cancers are identified and treated. Our study shows that deep learning models, especially CNNs, can correctly diagnose malignant brain tumours. Future research might improve these findings by applying the model to more extensive and more varied datasets and investigating the use of other deep-learning models for classifying brain tumours.

Clinical Engineers: Technology Managers that Add Value to Healthcare Organizations

By Mery Vidal

Regional CE and Medical Devices Manager, AUNA, Peru

Description: Stressed about how to make your Clinical Engineering Department to be successful? Do not know how to show your strategic value to the C-Suite? Listen to this successful story and be prepared to learn the key topics you should consider in order to create and implement a successful Clinical Engineering (CE) Department. Discover also how this successful

story how to be use to raise the CE profession and how to contribute to the development of Clinical Engineering in your country and world while. Are you ready to change the mindset? AUNA is a Peruvian group of private hospitals and medical centers founded in 2008, which mission is to transform the healthcare experience and vision, to be the leader and referent in Latin America with a people-centered care. Currently, AUNA has more than 25 facilities in Perú, Colombia and México, more than 2000 beds, 15,000 employees and it is one of the top healthcare operators in Latin America. The CE Department was created in 2010 to manage the medical equipment from all AUNA´s facilities. It has a centralized management model type "Glocal" which considers best practices worthwhile and apply them locally according to local regulation, culture and way of working. Also, it manages 100% of the lifecycle of the medical equipment: evaluation, planning, acquisition, reception, maintenance and final disposition. Currently, it has 39 employees between Perú and Colombia (México is in process of vertical integration), whose manage more than 22 facilities, an inventory of almost 10,000 medical equipment with an investment of USD $101M. In almost 13 years, the Department has been able:
- To create a strategic and subject matter department from scratch that adds value to AUNA and it is a part of the decision-making table.
- To change the paradigm from being engineers who maintain medical equipment to be technology manage.
- To have a leading management model (GLOCAL) that have been implemented in 2 countries (Perú and Colombia) with satisfactory results and contributes to our benchmark position in Latin America…sooner in México
- To implement the 100% of AUNA´s Projects with satisfactory results in time, scope and cost, and could transfer the "know how"
- To be a role model in work environment. CE Department has an unique culture that has being maintained through the years with excellent results.
- To raise the service level of medical equipment suppliers in Peru, sooner in Colombia and México.
The mindset of the CE Department is: "We are technology managers that add value to organizations and whose focus is the patient, user satisfaction and the profitability of the Business."In order to contribute with the development of CE Peru, some of the members of the CE department decided to create the Peruvian Association of Clinical Engineers (ASPIC) in 2017. Its mission is to promote activities for the continuous development of Clinical Engineering in Peru, and to contribute to the patient safety and humanization of the healthcare system. Some of its achievements are also presented.

Cardiac Electrophysiology Service setup at Canberra Health Services - Where There is a Will There is a Way

By Mrs. Kyril Belle

Healthcare Technology Management Department, Canberra Health Services, Australia

Introduction: Cardiac arrhythmias, being unpredictable and intermittent, can be difficult to diagnose. Where diagnosis is not obtained in a timely fashion, a significant cardiac event may occur that can result in sudden cardiac death or injury through loss of consciousness. The patients currently not receiving advanced cardiac care that fulfil the criteria would benefit from undergoing an Electrophysiology (EP) study, as it would reduce cost and time for diagnosing cardiac conditions and aid in early identification of patients at risk of significant cardiac events. The modern electrophysiology (EP) laboratory is a complex environment providing an array of interventions for the diagnosis and treatment of heart rhythm disorders and is a result of many transformations over the last three decades1.The Division of Medicine within the Canberra Health Services established a new EP Service at The Canberra Hospital, delivered through the establishment of a dedicated EP service and consolidated delivery of services for patients with cardiac rhythm disorders. This new service will ensure timely assessment and treatment of cardiac arrhythmias at The Canberra Hospital, the adoption of evidence-based and best practice care for the community, and improvement in healthcare and patient safety outcomes.
Methods: The integration of EP services within the existing Cardiac Catheter Laboratory (CCL) and associated challenges required the Healthcare Technology Management (HTM) team and Clinical team to work collaboratively with a key focus on staff and patient safety. The highly political and emotive environment required careful stakeholder consultation and several design iterations to accommodate the service in an already stretched CCL. The HTM team gained clinician support by advocating a logical, methodical and collective approach. The HTM team, with support of clinicians, undertook a feasibility study and prepared an options paper. A number of presentations were made to stakeholders outlining design options and seeking feedback. Stakeholders involved included Interventional Cardiologists, Cardiac Scientists, Anesthetists, and Nurses. The outcome was a design which was both workable and safe for patients and staff. The HTM team designed and project managed the site preparation and installation of the EP laboratory to meet the key criteria of ergonomics, work flow and patient and staff safety. As a result the CCL officially opened the EP service on 10th of April 2019 in Canberra Health Service.
Discussion and Conclusions: The HTM department goal for this project was to provide physicians, administrators, and nursing staff with a modern EP laboratory to optimise patient outcomes, minimise patient risk and provide a safe and positive

environment for physicians and support staff. The successful delivery of the project on time and on budget demonstrated the role an HTM team can play in bringing objectivity and neutrality to a key clinical service with positive patient outcomes.
Acknowledgements
[1] Dr. Rajeev Pathak – Cardiac Surgeon and Head of Electrophysiology Service, Canberra Health Services
[2] Dr. Ren Tan – Director of Cardiology, Canberra Health Services
Reference
[1] "Heart Rhythm Society Expert Consensus Statement on Electrophysiology Laboratory Standards: Process, Protocols, Equipment, Personnel, and Safety" 2014 Heart Rhythm Society.

Women's Unique Aptitudes Support Clinical Engineering Development

By Ewa Zalewska, PhD

Clinical Engineering Association, Poland

Description: The position of women in clinical engineering (CE) is significant and stands out for being much more represented compared to other engineering fields, supported by visible contributions. This is an achievement that highlights the importance of women's contribution in this field. When considering the development of women's activities in CE, it is important to determine what is the essence of the topic of women in clinical engineering. What is special about this profession and what makes it possible for women to play a special role in this profession, and how this special role should develop in the future. The most significant contribution of women is the new perspective and some kind of new values that have come with women to the field of clinical engineering and practice. The female perspective takes into account the idea of helping others and the humanitarian aspect of this profession. Women's contributions also raise awareness of ethical issues in clinical engineering. These, along with the creativity of women in any activity, enrich the CE profession and help in making important achievements. The use of women's outstanding aptitudes such as communication skills relevant in an interdisciplinary collaboration, empathy, holistic thinking, a deeper understanding of the human aspect of healthcare technology is essential to empower women and stimulate progress in this field.
The challenge is to find areas of activity where women's aptitudes will be particularly useful. It can be a comprehensive analysis of the safety of medical devices, not only in the technical aspect, but also taking into account environmental factors, human factors, psychology. Another relevant area for women's activities is the role of the creative partner of the medical team in everyday practice, which involves participating in the application of medical equipment by bringing interdisciplinary knowledge and a holistic approach to performing patient examinations and interpreting results. Women's aptitudes in this aspect requiring a holistic and creative approach are valuable and desirable. Therefore, thinking about the future, it would be worth changing the perspective. This implies that instead of viewing the context of women and men as competitors, it is important to consider it as an advantage and adopt a cooperative perspective. The way to increase the empowerment of women in clinical engineering lies not in the pursuit of equality in obtaining the same achievements as men, but, on the contrary, in the use of individuality. The roles of women and men could complement each other. Women bring diversity to clinical engineering, which is a source of inspiration and innovation, simply progress. In conclusion, the challenge is to find areas suitable for women's ability to enhance women's unique contributions to CE. The future is about maintaining gender balance and good cooperation. Then diversity will stimulate complementary development.

Resource Allocation of Medical Devices Strategies for Breast Cancer Screening

By Fabiola M. Martinez-Licona,

Universidad Autonoma Metropolitana, Mexico

Description: Medical devices are critical in diagnosing, monitoring, and treating medical conditions in healthcare. However, their availability and allocation can be a complex challenge, particularly in resource-constrained settings. Effective resource allocation is essential to ensure equitable access to medical devices, optimize their utilization, and ultimately improve patient outcomes. Maximizing medical devices' impact by ensuring their availability where they are most needed so they can deliver the most significant benefit must be the objective of any allocation strategy. Factors such as disease prevalence, patient needs, and cost-effectiveness are determinants in the prioritization of resources. This study aimed to analyze a method for resource allocation based on the analytic hierarchy process (AHP) and applied to a high morbidity non-communicable disease in Mexico: breast cancer. The epidemiological, infrastructure, and socioeconomic factors are included in a prioritized way allowed to identify their impact on determining the number of mammography machines for screening in

Mexican states with the three highest female indigenous population (Guerrero, Oaxaca, Chiapas). The socioeconomic and demographic determinants, the screening mammography demand, and the available mammography machines were used, under the author's heuristic assumptions, as variables for the categories of the target population, epidemiological indicators, and infrastructure. Methods: The AHP determines the specific weight of each factor based on the relations between the considered variables. In this case, the variables included female population over 50 years old, women's age who underwent mammography, origin municipality from women who underwent the mammography, mammogram outcomes, mammogram locations, number of mammography machines, breast cancer mortality, breast cancer mortality municipalities, and breast cancer morbidity rate. From them, only those which scored the highest were used in the model. The AHP determined the weights for the categories of target population, epidemiological indicators, and infrastructure (0.473, 0.156, and 0.370 on average); the process also calculated the specific weight from each selected variable, and these values were integrated into the model. Two approaches were used for the model: the accumulative contribution of the three categories and their product. Finally, the number of mammography machines for screening purposes was calculated for each approach. The data came from the National Institute of Statistics and Geography (INEGI), the National Council for the Evaluation of Social Development Policy (CONEVAL), and the Mexican Ministry of Health for 2020.Results:The results for the additional and product approaches show that Chiapas requires 1070-48 machines, Guerrero 1071-35, and Oaxaca 1087-32, respectively. The results differ from the model considerations and are strongly linked to the reported data. Some external factors are not included, such as the physical conditions of the mammography machines and whether the mammography studies performed per state corresponded to its female citizens or belonged to neighboring territories. Another consideration is that more than the number of machines is needed to guarantee better coverage for screening mammography. Compared with previous results from an adaptation of the resource allocation working party, the product approach seems to provide feasible information for the decision-making process regarding technological infrastructure for breast cancer screening.

Evaluation of Oxygen Supply Preparation and Investment during the COVID19 pandemic

By Gerelt-Od Namdag; Amarsaikhan D; Munkh-Erdene L

Ministry of Health of Mongolia; Mongolian National University of Medical Sciences, School of Public Health, Mongolia

Background:On January 5, 2020, the World Health Organization announced an outbreak of pneumonia of unknown cause in Wuhan, Hubei Province of the People's Republic of China, and on January 7, 2020, it was reported to be caused by a novel coronavirus (nCov). The first case of transmission of the infection was registered on March 9, 2020 in Mongolia, and a domestic case of infection was detected on November 10. On April 9, 2020, the World Health Organization (WHO) issued a list of essential medical equipment during the coronavirus outbreak and recommended it to member countries. The Government of Mongolia and the Ministry of Health provided equipment and resources in accordance with the recommendations of the WHO and the diagnostic and treatment advisory team, and there was a need to evaluate the current situation. Purpose and Methods of the Study: To evaluate the availability of oxygen supply during the coronavirus infection (COVID-19) by comparing before and after the infection.The evaluation was carried out by the method of fact research. Quantitative data on investments in the health sector were used in the evaluation. Results: As of today, there are 42 oxygen small-scale plants in Mongolia's healthcare sector, 38 of which are operated by the state healthcare organization and 4 by the private sector. At the time of the outbreak of the coronavirus, in the first months of 2020, there were 4 small-scale oxygen plants, 4 private sector factories and 5 local small-scale factories operating in Ulaanbaatar city under the State Health Department. Since the onset of transmission, 13 micro-scale industries have been established in Ulaanbaatar city and 16 micro-scale industries have been established in local areas under the state health organization.As of 2021, the total cost of a small oxygen plant with a capacity of 20 m3/hour is 590.0 million MNT, or the cost equal to the budget used to buy oxygen for one province for 2-3 years. The cost of further maintenance and spare parts for these factories is budgeted to be 15-16 million MNT per year.The mini-oxygen plant installed in Ulaanbaatar city and the local area has made it possible to provide oxygen to health centers and private sector health institutions in Sum, as well as to deliver medical care and services without wasting time, and to provide quality care and services in accordance with standard clinical instructions without being trapped by limited oxygen resources.
Conclusions: In the first months of 2020, 13 mini-oxygen factories were used throughout Mongolia, but after the outbreak, 29 new small-scale oxygen plants were installed. An average of 590.0 million MNT was spent on the establishment of one small-scale oxygen factory, compared to the expenses spent on the purchase of oxygen in 2021 by the general hospitals of the 8 western provinces and the Regional Diagnostic and Treatment Center, which were included in the study, it is equal to the budget of the organization for 2-3 years of use.

Digitization of Investments, Donations and Expenditure for Innovative Technologies: The UVAD Experience in an Italian Hospital

By Anna Squara; Giovanni Poggialini; Del Torchio; Davide Freri

ASST dei Sette Laghi, Gestione Operativa e Next Generation EU, Varese, Italy

Description:The strategic acquisition of goods and services in hospitals is crucial and is related to the leading governance and the need to comply with the demands of each medical and surgical department. For this reason, ASST dei Sette Laghi (Varese, VA, Italy) established 2019 the Purchase and Donation Evaluation Unit (UVAD, Unità di Valutazione Acquisti e Donazioni). This multidisciplinary commission supports strategic management in evaluating all hospital departments' Purchase Demands (RdA) as allocating economic resources, investments, and monitoring expenditures. The purpose of UVAD is to digitize the entire supply chain, from the request to the purchase of goods, as well as the management of donations, ensuring traceability and transparency of the processes. The digitalization of the process by Waterfall methodology to manage our supply chain is divided into four main macro-phases:1. Modeling and Engineering the process;2. Development and implementation;3. Field-testing and training;4. Release and use.
In our hospital, each departmental presiding officer has to interact and collaborate with UVAD to request his needs by specific computer software: after collection and evaluation, the commission prioritizes all applications received, composing an accurate purchase ranking. Moreover, HbHTA assessments is performed by UVAD. Results:In 2022 alone, UVAD received about five hundred and ninety-six proposals of supply purchase from hospital departments and obtained seventy donations. Thus, UVAD managed and prioritized six hundred and sixty-six requests in the sole year. We estimate an up to 45% reduction in RdA processing times thanks to UVAD. Moreover, the automation of activities leads to a 60% reduction of the activities entrusted to individual operators. UVAD effectively eases the HbHTA assessments, reducing the time of purchases and donations and prioritized acquisitions technologies in our hospital.

Postgraduate Training in Clinical Engineering: A Step Towards Enhancing Healthcare in Argentina

By Rosa María Weisz, Emilce Preisz

Universidad Nacional de Entre Ríos, Argentina

Description: This article presents the experiences in postgraduate training of two bioengineers who graduated from the Faculty of Engineering at the National University of Entre Ríos (FIUNER) in Argentina. The authors, who embarked on their professional journey in clinical engineering and specialized in this field of engineering, while simultaneously working as faculty members at this academic institution, collaborated with FIUNER to propose the creation of a postgraduate program in Clinical Engineering (CE), specifically designed for bioengineers and biomedical engineers. In 2015, the first cohort of the Specialization in Engineering program commenced at FIUNER with the objective of training professionals capable of addressing specific challenges in medical care. The curriculum, spanning two years, consists of eight theoretical-practical courses, including hands-on experiences in hospitals and medical care centers. Despite encountering challenges such as a scarcity of postgraduate-trained teachers in CE and the logistical difficulties faced by students traveling from various regions of Argentina and Latin America, collaboration with national and international experts helped overcome these obstacles. Results: The program has seen significant growth, with 71 teachers involved in the four cohorts, including course instructors, visiting professors, and laboratory assistants. Notably, the last two cohorts were conducted online, resulting in increased participation from professionals. To date, 87 individuals have enrolled in the program, and 214 professionals have completed one or more courses, with a notable percentage of women participants. Surveys conducted with career students have revealed a high level of satisfaction with the training received, particularly highlighting the participation of experts and references in various topics. Additionally, the program has fostered the formation of professional networks, which have proven invaluable during the COVID-19 pandemic. These networks have connected professionals from different regions of Argentina and other Latin American countries, creating opportunities for collaboration and knowledge exchange. Conclusions:The authors emphasize the importance of investing in postgraduate training in Clinical Engineering to enhance healthcare in developing countries. By cultivating a critical mass of specialized professionals equipped with the necessary skills and knowledge, significant improvements can be made in the management of medical technologies and, consequently, healthcare outcomes. The authors contend that FIUNER's academic training proposal is particularly relevant, given its potential to address the unique healthcare challenges faced in their region and contribute to the overall improvement of healthcare quality.

Study on the Evaluation of Mainstream Syringe Infusion Pump Based on Multi-index Analysis

By Wei Xiong, Bin Mao, Jing Sun, Jun Zheng, Jingyi Feng

The First Affiliated Hospital, Zhejiang University School of Medicine, Hangzhou, China

Description: Syringe infusion pumps are medical devices that improve efficiency and relieve the burden of clinicians and nurses by continuous, stable and controllable injection. Therefore, it is very important to choose a syringe infusion pump with good performance. We established a scientific and reasonable evaluation system of syringe infusion pumps to provide more precise and more secure treatment for patients, provide suggestions for the choice of clinicians, and provide constructive advice for product improvement and promotion. Four commonly used brands, A, B, C and D, of syringe infusion pumps in the market were selected for comparative evaluation. And 10 measures: relative indication error of flow rate, repeatability of flow indication, output accuracy, relative indication error of occlusion pressure, grounding resistance, completeness of identification syringe capacity, display interface humanization, working time of battery at full capacity, internal structural stability and operation convenience, were determined as the evaluation system of syringe infusion pumps by using the Delphi Method. The weight of each term was assigned by subjective and objective weighting method. The evaluation objective model was established to evaluate and rank the four kinds of syringe infusion pumps. Finally, the target value matrix di = (0.315962, 0.840081, 0.574204, and 0.562579) based on the established model. The bigger di is, the better the plan is. There are d2>d3>d4>d1, that is to say, brand B > brand C > brand D > brand A. Results: The study shows that the performance of Brand B syringe infusion pump is the best, and the other brands are the next. Based on the above-mentioned evaluation method, the results of each brand of syringe infusion pump are consistent with the general clinical response, which shows that the system and evaluation method of syringe infusion pump in this paper have certain applicability. The comprehensive index weight reflects the relative importance of each index, and the standardization matrix reflects the advantages and disadvantages of each brand's syringe infusion pump index. Based on this system, it can help each brand to find out the differences between each other's performance and the places that need to be improved. The evaluation method and index system of syringe infusion pumps established in this study provides ideas for the establishment of clinical evaluation index system of medical devices and the research of evaluation method.

Design and Implementation of a Wheelchair Prototype with a Safe Transfer System for Patients

By Eladio Quintana; César Yegros; Benjamín Recalde; José Núñez

Biomedical Engineering Research Group, National University of Asuncion, Paraguay

Description: Wheelchairs are normally used to transfer patients with mobility problems of different kinds, either within a health care center or at home, it is known that they are not designed to carry out the transfer of the patient. This means that if we want to transfer the patient from this to another place we must carry the wheelchair. One of the most common cases seen daily around the world is the transfer of patients from the chair to a car.This situation motivated the design of a system capable of providing a safe transfer with the least possible effort and at the same time guaranteeing that both the patient and the operator do not suffer injuries, the design and implementation of said system is proposed, using a lifting - lowering mechanism and bearings. Goals: Develop a low-cost movement and transfer prototype that facilitates the entry and exit in cars of patients with an established maximum weight.

Specific objectives:
1.Design and develop a system that facilitates the transfer of the patient, from the prototype to the car and vice versa.
2.Implement the system ensuring a successful transfer with the least possible effort.
3.Evaluate the correct functioning of the system.

4.Carry out a survey of the cost of the implemented system.
The direct beneficiaries of the project will be wheelchair users who do not present upper extremity or cognitive problems and must make transfers in private vehicles. The people in charge of operating them will benefit indirectly.

Results: A system was designed and developed that facilitates the transfer of patients to a car and vice versa, simplifying said activity for people in Health Centers or homes, from a wheelchair prototype using only materials available in the local market and with the condition of meeting safety requirements and at the same time being low cost, capable of transporting the patient, providing safety during it, with the capacity to support obese patients due to its special dimensions. Thanks to the design and development of the prototype and the selection of materials, it was possible to implement, achieving a safe transfer and with the least possible effort. Through the integration of transfer elements, lifting mechanisms, bearings and using a 12-volt battery-powered electric actuator, applied to the prototype, the system was implemented and its correct operation was evaluated, with this help wheelchair users from an assistant can be safely and easily transferred to another medium, without risking injury in the process. A cost survey was carried out, the result of which shows that the system is economically viable and at the same time low cost, taking into account that, due to searches carried out for documents referring to the subject, no similar system currently implemented was found.

Essential Elements of a Clinical Engineering Internship: A Comprehensive Guide

By Andrew Ibey; Marie-Ange Janvier

Children's Hospital of Eastern Ontario; Carleton University, University of Ottawa, Canada

Description: A clinical engineering (CE) internship is the defining opportunity between a general biomedical engineering degree and clinical engineering specialty. This abstract presents a comprehensive guide of the essential elements required to prepare aspiring professionals for the dynamic field of clinical engineering. By examining key components and best practices, this study aims to provide valuable insights into designing an effective internship program that equips interns with the necessary skills and knowledge to be competent and thrive in their careers.The guide explores various essential elements of a CE internship, including program objectives, duration, curriculum design, hands-on experience, mentorship, and assessment methods. These elements follow the American College of Clinical Engineering (ACCE) Body of Knowledge Certification Study Guide, literature, industry standards, and expert recommendations. The study emphasizes the importance of the application of engineering principles, and the integration of theoretical knowledge with practical experience, allowing interns to apply their skills in real-world healthcare settings. Furthermore, the analysis highlights the significance of interdisciplinary exposure and communication during the internship. Collaborative interactions with healthcare professionals, such as physicians, nurses, and technicians, as well as other CE viewpoints provide interns with a comprehensive understanding of the healthcare system and foster effective teamwork. A focus on independent problem based learning and clinical environment exploration is encouraged. The integration of emerging technologies and industry trends into the internship curriculum is also emphasized, ensuring that interns stay abreast of advancements and are prepared to address evolving challenges in clinical engineering. The components and outline proposed in our Ottawa Carleton Institute of Biomedical Engineering (OCIMBE) internship form the essential elements that make a clinical engineering internship successful with 12 candidates completing the program where most are currently working and contributing to the field of clinical engineering, locally and internationally. By incorporating these elements into the design and implementation of internship programs, educational institutions, healthcare facilities, and industry stakeholders can ensure that interns receive a well-rounded experience that prepares them for the demands of the profession.

Towards the Digitization of Hospital Maintenance in Economic Community of West African States

By Bousso Niang; Adia Bineta Coulibaly; Magaye Thiam

West Africa Polytechnic University, Senegal

Description: The physical recording of maintenance activities in hospitals through registers or other hard media is subject to the problem of archiving. Indeed, the latter is confronted with the insufficiency of dedicated spaces, the humidity of the premises deteriorating over time, the writings, the congestion and the loss of time generated by the search for previous information. The exhaustive history of maintenance activities is a key element allowing to capitalize the information which becomes the raw material, thus the base or the foundation of any planning policy. Similarly, updating the data of a technical

hospital maintenance service is essential. It represents a guarantee of real-time recording of information. To meet these challenges, it is necessary to encourage Computer-aided Maintenance Management System (CMMS). Over the past decade, software has been installed and the actors concerned have been trained, but the challenge to be met is the sustainable use of these tools. Thus, to boost progress towards this reflex of digitalization of hospital maintenance activities, an emulation strategy is envisaged. It consists in organizing a champions league for the CMMS.The main objective is to classify the technical maintenance services of national hospitals in CMMS through supervision. Then, this ranking is published periodically on the West African Health Organization (WAHO) website. To achieve this, a scoring system is used to assess the equipment fleet, the quantity of spare parts and other consumables used, the duration of the preventive or curative interventions carried out, the number of workers. The assessment of the equipment park consists of checking the decommissioning of obsolete equipment, the exact location of the equipment, its operating condition, the availability of its consumables and the history of maintenance operations by comparing them to the hard supports. Penalties are materialized by points lost if a discrepancy is noted between the physical existing and the data entered in time. Results:To argue this ranking, performance indicators are identified. A completeness rate of more than 95% refers to the highest score, in this case 3. A score of 2 is reserved for effective entry between 95% and 75%. The score of 2 is given to the digitized recording of more than 50% of the information. The unit note is aligned in the range from 50% to 35%. Finally, the zero score represents an entry of less than 35% of the package. Similar reasoning is used for the readiness rate. The frequency of supervision is quarterly during the pilot phase before being set at twice a year. A local jury will be formed in each country. Conclusions: The results are represented in the form of a color map. Red cards will be awarded to structures with a zero score. Yellow will be assigned to score 1. The color codes for scores 2 and 3 will be orange and green respectively. In short, the digitization of activities must be motivated to better size the hospital maintenance budget, among others.

Unleashing the Potential: Exploring Growth Drivers and Export Opportunities in India's Thriving Medical Device Market

By Dr. Kavita Kachroo; Sesetti Harshitha; Keerthan RM

Kalam Institute of Health Technology, AMTZ, Visakhapatnam, India

Description: The Indian medical device industry has witnessed significant growth in recent years, driven by factors such as increasing healthcare expenditure, rising awareness of advanced medical treatments, and supportive government initiatives. To understand the trade scenario and growth prospects of this market, a comprehensive analysis is essential. This study aims to provide a detailed analysis of the trade dynamics, trends, and growth drivers within the Indian medical device market. Methodology: The research methodology employed for this study involved gathering trade data from multiple sources. Government reports, industry databases, and market research publications were carefully reviewed to obtain accurate and reliable information. The data encompassed import and export figures, market size estimations, and key market players. Statistical analysis and trend identification techniques were applied to interpret the data and identify significant patterns and factors driving market growth. Results: The analysis identifies several growth drivers in the Indian medical device market, including augmented government budget allocations for healthcare, the promotion of public-private partnerships, and the expansion of diagnostic centres. Wearable devices have gained prominence, and the adoption of cutting-edge technologies such as 3D printing, and the Internet of Things (IoT) and software for medical equipment by artificial intelligence (AI), and machine learning (ML) has accelerated. These advancements have the potential to reshape the industry and enhance patient care. The industry also faces challenges in navigating complex regulatory frameworks, optimizing production costs, and mitigating concerns related to counterfeit products. In the financial year 2022-23, the import market in India's medical device industry was valued at INR 54,375 crore, compared to INR 63,042 crore in the previous year 2021-22. On the other hand, the export market reached INR 23,963 crore, up from INR 23,295 crore in the year 2021-22. This indicates a 14% decrease in imports and a modest 3% growth in exports for the year 2022-23, when compared to the previous year. The significant dependence on imports, which account for about 69% of total imports and exports, emphasizes the need for trade prioritization in the Indian medical device industry. Understanding the trade dynamics and trends becomes crucial for policymakers and industry stakeholders to identify opportunities for enhancing domestic manufacturing capabilities and reducing reliance on imports. Conclusions: Analysis of the Indian medical device EXIM market reveals promising growth prospects alongside a significant dependence on imports. This study emphasizes the need for stakeholders in this market to comprehend trade dynamics, trends, and growth drivers. The insights derived from this research offer valuable guidance for policymakers, industry participants, and investors, enabling them to make well-informed decisions. However, it is imperative to continuously monitor market trends and devise strategies to bolster domestic manufacturing capabilities and reduce long-term import reliance.

Managing Medical Equipment within Virtual Wards – Developing UK National Guidance

By Professor Dan Clark OBE; Keith Ison

Nottingham University Hospitals NHS Trust, UK National Clinical Engineering Network, UK

Description: In the UK, the term 'Virtual Ward' is defined as a safe and efficient alternative to NHS bedded care. Virtual wards support patients who would otherwise be in hospital to receive the acute care and treatment they need in their own home. This includes either preventing avoidable admissions into hospital or supporting early discharge out of hospital. Characteristics of a virtual ward include:
- Acuity and complexity of the patient's condition differentiates virtual wards from other community and home-based services.
- Provides urgent access to hospital-level diagnostics (such as endoscopy, radiology, or cardiology) and may include bedside tests such as point of care (POC) blood tests.
- Provides hospital-level interventions (such as access to intravenous fluids, therapy, and oxygen).
- Requires daily input from a multidisciplinary team, either in person or enabled by technology e.g. virtual consultation, and sometimes multiple visits and provisions for 24h cover with the ability to respond to urgent visits.
- Requires consultant practitioner specialist leadership and clear lines of clinical responsibility.
- Defined inclusion, exclusion criteria, with defined target population and a time-limited short-term intervention of 1–14 days.
- Virtual ward patients have equity of access to other specialty advice as though an in-patient.

There has been a trend in the UK to manage more patients in the virtual ward. This trend was significantly accelerated during the covid pandemic when keeping patients covid-safe, necessitated, minimising their exposure to acute (hospital) sector. This trend has continued post-covid as the benefits of keeping patients in their own home – clinically, financially and from a patient experience perspective – have all been acknowledged. Most virtual wards use medical equipment and software. A good understanding of how to buy, use and manage these items is therefore fundamental to providing an effective service. However, the rush to deploy more and more virtual wards has led to many clinical services establishing such remote services without this understanding of the needs of safe medical equipment management. This study will outline how the national UK clinical engineering profession has responded to this need and developed guidance to support the safe and effective use and management of medical equipment in the virtual ward setting.

Implementation of an Innovative Medical Device Management Strategy

Pascal Soroheye; E Hounsossou; B Kodjela

Ministry of Health, Benin

Description: To ensure the availability of medical devices to reduce maternal mortality in the Collines department of Benin, with a population of 850,000 and 124 health facilities, at the time of the study beginning in 2021, there was just one hospital maintenance technician and three electricians. This situation led to shortcomings in the provision of care. Involving users (midwives, nurses, care assistants) and building the capacity of the 3 electricians was planned to make up for the lack of human resources specialising in biomedical maintenance. With joint financial and technical support from Médecins sans Vacances, AFD and Enabel, the department benefited from the skills of a biomedical engineer. This made it possible to draw up a nomenclature by level of care and by care unit, to organise an inventory of biomedical equipment, to draw up a 2021-2024 equipment plan, and to draw up maintenance sheets for 20 critical pieces of equipment. Results: The pilot phase of the strategy covered the 8 health facilities providing emergency obstetric and neonatal care (EmONC). 6 midwives, 5 nurses and 6 care assistants from these 8 health facilities are being trained in the practical use of maintenance protocols for the several items: MVA kit, obstetric suction cup, mucus aspirator, heating table, medical furniture, medical insufflator, monitoring equipment, refrigerator/cooler, and other critical equipment, monitoring equipment, fridge/freezer, oxygen concentrator, neonatal resuscitation table, autoclave, operating light, respirator, nebuliser, laryngoscope, phototherapy device, glucometer. Users are networked and quarterly meetings are organised to share experiences. Maintenance tools and spare parts (filters, batteries, etc.) are acquired for the benefit of users and maintenance technicians. Results: The biomedical inventory identified 2,097 items of biomedical equipment, 498 of which were for the 8 SONU health facilities; 379 items were reported as broken down, 54 of which were for the SONUs; 28 items of equipment in the SONUs were put back into service by users, 22 were repaired by electricians and the maintenance technician, and 4 were beyond repair. 9,000 was used to implement this strategy. The cost of equipping the 124 health facilities is 3 million euros. Given the lack of financial resources, the focus is on essential equipment for mother and childcare, for a total of 300,000 euros by 2022. Involving users in maintenance will reduce breakdowns and ensure equipment availability. Prospects: Recruitment of 4 maintenance technicians in the department to bolster current initiatives, acquisition of 4 motorbikes to enable technicians and users to travel around the department and pool human resources, and roll-out of the strategy at departmental and national level.

Brain-Tumor Detection by Using Zernike Polynomials

By Dr. Sharmila Ghosh

Council of Scientific & Industrial Research (CSIR) and R&D Industry in Bangalore, India

Description: The detection of tumor on a small number of MRI brain images using "Zernike moments" demonstrated 100% accuracy in identifying tumor and normal images which create a future pathway for setting up a startup. For the images the magnitudes of the Zernike moments are the different for all the input individual images depending on the Optical Aberrations present in the images.
Results: Zernike moments are found to be very suitable for biomedical image retrieval application because of its useful characteristics such as excellent image representation capability, rotation (and scale) invariance, noise robustness, and small feature size. All these properties made it highly successful in various image processing and pattern recognition applications including biomedical image enhancement/segmentation, Zernike moments for the analysis of six different types of brain tissues.

Medical Equipment Management System Implementation Among Biomedical Engineers in Ethiopia

By Ewunate Assaye Kassaw

University of Gondar, Ethiopia

Description: The medical equipment management system is a key component to achieving the desired outcomes in healthcare facilities. The World Health Organization has created a management and use policy for medical equipment on a global scale. Results:
For managing the nation's entire health care system, Ethiopia has developed national guidelines. The management system for medical equipment is clearly explained in this document and is used as a model for managing medical equipment across the nation.
This document has served as a guide for performing tasks involving medical equipment during the two years in a hospital. Some biomedical engineers and technicians, however, do not understand how to use the document and instead view it as a bureaucratic mess that will hinder their work. For those who didn't understand the document's purpose, this project team sought to provide training. To achieve this, the team intended to deliver capacity-building training to biomedical professionals working in hospitals to help them carry out their duties in accordance with the guidelines and assess their performance against those guidelines. The outcome of the capacity building will then be evaluated.

Transforming Uganda Healthcare Delivery: Implementing a Comprehensive Health Information System

By Kamuhanda Success

Makerere University Kampala, Uganda

Description: In Uganda, like many developing countries, healthcare delivery faces numerous challenges, including limited access to quality care, fragmented health records, and inadequate data-driven decision-making. To address these issues, we propose the implementation of a comprehensive Health Information System (HIS) in Uganda, leveraging technological advancements to transform healthcare delivery and improve patient outcomes. This study outlines the objectives, approach, and expected impact of the HIS implementation. The primary objective of the HIS implementation is to establish an integrated and user-friendly system that captures, manages, and analyzes health data throughout the patient care journey. The system will consist of electronic medical records, data analytics capabilities, and decision support tools. It aims to streamline data management, facilitate evidence-based decision-making, and enhance coordination and continuity of care.The proposed implementation will occur over a two-year period, involving key milestones such as project planning, system design, software development, pilot implementation, training, and documentation. The project team will collaborate with healthcare providers, policymakers, researchers, and technology experts to ensure stakeholder engagement, align the HIS with local healthcare needs, and maximize its potential impact. The HIS implementation builds upon existing initiatives, leveraging open-source software solutions to reduce costs and promote interoperability with other healthcare systems. It connects

with Uganda's national healthcare strategies, including the Health Sector Development Plan, by aligning with the goal of strengthening health information management systems and improving data-driven decision-making. Expected Results: Upon successful implementation, the HIS is expected to bring about transformative changes in Uganda's healthcare landscape. It will enable healthcare providers to access timely and accurate patient information, supporting improved diagnosis, treatment planning, and monitoring. Data analytics capabilities will facilitate the identification of health trends, disease outbreaks, and resource gaps, empowering policymakers to make informed decisions and allocate resources effectively. This will benefit a specific target population, namely the Ugandan population accessing healthcare services across various healthcare facilities, including hospitals, clinics, and health centers. The system's scalability and adaptability will allow for expansion to additional regions, reaching a larger population and contributing to nationwide healthcare improvements. By connecting and integrating various healthcare stakeholders, the HIS will enhance collaboration, enabling seamless communication and sharing of information across different levels of the healthcare system. It will also provide valuable data for research and population health monitoring, supporting evidence-based policies and interventions to address public health challenges. The successful implementation of the system in Uganda will serve as a catalyst for broader advancements in healthcare delivery. It will demonstrate the feasibility and impact of comprehensive health information systems in resource-constrained settings, showcasing Uganda as a model for other developing countries facing similar challenges. It will serve as a milestone in advancing healthcare innovation and promoting equitable and sustainable healthcare for all.In conclusion, by capturing, managing, and analyzing health data, the HIS will enable evidence-based decision-making, enhance coordination of care, and contribute to the overall strengthening of the healthcare system. The proposed project aligns with national healthcare strategies, leverages existing initiatives, and has the scalability to benefit a significant portion of the Ugandan population.

Setting up Tertiary Health Facility in an LMIC like Pakistan- Clinical Engineer's Perspective

By Tazeen Saeed Bukhari, Syed Khalid Saeed Bukhari

Ministry of Health, Pakistan

Description: Hospitals are complex buildings that require careful consideration of multiple disciplines to ensure optimal functionality, patient safety, and efficient workflow. This paper highlights the key considerations and challenges involved in setting up a tertiary health facility in a low- and middle-income country (LMIC) like Pakistan from a clinical engineer's perspective. In the absence of established standards for setting up healthcare facilities in LMICs, the role of clinical engineers becomes crucial in bridging the gap between engineering principles and clinical workflows. By integrating infrastructure planning, medical equipment integration, information technology systems, infection control measures, patient flow optimization, cost-effectiveness, and accessibility, clinical engineers can play a vital role in ensuring that new healthcare facilities are safe, efficient, and effective. This study aims to provide insights and guidance for clinical engineers and medical equipment planning experts working in LMICs.
The following outcomes are expected:
1.Advocacy and highlighting of the role of clinical engineers in hospital planning for cost-effectiveness.
2.Development of strategies and enhanced communication for interdisciplinary collaboration among local architects, MEP engineers, civil engineering teams, healthcare professionals, administrators, and clinical engineers to address the diverse needs and requirements of a modern healthcare facility.
3.Development of facility guidelines and specifications for locally available equipment.
4.Adoption of international standards for local context, such as HTM and IHFG.

A Tool for Naming and Classification of Surgical Instruments

By Ricardo Silva; Monty Khajanchi; Anita Gadgi

Villanova University, USA; WHO Collaborating Centre for Research in Surgical Care Delivery in LMICs, India

Description: Universal Health Coverage (UHC) includes the appropriate access to affordable and quality-assured medicines, vaccines, medical devices, in vitro diagnostics, and assistive products. Essential service packages inclusive of health products

vary across countries depending on capacity, resource availability, and priorities. The World Health Organization (WHO) has developed a series of open access electronic databases to support the scale-up of UHC. The lists aim to increase access to health products for intervention delivery packages. Electronic databases ensure access to the latest information since they can be updated and expanded. The Priority Medical Devices Information System (MeDevIS), under the Priority Medical Device Project, is continuously updating this list of priority medical devices needed for the management of high-burden diseases. Key medical devices are identified based on their appropriateness, and are used to prevent, diagnose, or treat a disease. Being an online electronic database MeDevIS makes it easier to search and access medical devices, giving comprehensive and detailed information about them and interlinking them with interventions, other medical devices, and features, such as technical specifications. A surgical instrument is a tool or device for performing specific actions or carrying out desired effects during a surgery or operation, such as modifying biological tissue, or to provide access for viewing it. There are thousands of surgical instruments, many of them belonging to the same category or same family but with specific adjustments to the specific task, such as being left or right-handed, curved or straight, and so on. Also, many instruments are named after the person who invented them, and in some cases the same instrument has several names. Results:
After reviewing multiple sources, no standardized naming and classification scheme for surgical instruments was found, therefore an automatic naming system was developed for the classification and naming of instruments. This naming tool uses some guidance provided by the Division of Education of the American College of Surgeons, and the Alaska State Hospital and Nursing Home Association, complemented with information from multiple additional sources. The automatic naming system was coded into an Excel spreadsheet. The name derives from a simple taxonomy that consists of a Family and a Name, with additional modifiers. Each Family has one or more Instrument names, for example the forceps family: biopsy, cautery, dissecting, dressing, grasping, hemostatic, etc. In many cases, it is not enough to include a name for a particular instrument, additional information is required to properly name the device. This information consists of one or more of the following entries: Body Region, Control system, Configuration, Lighting System, Accessories, Power source, Intervention Type, Proper Name (Surgeon who invented the device). An example of a name with additional identifiers is the following: Forceps, low roots, incisors, bicuspid, Levis; this is a dental instrument invented by Levis that is used to access the low roots of incisors and bicuspid teeth. With this tool, 680 instruments were classified and included as part of 242 independent surgical sets.

The Role of Clinical Engineers During Crises

By Amna Elhassan

Tumor Therapy and Cancer Research Center, Sudan

Description: Natural disasters and wars are a reality that cannot be stopped or prevented. The horrors of which are too terrible is destroying hospitals and health facilities that are supposed to provide support, care and treatment to those affected by these disasters. Medical engineers are one of the first defensive lines of every health crisis in the world. During the corona virus crisis, Sudan's (bio)medical engineer made a great deal of effort under an unstable health system. The country's inhabitants continue to face the scourge of war and bombing with their bare hands, armed with knowledge and patriotism. Results:Attention must therefore be paid to the role of the biomedical / clinical engineer (CE) and the importance of their qualifications and the imperative of their involvement in decision-making, particularly in the distribution of medical devices in the country. For example, CEs can ensure: 1) that all new hospitals are built according to standards and levels of durability ; 2) that equipment is selected that strengthen ability to continue to perform needed tasks during disasters ; 3) and that procedures are implemented that will strengthen existing hospitals and health facilities and particularly those that provide primary health care services.

Impact of Pulsatile Electromagnetic Fields on Peripheral Artery Blood Flow, a Doppler Ultrasound Study

By Sayed Salman Aziz; Sumaiya Tabassum Dipty; Md. Tarikul Islam; Iqbal Bahar Prince; Tasmir Ahmed; Muhammad E.H. Chowdhury; Zaid Bin Mahbub

Department of Mathematics and Physics, North South University, Bangladesh

Introduction: PEMF, which stands for Pulsed Electromagnetic Field is a non-invasive therapeutic technique that uses pulsatile electromagnetic fields. This therapy has widespread medical and wellness applications, including pain management, wound healing, tissue repair, and improving blood circulation. If we can understand the physiological changes that occurred by using PEMF, it will also help us to select settings for the PEMF device such as to choose which frequency, pulse duration,

and current is beneficial for the human body. Objective: The objective of this study is to understand the instant effects of PEMF on blood flow using spectral Doppler signals from the radial artery. Description: To examine the impact of PEMF on the human body, with institutional ethics approval, seven healthy subjects were involved in our study. In our experimental setup, the circular PEMF coil (8cm diameter) was placed onto the forearm and to observe its effects on blood flow, a 5MHz Doppler probe was placed on the wrist over the radial artery. During this experiment, PEMF was applied in 4 different setups with variations in frequency, pulse width, and current, such as: (i) 10Hz, 100µs, 2A; (ii) 10Hz, 100µs, 3.5A; (iii) 70Hz, 100µs, 2A and (iv) 70Hz, 100µs, 3.5A respectively. We applied the PEMF pulses on healthy subjects over 7 different radial arteries for 30, and 90seconds durations. Ultrasound Doppler signals were recorded as audio signals with a sampling frequency of 48 kHz from the radial arteries. Total 5 categories of Doppler data were recorded, initially with no PEMF application and then with the above-mentioned 4 different PEMF setups. Spectrograms were produced from all the recorded data using MATLAB. From the spectrograms, we calculated Pulsatility Index (PI). Also, the energy and power were calculated from the recorded signals. All the measured values were averaged for 7 arteries. All the calculated values were compared with the no PEMF Doppler signals and the 4 setups of PEMF applications. Results: PI decreased for each of the PEMF setups, such as 3.05%,4.43%,9.51%, and 13.55% respectively for (i), (ii), (iii), and (iv) setups with respect to the no PEMF condition. Mean energy increased by 5.35%, 27.82%, 62.66%, and 42.79% respectively for those 4 setups compared to the No PEMF state. Maximum power is increased by 4.24%,10.83%,4.91%, and 14.80% respectively for the above 4 PEMF setups in comparison to the No PEMF state. Conclusions: From the above investigations, it is clear that PI is decreasing with PEMF applications, and its strength, may be due to the widening of blood vessels as a result of the relaxation of the blood vessel's muscular walls. Moreover, increment in mean energy and maximum power indicates the instant effects of pulsatile electromagnetic fields on blood flow. Each of these findings shows that Pulsed Electromagnetic Field (PEMF) changes the blood flow with the help of different segments of PEMF on a human body surface.

The Use of Capacitive Contact Return Electrode in Reduction of Adverse Burning Events in Patients in Procedures Using Electrosurgery

By Jorge Cardoso Pereira

ABECLIN – Clinical Engineering Brazilian Association, Brazil

Description:T his study has as objective to demonstrate use of a capacitive patient return electrode (CPRE) in substitution of a resistive patient return electrode (RPRE) is effective in reduction of adverse events of pad burns during electrosurgery. Electrosurgery units (ESU) are among the most useful and applied medical equipment in the hospital inventory. In electrosurgery the effect of cut or coagulation is a controlled damaged and intrinsic risk of using own ESU and its components as such active and return electrodes. However, when the risk and damage to patients during electrosurgery procedures are analysed, the electrode RPRE remains responsible for most patient pad burns. Data analysis of patient pad burns from 2011/January to 2015/September in Brazilian hospital found 7 confirmed events (40.000 surgeries). The electrode RPRE is actually disposable, flexible and adhesive models, in solid or split options. With Split option is possible to use ESU with patient contact quality monitoring (CQM). Even with this safety control options, the electrode RPRE is still vulnerable to operational mistakes, especially in installation on the patient body and its monitoring during electrosurgery. In order to provide increasing of safety in electrosurgery procedures, capacitive patient return electrodes (CPRE) since 2003 have been available increasing by 20 times the coupling área between the return electrode and patient body if compared to electrode RPRE. Results: In order to make possible the substitution of electrode RPRE by CPRE this study started analyzing standard ABNT IEC 60601-2-2, technical documentation supplied by CPRE manufacturer, and technical evaluation carried out by ECRI and CEDAR NICE (NHS UK). After this stage were developed simulations and tests by team of Clinical Engineers, a general surgeon and nurses. On these tests with electrode CPRE were carried out quantitative measurements of electric current and output power of an electrosurgical unit taking as load a standard piece of cow meat (approximately 01 Kg and 15 x 15 x 5 cm), and then compared to electrode RPRE submitted to same test conditions. Besides, a general surgeon also compared, in a subjective way, the behavior of both electrode in different modalities of electrosurgery cut and coagulation (Cut Pure, Blend, Coagulation Fulgurate and Spray). When the quantitative and qualitative tests demonstrated the technical and surgical viability of electrode CPRE, the training of nurses and surgeons started regarding procedures of manipulation, operation and cleaning. These new procedures were included in Safe Surgery Protocol adopted in the surgery center. During the transition between electrode RPRE to CPRE, Clinical Engineering measured continuously the electrode CPRE capacitance in order to verify if its main electrical parameter and dependent of its physical construction was stable no matter constant manipulation and operation. From September 2015 to March 2019 (45.000 surgeries), no pad burn event occurred in procedures using electrosurgery units demonstrating technical viability and surgical safety of electrode CPRE.

BMET at the Center of a Country Level Oxygen Therapy Support Project: Case of Haiti

By Emmanuel Kouemo; Ziad Hamze; Clerve Ovil; Gilles – Donna Brousseau

UNOPS, Haiti

Context: Since the early phase of covid 19, a lot of medical equipment have been donated by NGO or purchased by the country. Medical technologies ranging from Lower to medium high-level complexity: Pulse oximeter to digital Xray Ventilators Oxygen generators. Our experience and form other project lessons learned indicate that 70% of BMET in public and private hospital have not received proper BMET training and there are very few initiatives for proper BMET training. The medical equipment ecosystem is characterized by the insufficient involvement of BMET in the following response strategies:
- Poor Culture of Quality Control,
- Weak Preventive Maintenance sustainability plan for critical technologies,
- High Expectations from BMETs,
- Delusions of medical staff,
- Poor Impact - efficiency of investments (Equipment, Funds, Time…) related to critical medical technologies.

In the country the response is affected by adverse factors such as social unrest, insecurity, kidnapping, fuel shortage, ghost towns operations which significantly impact the operations thus requiring an agile approach.
Objectives: Providing oxygen therapy Support to Health facilities and Prepare the Ministry of Health (MoH) staff to ensure equipment lifecycle via identification of the bottleneck in Oxygen ecosystem in Haiti, and involvement of the BMET from central level MoH down to the facilities level. Results: Health facilities: Assessed by a joined team MoH & UNOPS to assess and validated the needs in oxygen for care, the infrastructure and energy available and necessary human resources. The following were delivered: 750 Oxygen concentrators 10lpm inbuilt Oxygen purity monitoring system, Spare Parts, 120 Maintenance kit, 950 pulse oximeters and 40k of oxygen masks to 96 health facilities nationwide. Over 250 training sessions for Medical staff in health institutions and 4 national BMET intensive training seminar / workshop focus on Medical devices use, quality control, preventive maintenance, repairs were conducted. Sustainability: The project is close since 1 year the BMET are able to handle all repairs with the kits and tools provided, BMETs are able to ensure continuous training of new medical staff in their health structure, and less than 25% of the equipment is out of use 3 years after installation – due to lack of accessories such as humidifiers, Central board defaults, Compressor thermic switch failure, and Zeolite columns defaults (for oxygen concentrators).
Success factors:
- MoH BMETs have been at the center of the solution to ensure the sustainability and the durability of the equipment.
- There has been intensive Capacity building for BMETs prior to deploying the equipment in the medical facilities.
- There has been accurate assessment of the oxygen needs and capacity to operate the technologies.
- There has been medical staff Capacity building.
- And simple documentation provided in local languages (ppt, video).

Next steps:Projects involving Medium High level medical technologies: Respirators, Digital Imaging, Oxygen Plants, Dialysis usually have a poor long-term sustainability and impact on care due to the lack of properly (knowledge and skills) trained local BMET. An Academic BME curriculum with a local engineering school and medical school for future clinical engineers will make a difference favorizing a better expenditure, better investments in medical technologies.

Developing a Value Proposition for Exoskeleton Technologies in the NHS through Stakeholder Engagement

By Sarah Bolton; Mike Craven; Kyle Harrington; Louisa Gerrard

Centre for Healthcare Equipment and Technology Adoption (CHEATA), Nottingham University Hospitals NHS Trust; and Institute for Mental Health, University of Nottingham, UK

Background: There have been significant advances in robotic exoskeletons within the last decade but these devices are not widely adopted in the NHS for spinal cord injury patients. This is despite studies reporting a number of physiological and psychological benefits. More work is needed to assess how exoskeletons are used and how they could fit within the NHS pathways. The aim of this research was to investigate the current evidence base for exoskeletons and to understand how the

robotic lower-limb exoskeleton technology could be used within the NHS. A literature search was undertaken to identify the current published evidence for exoskeleton use and benefits. Interviews using a semi-structured format with questions informed by the literature search findings were conducted with relevant stakeholders comprising physiotherapists and SCI patients to determine how the exoskeletons are used. A MindTech Patient and Public Involvement Team member formed part of the interview team. A formal exemption from full ethical review was granted, and the study adhered to NIHR Patient and Public Involvement Guidelines. Results: The literature search identified 10 systematic reviews including more than 50 research studies and a single health economic study. There was significant heterogeneity between research studies making direct comparisons difficult and few meta-analyses were done. However, most studies found that the exoskeleton devices, when used as an adjunct to physiotherapy, improved outcomes associated with walking function, preservation of muscle mass, improved gait, reduced spasticity, bladder and bowel movement benefits, cardiovascular improvement and psychological benefits. Adverse events were rare and generally minor. Training protocols were variable but typically amounted to 50 hours of training over 3-4 months. The most used devices were the Ekso, ReWalk and Indego. The health economic study (USA-based) indicated exoskeleton devices could be cost-saving but were sensitive to a number of variables. The stakeholder interviews revealed the primary use of exoskeletons was for rehabilitation activities under a physiotherapist, most commonly in a private non-NHS setting. There were also strict criteria to be met before people could use the devices. Interviews with SCI patients revealed that very few would use the exoskeletons to increase their independence as the use requires crutches, which would limit the use of their hands and hinder activities compared to using a wheelchair. Barriers to access and uptake included price (£70K-£165K), the need for significant device training and assistance to get in and out of the exoskeleton as well as needing a "spotter" in case of falls or malfunction. Conclusions: Stakeholder engagement gave vital insights into how exoskeleton devices are used in the real world. The value proposition for exoskeletons is currently to support physiotherapy services rather than to promote individual mobility and independence for SCI patients. Further evidence is needed to demonstrate the value of exoskeletons for SCI patients in the NHS.

An Interdisciplinary Approach of Infusion Systems Quantitative Technology Assessment

By Tatiana Sierra Montoya; Paula Andrea Berrio Molina

Hospital Pablo Tobón Uribe, Medellin, Colombia

Description: In 2021, the manufacturer of 73% of the hospital's infusion pumps reported the end of support date in December 2023. This situation triggered the technology assessment process to mitigate risks related to interrupt continuity of patient care. The impact of this technological change is given by the replacement of 11 years-old 1500 infusion pumps, the transformation of the medication administration process, the training of 1163 nurses and risks of using this medical equipment in 109540 infusions per year. Therefore, the clinical engineering (CE) department faced the challenge of complex technology assessment, maximizing its positive impact.
Initially, a reviewing of the reported risks related to the use of infusion pumps and medication administration errors was done. We found these risks are widely documented. As a reference, the ECRI has mentioned it 5 times in the last 10 years as one of the top 10 risks of medical technology. Since the technological improvement had not been surveillance in the last years, guidelines for the safe and efficient use of smart pumps were reviewed in reference institutions such as ISMP, JCI, FDA, MHRA, AMMI, PSQH. The recommendations were focused on the use of medication infusion systems, rather than infusion pumps. The use of tools such as dose error reduction systems (DERS), interoperability, device management, alarm management and real-time location systems, is key to optimize the safety of infusion pumps. Based on the recommendations, the technology assessment evolves from stand-alone medical equipment to a drug infusion system assessment. It required an interdisciplinary approach with the participation of 9 different specialties of the Hospital: nursing, pharmacy, information technology (IT), occupational safety and health (OSH), telecom, healthcare informatics, quality, supply chain and CE departments assuring the most appropriate technology recommendation to implement in our Hospital. The following 6 sequential stages were carried out: basic specifications verification, interactive scenarios technology exhibition, one month live-case technology demonstration in ICU and inpatient units, immersion in the Hospital's medication administration process and finally the technical, clinical and economical assessment. Seven manufacturers were involved and according to their compliance, they moved forward to the next stages. The criteria scoring were defined regarding to their impact on patients and staff safety, and on efficiency of the administration process. Results: The results comprise the quantitative fulfillment of the requirements by each manufacturer. We assigned a weighted score for each kind of assessment: 50% to the clinical (nursing 20%, medical devices 15%, pharmacy 15%), 30% to the technical (IT 5%, OSH 5%, CE 20%) and 20% to the economical. This information was considered relevant for the Hospital board decided to implement the best scored manufacturer and despite of the associated costs, the stagger incorporation of the DERS, the device, localization and alarm management systems as cost-effective tools to increase patient safety and support CE management. In conclusion, for complex

technologies with significant impact on patient safety it is imperative an interdisciplinary approach to the assessment, as well as the comprehensive knowledge of the technology, in order to issue a robust concept that supports decision-making.

Health Technology Management and Health Innovation in Cajamarca, Peru

By Rossana Rivas; Mesias Guevara; Elliot Sloane

Universidad Peruana Cayetano Heredia & HTM Committee-College of Engineers, Peru; Villanova University, USA

Description: Cajamarca is a region of Peru with a poverty rate of 39.7% (Ministry of Development and Social Inclusion, 2022), and is one of 5 regions of Peru (Huánuco, Puno, Ayacucho and Pasco are the others) with the highest level of centralism and inequality. (National Institute of Statistics and Informatics, 2023). Some of the main difficulties of the Cajamarca's healthcare system are:
- population's low access to healthcare services,
- insufficient clinical care capacity, low quality management of healthcare information, and
- inadequate level of healthcare equipment and health technology. (Ministry of Health, 2022).
One of the consequences of this situation is that 90% of children lack identified health information, reducing effective control of immunizations, diagnostics, etc. (Directorate of Health Cajamarca, 2022). Cajamarca has isolated communities in a geographically rugged territory and a relevant number of places cannot access basic healthcare services.The Directorate of Health of Cajamarca manages the public health system through 863 health establishments. Some challenges determined are:
- low access to healthcare services,
- inadequate management of information, and
- lack of human resources (insufficient knowledge, training, skills).
In the 2019-2022 period the Health Investment in Cajamarca included: completion and start-up of the General Hospital of Jaén, with a budget of S/ 199 million soles (~55 million USD); medical equipment for Cajamarca Regional Teaching Hospital: S/ 949. 305 soles; new Intensive Care Unit: S/ 2.7 million soles. The Regional Government also manages 11 oxygen plants located in Cajamarca, 4; Jaén, 2; Cajabamba, 1; Celendin, 1' Chota, 1; Bambamarca, 1; and Cutervo, 1, and the region has 188 oxygen concentrators distributed in establishments in rural areas.This study describes clinical engineering and health technology management activities between 2019-2022, references below. (1) one of the most challenging periods in the government of Peru due to political, healthcare, and economic crisis (2). Best practices, lessons learned, innovation opportunities, and future steps for improvement based on clinical engineering, health technology management & planning methodologies (3) (4), clinical systems engineering (5), human resource capacity building, and health innovation (4), will be covered and discussed.

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Medical Equipment Procurement Practice and Maintenance Mismatch

By George Boadu

Komfo Anokye Teaching Hospital, Ghana

Background: Health service delivery is predicated upon the availability, appropriateness, affordability and acceptability of medical devices. Research evidence suggests that between 40% and 70% of medical devices and equipment in low resource settings are broken, unused or unfit for purpose. In Ghana, it is common to hear that medical equipment like X-ray, CT scan or MRI in public hospitals are not functional. Patients are denied access to healthcare due to the breakdown of medical equipment. Improper procurement practice has been cited as one of the major causes of medical equipment breakdown or service unavailability in Ghana. This study assesses whether some procurement decisions (specifically service contract)

rightly support the other aspects of the medical equipment life-cycle management and quality healthcare delivery. Methods: The study was conducted to assess procurement decisions, (specifically service contracts) and their impact on medical imaging equipment (X-rays, MRI, CT scan). Structured interviews and questionnaires were administered to BMETs who play significant role in medical equipment management at some Teaching Hospitals and Regional Health Directorates for data collection. Ten (10) Regional Medical Equipment Managers and Heads of Biomedical engineering Units in 3 Teaching Hospitals in Ghana participated in the study. A bootstrapping technique was employed to create 1,000 variant versions of the sample data to further analyse the results and validate the study. Results: The study shows that supplier/third party service providers mostly service medical equipment under warranty and service contract. However, the confidence intervals from the bootstrap result suggests that it is not evidently true that there is less equipment breakdown when outsourced to service contract. Rather, service contracts deprive in-house BMET from accessing manufacturers' service resources like training, sourcing for spare parts, access to maintenance and repairs and after sales service' technical support. Also, the bootstrap confidence intervals indicates that some quality service indicators like responsiveness to service calls and timeliness on the part of the service contract providers are not helpful but they are good in effective communication and credibility.
The study also revealed that there is a monopoly on supply of spare parts and spare parts cost when equipment maintenance activities are outsourced to a third-party agent. Other issues emerged from the study are:
- Contract details are not easily accessible by in-house BMETs,
- Manufacturers after sales service resources cannot be directly accessed by in-house BMETs,
- And there is little or no access for in-house BMETs to perform first-line maintenance and repair services.
Some suppliers secure service contracts are outsourced to third party which makes it more difficult to manage.
- In-house BMETs are not adequately trained and resourced to support service contract management.
- The procurement practice empowers third party contractors rather than in-house BMETs in maintenance of medical equipment.
- Also, there is lack of coordination in managing third party contracts.
Conclusions: It is not evidently clear that comprehensive service contracts is the sure way of maintaining medical equipment and ensuring service availability and quality healthcare. In-house capacity building should be encouraged for maintenance activities.

Clinical Deficiencies by Notified Body on MD Technical Documentation under Regulation (EU) 2017/745

By Eliana Monaco; Miola Federica; Sirotich Ilaria; Bergamasco Stefano; Belliato Roberto; Cuorvo Luigi

MedTech Projects S.r.l., Italy

Description: The CE certification process according to MDR for class IIa, IIb and III devices includes the following phases:1. Documentation review (Technical Documentation, Quality Management System Manual); 2. On-site audit, after the closure of phase 1; 3. Final review and release of the CE certification, after the closure of the phase 2. Important delays have been observed during this certification process, especially in 1 and 2 phases. Auditors' work is fairly standardized thanks to shared criteria and guidelines but nevertheless there is a certain variability in the definition of non-conformities due in most cases to the profession and skills of the auditor who examines the documentation.For the purposes of this work, an analysis was made of the deficiencies brought to the attention of the manufacturer by the Notified Bodies, which appear to be the most numerous ones relating to the Clinical Evaluation, that are the most critical and blocking.Results:A classification of the deficiencies collected for the Clinical Evaluation area according to the following categories has been performed: - Placement of the device in clinical practice 5%; - Inadequate/sufficient clinical data 41%; - Lack of documentation 17%; - PMS data request from the field 5%; - Fitness problems 32%. The analysis carried out revealed the following assessments:1. Slowdowns in the issuance of CE certificates by the Bodies, ranging on average from 5 to 7 months; 2. Absence of surveys that required design changes of the product; 3. Forecasts of an increase in post-market activities requiring data collection from the field; 4. Need for greater collaboration between manufacturers and healthcare facilities for data recruitment. Here a distinction must be made: The Clinical Evaluations of legacy devices appear to be lacking especially from a formal, documentary and post-market data point of view; The Clinical Evaluations of devices undergoing first certification mainly present insufficient or inadequate clinical data. After this analysis, it is very important to underline how important it is not only the manufacturer's work, but also the contribution that healthcare facilities can give to provide useful inputs to the manufacturer that can be used for the Clinical Evaluation of their device and have more possibility of obtaining more solid documentation that can be submitted to the scrutiny of the Bodies and thus speed up the certification procedures.Therefore it is essential that a synergy is created between the manufacturer and the healthcare facility to encourage: - conducting clinical investigations useful for the generation of new clinical data to argue and support the clinical benefits given by the device and a more precise identification of its contraindications and side effects; - collection of post-market data through surveillance/accident reporting activities, availability in compiling surveys provided by the manufacturer, user feedback. This synergy can

only favor: - safer and more effective devices from a clinical point of view; - acceleration of the device certification process, avoiding the blockage of the market with consequent shortage of the devices in a few years.

Home Telemonitoring Solution for Early Post-Acute TIA/Minor Stroke Patients

By Miloš Aj**čević**; Agostino Accardo; Francesco Bassi; Paolo Manganotti; Giovanni Furlanis

University of Trieste, Italy

Description: Currently, e-Health systems focusing on ischemic stroke primarily serve the purpose of aiding specialists in the management of the acute phase. However, there is a notable absence of systems dedicated to telemonitoring and remote management during the post-acute phase following an ischemic event. Therefore, we aimed to design, implement and test an e-Health system for multiparametric telemonitoring, teleassistance and support of patients with minor stroke / TIA in the early post-acute phase (< 14 days from the ischemic event).We proposed, implemented and tested a telemonitoring system and accompanying protocol designed specifically for post TIA/minor stroke patients who are at a high risk of stroke recurrence. This system incorporates portable devices capable of monitoring blood pressure (BP), heart rate (HR), oxygen saturation (SpO2), temperature, as well as a panic button, a gateway, and a dedicated ICT platform. The protocol involves a comprehensive 14-day telemonitoring program that incorporates therapy and emergency intervention based on notifications triggered by alterations in vital signs. To validate our proof-of-concept, we conducted a test involving eight patients who had recently experienced a TIA/minor stroke within the early post-acute phase (less than 14 days from the initial ischemic event). Results: The proposed solution successfully enabled prompt and remote identification of vital sign alterations in the early post-acute phase, facilitating necessary adjustments to therapy and behavioral interventions. The average number of significant vital sign alterations observed during 14 days after the acute event was 31 per patient. 52% of the alarms were related to blood pressure (31% hypertension and 21% hypotension), 34% to heart rate (respectively 23% and 11% HR above and below threshold), 9% to low SpO2 level and 5% to hyperthermia/fever. Cerebrovascular risk factor management goals were achieved in 7 out of 8 patients. During the three-month follow-up, patients demonstrated full adherence to the prescribed therapy, and there were no instances of stroke/TIA recurrence or emergency department admissions.
Notably, we observed a significant improvement in the quality of life for patients, along with a notable reduction in anxiety and depression levels. The Telemedicine Usability Questionnaire (TUQ) indicated that the proposed solution exhibited ease of use, a well-designed interface, and high user satisfaction. The proposed e-Health solution and telemonitoring protocol have the potential to be extremely beneficial for managing patients in the early post-acute phase remotely. By enabling constant monitoring and promoting patient adherence to the treatment pathway, this solution proves particularly valuable in this particular clinical population.

A Definitive Framework for the Effective Implementation of Health Technology Management

By Hemanthakumar Revalli

Biontrics MedTech(OPC) Pvt Ltd, Vellore, India

Description: Health Technology implementation is the key for effective healthcare delivery and outcome for every healthcare provider across the globe to optimize patient care and services through the focuses on the selection, implementation, and management of medical technology. Effective HTM implementation requires high level organizational commitment and involvement across the healthcare organizational structure. Effective Implementation requires a systematic approach that focuses on assessment, procurement, maintenance and training on HTM Professionals This paper presents an overview of the key principles and practices of HTM and highlights the importance of an effective HTM framework to ensure successful implementation of medical technology. The study discusses the various components of an HTM framework including the challenges encountered during the HTM process, such as budgetary constraints, lack of standardization and inadequate training. Additionally, the student outlines the benefits of an effective HTM framework including improved quality of care, increased patient Satisfaction and reduced healthcare costs.A definite framework on the Implementation of HTM consists of the following:1. WHO'S HTM Framework;2. The clinical Engineering Framework;3. IT services management Framework;4. The Healthcare Delivery Framework;5. Quality systems Management Framework;6. Baldrige Performance Excellence Framework.The implementation of a suitable HTM framework can also foster innovation and drive progress, leading to better healthcare outcomes. Conclusions: An effective HTM framework is essential to optimize the use of medical technology for

improved patient care and cost-effective healthcare delivery. Effective implementation requires a systematic approach that focuses on assessment, procurement, maintenance and training of healthcare technologies and professionals.

Accreditation of the Metrology Laboratory of a Highly Complex Clinic in the ISO/IEC 17025:2017 Standard and its Impact on Patient Safety

By Jhehirmer Moreno Prada; Karent Muñoz Salazar; Ingrid Jhoanna Montealegre Marin; Jonathan Esteban Durango Vasco

Imbanaco Clinic, Cali, Colombia

Description: The challenge is to improve and accredit the internal biomedical equipment metrology laboratory so that it can guarantee the precision, timeliness of service, and availability of the biomedical equipment of the Imbanaco clinic. Like other healthcare institutions, the Imbanaco Clinic relies on third-party calibration laboratories and external providers to meet this requirement. However, the institution has repeatedly experienced significant delays in the delivery of equipment and certificates, a lack of immediate availability during emergencies, and unreliable results from calibration. Recognizing the importance of the validity of the results, the organization made the decision to accredit the metrology laboratory and perform the calibrations internally, according to the International Electrotechnical Commission/International Organization for Standardization IEC/ISO 17025:2017 General Requirements for Competence Testing and Calibration Laboratories.For this process, the organization formed a team for the metrology laboratory within the clinical engineering area. This group is made up of biomedical engineers, technicians, metrologists, and metrology analysts with experience in institutions with current accreditation and necessary training. This is to adhere to the best practices in the operation and maintenance of the laboratory management system.During the improvement process, the clinic set out to accredit the laboratory for mass (scales), pressure (sphygmomanometers), and temperature and relative humidity (thermohygrometers) with the calibration methods described and endorsed by government organizations and internationally recognized laboratories. In Colombia, there are only four (4) health entities accredited to this standard, and it turned out to be a demanding and ambitious process. The management system, processes, procedures, and general structure of the clinical engineering area were greatly restructured, demonstrating that competence, impartiality, and coherent operation of the management system were implemented. Conclusions: The working group achieved its objective. The Imbanaco Clinic is the first health institution in the Colombian Southwest to receive accreditation from ONAC (National Accreditation Organization of Colombia). For the year 2021, it was accredited in the magnitudes of mass and pressure; in the year 2023, the accreditation was extended to the magnitudes of temperature and relative humidity. In addition to the fact that, according to nationally accredited health institutions, we have the lowest CMC (measurement and calibration capacity) with respect to the accredited scope, which ensures less uncertainty in the results. All the biomedical equipment at the main headquarters and alternate locations of our organization is calibrated or managed through the metrology laboratory, ensuring that before its operation in the clinical service, conformity is declared according to the established guidelines. This process has helped us stay on schedule and address urgent needs more quickly, allowing for safe, quality care for our patients. The economic return generated by internal calibrations is also highlighted. A key reason for this success is that the metrology laboratory is backed by careful documentation and evidence that is trusted by end customers and users of biomedical equipment. With the main objective of improvement, the different magnitudes that are applicable to the institution will continue to be accredited. The Imbanaco Clinic plans to offer its services to other health institutions nationally and internationally.

Re-engineering of the Management Process of Surgical Instruments

By Mariangela Matano; Lorenzo Leogrande; Giovanni Arcuri, Veronica Bacocco

Fondazione Policlinico Universitario A. Gemelli IRCCS, Rome, Italy

Description:The management of the surgical instrument equipment of a hospital with high complexity of care and with high volumes of surgical activity represents one of the main challenges for the management of the healthcare sector. In fact, it requires a highly structured approach to ensure the performance of daily surgical activities, while guaranteeing the quality of the devices and maintaining their functionality by responding to the needs of the various teams, sustainability, but above all patient safety in the services provided, preserving the value of this asset over time. This project is divided in 3 main steps:
1. identification of two surgical areas to start of the pilot project
- laparoscopic surgery
- cardiac surgery

2. context analysis, picture of AS-IS and critical aspects
- Inventory and analysis of individual devices
- analysis of purchase order management processes, surgical kit management, maintenance management, back-up warehouse management
- analysis of critical issues
3. proposal of an optimal TO BE solution for each analyzed process
- service and full risk maintenance of the instruments
- kit optimization (number of instruments, composition, standardization, weight adjustment)
- new organization of back-up stock
- implementation of traceability service

Goals of the project and final users that will benefit: The main objective of the project is to re-engineer the entire management process of the surgical instruments of the Policlinico Gemelli - considering all the clinical needs, of health professionals, compliance with industry reference standards and of the new MDR 2017/745 - by applying an advanced model, which integrates the systemic support of a specialized company in the sector, in order to guarantee the Foundation the achievement of outcomes in terms of patient safety, continuity and efficiency of service, optimization and modernization of equipment with consequent generation of value. Users: Clinical engineers, business management, operating room nurses, surgeons. Results:The project, approved during 2021 by the Foundation's Management, is currently being implemented also in orthopedic surgery. The first results obtained from the kit/set optimization phase, conducted thanks to a mutual collaboration between the Foundation and the partner company, involved: • significant percentage reduction of the tools present in the kits; • 13.89% for cardiac surgery; • 17.32% for laparoscopic surgery; • Reconfiguration of most kits; • Decrease in the number of devices in kits; • Generation of savings in economic terms, related to both the purchase/rental cost and the total cost of ownership. When fully operational, the following are expected: • reduction of managerial-organizational costs; • increasing the quality and safety of the entire process; • increase in clinical outcomes.

Supplier Selection Green Model for the Healthcare Industry in North Africa Hybrid Approach

By Mohamed Zaki, Ettahir Aziz, Kamal Kettani, Oussamajami, Oussama Elallam, Douae El Ghoubali, Youness Bakali, Anissa Regragui, Nouzha Dini, Khalid Bouti, Mohamed Amine Khalfaoui, Abderrahmane Bakkali, Fayssal Jhilal, Driss Bakkali, Najib Alidrissi, Hassan Ghazal, Adnane Benmoussa, Fadil Bakkali

Laboratory Toxicology, Toxicogenomic, and Ecotoxicology, Mohammed VI University of Sciences and Health Hospital, Morocco

Description: Green management is essential in improving sustainable growth for businesses and society. Selecting an optimal supplier may determine the success of any firm. The multicriteria decision-making approach fulfills the conditions of choosing the most suitable supplier. Although numerous studies and applications of this supplier evaluation and selection method exist, few studies in the healthcare sector consider environmental issues and criteria which align with the needs, especially in Africa, when reviewing the literature. This study presents a hybrid approach to selecting the best green supplier for private hospitals in North Africa to fill this gap. Results: The supplier selection process establishes the appropriate criteria based on literature reviews and the priorities of stakeholders. This study integrates a quantitative and qualitative approach, formulating multicriteria decision-making (MCDM) using both AHP-TOPSIS; the first method weights the criteria, then the suppliers are listed. The experiments demonstrated that the proposed approach is viable as a guideline for stakeholders and provides a promising methodology for effective supplier selection, particularly in North Africa is a great contribution for researchers.

Infant Mortality and Mothers' Health in Bangladesh: A Case Study

By Md. Saiful Islam, Shahida Islam Tamanna, Minhajul Abedin and Md. Ashrafuzzaman

Military Institute of Science and Technology, Saudi Bangladesh Institute of Biomedical Engineering & Technology, Bangladesh

Description: Infant mortality remains a major public health concern in Bangladesh, and an array of factors play a role in this pressing issue. The aim of this study is to thoroughly evaluate the factors that contribute to infant mortality in Bangladesh and their intricate relationships with maternal health. This review gives a summary of the current situation with regard to infant mortality and maternal health in Bangladesh by analyzing a wide range of literature sources, including study papers,

reports, and demographic information. This study identifies a number of important factors, such as infections, complications of preterm delivery, birth asphyxia, congenital anomalies, and malnutrition, are responsible for high infant mortality rates in Bangladesh. There is an increased risk of newborn death as a result of the frequent interactions and aggravations between these factors. The review also identifies socioeconomic factors that affect infant mortality, including deprivation, a lack of education, insufficient access to healthcare, and a lack of knowledge about mother and child health practices. Results: The study further explains how important a mother's health is in determining the outcomes of infants. Infant survival rates are greatly impacted by maternal factors including the mother's age, nutritional status, reproductive history, and access to prenatal care. The review highlights the significance of boosting antenatal care coverage, encouraging exclusive breastfeeding, alleviating maternal malnutrition, and ensuring skilled birth attendance as ways to improve mother's health. In conclusion, this review study highlights the intricate interplay between numerous factors that contribute to infant mortality in Bangladesh. It emphasizes the need for numerous approaches to deal with both the root causes of infant mortality and the factors that affect the health of mothers. Significant progress can be made in lowering infant mortality rates and promoting better health outcomes for mothers and infants in Bangladesh by enacting evidence-based strategies and policies that are focused on enhancing maternal health, increasing access to healthcare, and addressing socioeconomic disparities.

Clinical Alarm Management Program in the Patient Care Environment: Imbanaco Clinic

By Karent Muñoz Salazar; Margarita Sarmiento; Dr. James Zapata; Nancy Zapata

Imbanaco Clinic NICU, Cali, Colombia

Description: The clinical alarm management at Imbanaco Clinic, was implemented following a methodology of planning, execution, verification, and action within the framework of the deployment of medical technology in the intensive care units. The development is carried out based on clinical decisions that review events and trends in clinical workflows, data collection for respective analysis, establishment of criteria to provide information and tools that help prioritize alarms to reduce fatigue, and ultimately the review of findings, configurations, and education of staff in order to reduce the risk associated with clinical alarm systems used in patient care. The clinical alarm management was developed in accordance with international accreditation standards described by the Joint Commission International (JCI) in the COP 3.1 standard: Patient Care to reduce the risk of harm associated with clinical alarms through the development and implementation of strategies used in patient care. Therefore, our goal was to reduce the risk of harm associated with clinical alarms by complying with measurable elements: Conclusions:In the development of clinical alarm management, the responsible individuals developed and implemented a program for alarm signals that pose a risk to patient safety. The program identified the most important alarm signals that should be managed based on the risk to patient safety. Furthermore, the responsible individuals developed strategies to manage alarms that consider patient safety, and appropriate healthcare professionals and other staff received training on the purpose and proper functioning of the alarm systems for which they are responsible. The results of clinical alarm measurement are obtained from data extraction from monitoring software. In the diagnostic measurement of the Intensive Care Unit, there were 43,406 physiological clinical alarms, with oxygen saturation influencing 14,336 alarms. In the post-training measurement, there were 23,257 physiological clinical alarms, with a predominance of oxygen saturation and a reduction to 6,435 alarms. The results obtained in physiological alarms reduced 47% of physiological alarms in the Intensive Care Unit; however, their activation pattern remained consistent during the evaluated period. Similarly, in the diagnostic measurement, there were 213,024 technical clinical alarms, with electrode-free respiration being the most frequent with 84,575 alarms. In the post-training measurement, there were 52,006 technical clinical alarms, with a reduction to 26% and a predominance of electrode-free respiration.

Accessible Magnetic Resonance Imaging (MRI)

By Rafael G. Lara Estrada; Miriam Perez-Acho; Andres Moron-Mendoza; Axayacatl Morales-Guadarrama; Joaquin Azpiroz-Leehan

Centro Nacional de Investigación en Imagenología e Instrumentación Médica (CI3M), UAMI, México

Description: Magnetic Resonance Imaging (MRI) is an imaging diagnostic technique that uses magnetic fields and radiofrequency waves to visualize soft tissues in the body. While it is a versatile tool for detecting a wide range of medical conditions, its high cost poses a challenge to accessibility. At the Centro Nacional de Investigación en Imagenología e Instrumentación Médica (CI3M), we have implemented various measures to make MRI studies more affordable. First, we conducted research

on the prices offered by nearby laboratories. While some places offered more competitive rates or special discounts, the image quality was lower as they used 1.5 Tesla equipment. In contrast, our center has 3 Tesla equipment, which provides higher-quality images at lower prices. Additionally, we established partnerships with medical insurance companies to cover the costs of MRI scans. We also provide support to patients in complying with the procedures and requirements set by insurers so they can take advantage of the available benefits. As a research and teaching center, we offer reduced-price or even free MRI studies, as long as they can be used for training and case studies. We have also partnered with medical institutions and nonprofit organizations that offer financial assistance programs to low-income individuals, including access to MRI studies. However, the most effective action we have taken to make MRI studies more accessible is to optimize imaging protocols. Through this optimization, we have improved efficiency, reduced acquisition time, and increased image quality. Results:To achieve this, we have implemented various strategies. Firstly, we make intelligent selection of MRI sequences to be used in each case. We carefully evaluate which sequences are most relevant and discard those that do not provide significant diagnostic information. This approach allows us to avoid unnecessary sequences and optimize acquisition time. We also employ acceleration techniques such as parallel acquisition or parallel imaging in space and time (SENSE) to reduce acquisition time. These techniques enable simultaneous acquisition of multiple lines of data, shortening the time required to complete a study without compromising image quality. Another measure we have taken is the use of appropriate coils for each anatomical area. This careful selection improves the signal-to-noise ratio and image quality in less time. Adjusting sequence parameters based on the study objective, such as repetition and echo times, number of excitations (NEX), slice thickness, and spatial resolution, helps us obtain high-quality images without redundant data. Implementation of standardized protocols has also aided technicians and physicians in following a consistent and efficient workflow. It helps to avoid unnecessary repetitions or repetitive changes in patient positioning and orientation, while facilitating image comparison across different patients. It is important to balance efficiency with image quality and accurate diagnosis. We always ensure that our imaging protocols meet clinical standards and do not compromise the necessary quality and information for proper diagnosis.

Piloting of Photovoltaic (PV) Solution for powering Pressure Swing Adsorption (PSA) Oxygen Plant at Province Hospital, Surkhet, Nepal

By Samriddha Rana

World Health Organization, Nepal

Description: As a result of the oxygen crisis faced during the COVID-19 pandemic, oxygen scale-up was undertaken throughout the county. Installation of the PSA Plant was one of the approaches with which rapid escalation of Oxygen was achieved. The capacity of these hospital-based systems was chosen considering the surge requirement. The investment was massive. These systems currently sit ideal in many healthcare facilities because of the low regular oxygen requirement, wherein purchasing a few bottled oxygens is reasonable and inexpensive. Also, where the systems are running, it's below full utilization. The annual maintenance costs are added to the daily operational expenses. In such scenarios, it is essential to sustain these systems to ensure the availability of Oxygen, especially during the increased requirement in the country. One of the valuable lessons learned in the COVID-19 pandemic was to ensure the availability of Oxygen in the country at a scale larger than the everyday need. With support from WHO Nepal, the Ministry of Health and Population (MoHP) has been devising different strategies to sustain these systems. One is reducing the electric expense by installing a Solar Panel System. It comes as a pilot project. Provincial Hospital, Surkhet has two functional PSA oxygen plants. The Oxymat (brand name) PSA System was inaugurated on February 19, 2022. However, due to an underlying electrical issue, the PSA system could be powered only through a diesel generator. This was a severe issue demanding a quick fix at a hospital with a significant oxygen requirement. Therefore, the pilot project's scope, which initially aimed at reducing electric costs, was extended to address the intermittent problem as well. The project has provided an added value as it would not only mitigate electric charges but also make the plant function with electricity, thus eliminating the dependency on diesel. It is informed that the cost incurred in purchasing diesel has crossed one crore rupees. Hence, the project has made an enormous impact. Similarly, there are a number of hospitals in Nepal wherein the PSA plant can't be operated on electricity due to the poor electrification status of that region. This is especially relevant in the Karnali province. The dependency on diesel has made the operation of the PSA system very expensive. The provision of PV solar systems could truly aid healthcare facilities in such areas where electricity is not reliable. The social cost of not having electricity in such places is undoubtedly much more than the cost required to equip those facilities with PV Solar Systems. Conclusions:The impact of the 150 KW PV solar system installation along with the provisioning of needful electric configuration was immediately seen in the Province Hospital, Surkhet. This has opened doors for the possibility of a similar kind of arrangement in other hospitals with similar problems. As the system generates electricity, the data collected from the site would help in establishing the feasibility of the project.

CE/HTM Practice in the Government Medical Institutions & Hospitals of the Indian State of Tamil Nadu

By Jagadesh Kumar Dhayalan; Alfred Roger George

Tamil Nadu Medical Services Corporation Limited, Tamil Nadu, India

Description: Tamil Nadu Medical Services Corporation Limited (TNMSC) is a state-government undertaking of Government of Tamil Nadu located in the Indian state of Tamil Nadu. TNMSC was set up with the primary objective of ensuring ready availability of all essential drugs and medicines in the Government Medical Institutions throughout the State by adopting a streamlined procedure for their procurement, storage, and distribution. The TNMSC was incorporated under the Companies Act, 1956 on 1 July 1994 and commenced its operations from January 1995.Subsequently, TNMSC has assumed wider responsibilities for the following range of services to the Tamil Nadu Government Medical Institutions & Hospitals but not limited to:
1.Procurement, Testing, Storage and Distribution of Drugs, Medicines, Surgical & Sutures, Kits, Reagents etc.
2.Procurement, Supply and Maintenance of Medical Equipment and Instruments to the Institutions & Hospitals
3.Administration and operation of Drug Warehouses, Diagnostic Imaging Centres, Radiation Therapy Centres, Nuclear Imaging Centres, Lithotripsy Centres, Master Health Check-up Centres, Pay Ward Centres.
The study seeks to provide an overview of the CE/HTM practices adopted by TNMSC, its impact & share our experiences in the delivery of Medical Equipment Maintenance & Management services to Tamil Nadu Government Medical Institutions & Hospitals.

Kidney stones detection based on ultrasound images using MATLAB

By Md Saiful Islam; Md. Ariful Islam; Md. Mokhlesur Rahman; Dr. Avijit Basak; Shyam Sundar Shaha; Ropak Chandra Roy

Department of Medical Physics and Biomedical Engineering, Gono University, Dhaka, Bangladesh

Description: Kidney stones are one of the most common disorders of the urinary tract. Kidney stone problem occurs as a common problem to every human being, due to the nature of living. A kidney stone termed renal calculi is a solid piece of material that forms in a kidney when substances that are normally found in the urine become highly concentrated. The ultimate aim of medical image segmentation is to reduce the amount of time a radiologist needs to spend looking at an image to identify the portions of renal calculi. The research focuses on the development of a computer-aided method for detecting kidney stones in ultrasound images. Kidney stones, or renal calculi, are common urinary tract disorders that can cause severe pain and complications if not diagnosed and treated promptly. The current standard for kidney stone detection involves visual inspection by medical professionals, which can be subjective and time-consuming. Therefore, an automated and accurate detection method is crucial to improve diagnostic efficiency and enhance patient care. This study proposes a novel approach for kidney stone detection using ultrasound images and MATLAB as the primary tool for image processing and analysis. The research begins by acquiring ultrasound images of the kidneys and urinary tract from patients with suspected or confirmed kidney stones. These images are then preprocessed to enhance their quality and remove noise using techniques such as grayscale conversion, median filtering, and thresholding. Connected components analysis is performed to identify potential kidney stones based on their shape and size characteristics. Features such as area and bounding box dimensions are extracted, and a set of predefined criteria is applied to differentiate kidney stones from other structures present in the image. Furthermore, the method allows for the region of interest extraction, enabling more focused analysis and additional processing techniques specific to the kidney stone regions. Results: The proposed method is implemented using MATLAB, which provides a comprehensive platform for algorithm development, feature extraction, and classification. MATLAB's extensive library of functions and toolboxes, along with its ability to handle complex image-processing tasks, make it an ideal choice for this research.
The developed method is evaluated using a dataset of ultrasound images with known kidney stone cases. Performance metrics such as sensitivity, specificity, accuracy, precision, and F1 score are calculated to assess the effectiveness of the proposed method. The results demonstrate good accuracy and efficiency in detecting kidney stones, highlighting the potential of the developed approach for clinical application. A computer-aided method for kidney stone detection based on ultrasound images using MATLAB. The proposed method offers an automated and objective approach to assist medical professionals in identifying kidney stones accurately and efficiently. With further refinement and validation, this method has the potential to improve the diagnosis and management of kidney stone-related disorders, leading to enhanced patient care and outcomes.

Ensuring Safe Operation of Autoclaves in Bangladesh

By Ariful Islam Arif

Faman Tech Corporation, Bangladesh

Description: The autoclave, undoubtedly a crucial piece of equipment that is widely used in healthcare facilities and laboratories in Bangladesh, plays an important role in sterilizing medical instruments and equipment. A rising number of pharmaceutical companies, laboratories, and hospitals in Bangladesh are demanding more autoclaves. However, ensuring the safe operation of the autoclave is the main concern to avoid accidents and improper use of the autoclave as well as maintain the integrity of the sterilization process. The purpose of this research is to present an overview of the current scenario of autoclave operations in Bangladesh and practices necessary to ensure the safe operation of autoclaves. Several factors are responsible for the improper use of autoclaves in Bangladesh. One significant problem is the inadequate training given to the operators and technicians in charge of the autoclave operations. Limited awareness and a lack of proper understanding of the safety guidelines and regulations specific to autoclaves are also big factors in the safe operation of autoclaves. Frequent maintenance and calibration are much more important for the safe operation of an autoclave. However, the lack of proper maintenance and calibration practices is a common problem in Bangladesh. Due to the limited automated control of old-fashioned manual autoclaves, it can possibly create challenges and increase the risk of improper or unsafe operation. Working on several automation projects on autoclaves and a number of autoclaves troubleshooting projects, visiting several autoclaves for maintenance purposes. Using this real-life experience with autoclaves, this study analyzed the factors responsible for ensuring the safe operation of autoclaves in Bangladesh. Results: Adequate training for operators and technicians will cover the right operation of autoclaves, loading techniques, safety measurements, maintenance procedures, and emergency procedures. Autoclave operation should comply with the standards and regulations of national and international standards, such as those of the Bangladesh Standards and Testing Institution (BSTI). The autoclave should have automated control systems, scheduled maintenance and calibration to improve the sterilization process. There should be at least one biomedical engineer to monitor the overall autoclave performance and operation. Proper documentation and recording with proper monitoring is vital. However, the culture of safety operations needs to be vastly promoted to ensuring the safe operation of autoclaves in Bangladesh. Remote monitoring and data archiving will help to monitor the exact operation and performance of autoclave. It will help the upper management and biomedical engineers to monitor the autoclave operation from anywhere. In case of any failure and mismatch of operation then every person assigned to the monitoring system will get text messages to their phone & email notifications. The real and practical analysis of this study presents the key factors responsible for the safe operation of autoclaves and paves the way to the advancement of operation as well as maintain the regularities for safe operations. Finally, ensuring the safe operation of autoclaves in Bangladesh necessitates a multi-faceted approach that includes comprehensive training, remote monitoring and notifications, adherence to safety guidelines, regular maintenance, quality control, and a culture of safety.

UCvenT BPAP Ventilator: A Solution for Respiratory Support in the Pandemic and Post-Pandemic Developing World

By Sarah McEwan; Saberi, Marais; Sudesh Sivarasu Ph.D.

UCT MedTech, Biomedical Engineering Research Centre Division of Biomedical Engineering, Department of Human Biology Faculty of Health Sciences, University of Cape Town, South Africa

Description: The Covid-19 pandemic highlighted the critical shortage of ventilators worldwide, with developing regions facing even more significant challenges in accessing these life-saving devices. In response to this crisis, the UCvenT Bilevel Positive Airway Pressure (BPAP) Ventilator was developed by a team at The University of Cape Town in South Africa. The primary objective was to provide a rugged and portable solution that can be easily manufactured and repaired within the region. The UCvenT BPAP Ventilator was developed in strict compliance with international and national guidelines for non-invasive ventilators (NIV) established by the World Health Organization (WHO) and the South African Society of Anaesthesiologists (SASA). The UCvenT system delivers Continuous Positive Airway Pressure (CPAP) and BPAP to non-intubated patients, with adjustable pressure levels during inhalation and exhalation. These specifications were established as the minimum requirements for the ventilator system design. This ventilator addresses the increasing global demand for NIV, especially in emerging markets. The pandemic emphasized the crucial role of NIV in treating respiratory conditions such as Acute Respiratory Distress Syndrome (ARDS) and Chronic Obstructive Pulmonary Disease (COPD). Furthermore, factors such as air pollution, climate change, an ageing population, and lifestyle-related risks contribute to the anticipated rise in respiratory diseases, including the potential for future global respiratory pandemics. Results: The UCvenT BPAP Ventilator

incorporates a modular design, utilising readily available Commercially Off-The-Shelf (COTS) components, which can be easily obtained from local suppliers. The design eliminates the need for sterilisation by replacing consumable filters and accessory components. Additionally, the ventilator has a long battery life, enabling uninterrupted operation during power outages common in many developing regions. This feature enhances the device's usability and extends its application in areas with unreliable grid power infrastructure.One of the key advantages of the UCvenT BPAP Ventilator lies in its software-defined ventilation parameters, which are not constrained by hardware constraints. This flexibility allows healthcare professionals to modify the ventilation strategy to suit evolving respiratory conditions, ensuring optimal treatment and patient care. The UCvenT BPAP Ventilator prioritises ease of use and maintenance, featuring a user-friendly interface that simplifies operation, making it accessible to minimally trained users. Currently, at a technology readiness level (TRL) of 4/5, the development team aims to achieve a TRL level of 6/7 by the end of the year, signifying significant progress in the technology's maturity and readiness for commercialisation. In parallel to the technical development, a detailed market research is being conducted to ensure the solution's suitability for the post-pandemic African market.
In conclusion, the UCvenT BPAP Ventilator represents a significant advancement in meeting the demand for accessible and adaptable respiratory support solutions, particularly in developing regions. The UCvenT BPAP Ventilator has the potential to have a substantial impact on respiratory care within the African region by establishing a foundation for long-term respiratory support in a changing healthcare landscape.

Developing a User-Centered Mobile Application for Medical Equipment Users and Engineers in Uganda:Opportunities and Challenges

By Wodidi Jonah

Ernest Cook Utrasound Research and Education Institute (ECUREI), Uganda

Introduction: Medical equipment plays a critical role in delivering timely and high-quality healthcare services, enabling accurate diagnoses, effective treatments, and improved patient care (Keller JP, 2005). This role relies on the proper use and effective management of these equipment, which involves a multidisciplinary team of biomedical engineers and other healthcare workers (WHO, 2017). However, low and middle-income countries like Uganda, this team faces significant challenges in accessing the necessary information and training resources required to effectively manage healthcare technologies. The lack of reported data on the percentage of healthcare workers in Uganda receiving formal training in medical equipment maintenance and repair underscores the issue. This deficiency in access to information and training adversely impacts healthcare delivery and patient outcomes. Ssekitoleko's study in 2021 provides evidence of this, revealing that 4% to 54% of medical equipment in nine tertiary hospitals and five research institutions in Uganda was non-functional. Existing solutions like equipment manuals, troubleshooting guides, and online workshops have limitations in terms of comprehensiveness, currency, and accessibility. Traditional training methods face constraints in cost, scalability, and expert availability. In Uganda, challenges such as inadequate infrastructure, limited connectivity, and skill shortages exacerbate the situation. Objective: The proposed app aims to improve safety, effectiveness, and outcomes, offering a cost-effective solution. It enables seamless communication, collaboration, and device procurement. Streamlining troubleshooting, reducing downtime, and enhancing healthcare in underserved areas, it holds potential for innovative solutions. User requirements: To develop a user-centered application, a survey was conducted involving equipment users and biomedical engineers. Their requirements and specifications were gathered to inform the application's development. The survey findings highlighted that the application should include medical device operation and service manuals, an intuitive interface, comprehensive resources, and interactive features. These elements would facilitate efficient equipment operation, troubleshooting, and collaboration. User recommendations indicated significant potential for widespread adoption of the mobile application in healthcare settings. Strategies: We aim to establish partnerships with equipment manufacturers, suppliers, and online libraries such as BMET library.to obtain comprehensive equipment manuals and troubleshooting guides. Incorporating user feedback, the user-centered application will include expert-led videos, intuitive interfaces, and cross-device compatibility. Collaborations with local healthcare facilities will ensure accurate information and contribute to improved healthcare outcomes. Conclusions: A future user-centered mobile app will provide comprehensive resources and intuitive features to address challenges in Uganda's healthcare. Partnerships will be formed for up-to-date manuals, while collaborations with local facilities will enhance outcomes. This solution holds transformative potential for underserved areas.
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Design and Development of a wearable device to mitigate infectious disease transmission. Case study: Covid 19

By Joseph Habiyaremye, Ph.D.; Prof. Damien Hanyurwimfura; Dr. Jimmy Nsenga; Desire Ngabo

Rwanda Association of Biomedical Engineering, FDA Rwanda

Description: During the novel and deadly Covid-19 pandemic, countries including Rwanda have locked their population at home to mitigate its spreading and this affected the social life and economy. Victims of this virus presented some signs related to breathing as the virus used to affect respiratory channels. A lot of solutions for reducing the aforementioned diseases have been proposed, in the same way, a research team from the African Center of Excellence in Internet of Things (ACEIoT) of the University of Rwanda and NARADA LTD (a private company) with the support of National Council For Science and Technology (NCST) Rwanda through an Academia and Industry collaboration funding scheme, have designed and developed a wearable device to monitor the spreading of communicable diseases such as Covid-19.Results:With the help of artificial intelligence, we tried to embed some machine learning models in a low resources microcontroller; Arduino Nano 33 Ble sense through the TinyML structure. The design and development resulted in a 40 g 55.8*54.9*19mm gadget with a debugging micro USB port, Bluetooth Low Energy (BLE) 5.0, a GPS with an accuracy of 2m, a PDM-based Microphone, with some sound notification and vibration that can monitor some body temperature such as temperature, blood oxygen concentration, heart rate, etc. Apart from this, the device can help in monitoring social distancing, cough detection, detecting falling and sleeping, and geo-fencing. All this information is displayed on a small 0.96'' OLED screen and wirelessly transmitted to a remote database.

Health Technology Management in Ethiopia

By Mulugeta Mideksa Amene

PhD candidate in Leadership and Management, Consultant, UNICEF, Ethiopia

Background: Most LMIC have challenges to manage healthcare technologies (medical devices) effectively, as the majority are imported with low cost, with low quality and donated from western countries which are disposed medical devices without a company technical support. Biomedical and Clinical Engineers (BME and CE) are involved mainly in maintenance activities not fully managed the whole life cycle management of the medical devices. There are almost 38 countries in globe did not have Healthcare technology management (HTM) policies including Ethiopia (WHO). Without the policy countries cannot develop any local enforcement documents on HTM, HTA and HTR. Like: direction, regulation, proclamation. This study aims to identify and assess the main problems facing medical devices in Ethiopia, as well as the role of BME department at all levels of health sectors.
Methods: The author conducted two key people that were interviewed in each seven categories: Policy makers, BME departments in health facilities, Hospital managers, MOH and agencies, Partners, and BME/T training institutes. The requests were based on seven categories with thirty-three questionnaires to fourteen interviews, the researcher made a tailored to the context of Ethiopia's health service which is structured into a three-tier system: primary, secondary, and tertiary levels of care. Reviewed documentation. Results: The findings of the survey show that the role of BME is limited in all HTM life cycle managements. Biomedical engineering departments are not empowered in most health facilities. No national policy which can empower BME departments and help them to produce proclamation, regulation, and directive on medical device management life cycle. Still the average non-functional medical devices are between 15-20%. The most challenging is that the HTM led by pharmacist in all MOH and Agencies. More than Two hundreds of BME/T graduate from the university and colleges but most of them are not recruited. This challenge must be addressed by policy, strategic/roadmap on medical device management and health technology needs assessment (HTA) and innovation. The ability of each key actor to address these problems (the degree of political or administrative power they possess) was inversely proportional to their perception of the severity of the problems. Conclusions: The lack of policy on HTM, HTA and HTR processes could reinforce many of the continuing problems in Ethiopian's medical device management system. The main solutions can be developing a separate policy that make a change to these problems, it is necessary to advocate for decision maker and political possess.

Breaking the PET Barrier: Machine Learning-Enabled Cancer Diagnosis Using Common Features in CT/MRI Imaging

By Mohammad Anamul Haque Chowdhury; Md Sharjis Ibne Wadud; Sadia Nawsheen Nijhum

Department of Biomedical Physics & Technology, University of Dhaka, Bangladesh

Description: Accurate cancer detection is crucial for effective treatment, but in cases where cancer cannot be detected by CT or MRI alone, PET or PET-CT/MRI scans are often employed. However, this approach increases the use of radiotracers and escalates imaging costs. This study aims to identify common features in CT or MRI images that can diagnose cancer without the need for PET-CT/MRI, thus benefiting both the general population and reducing the dependence on radiotracers and expensive imaging techniques. The primary goal of this work is to develop an alternative method for cancer diagnosis that eliminates the requirement for PET-CT/MRI scans when CT or MRI alone cannot detect cancer. By analyzing CT or MRI images and comparing them with the corresponding PET-CT/MRI images, common features indicative of cancerous regions are identified. This research investigates the shared characteristics that can be effectively leveraged for accurate cancer diagnosis using CT or MRI alone. The proposed approach not only provides a cost-effective solution but also addresses accessibility issues in regions where PET-CT/MRI scans may be limited. By reducing the reliance on radiotracers, patient exposure to radiation can be minimized, and imaging costs can be significantly decreased. This work aims to improve efficiency by streamlining the diagnostic process, offering a practical and accessible method for cancer detection. Results: The accuracy and reliability of the developed method are rigorously validated using diverse datasets. The performance of the alternative diagnostic model is compared with the results obtained from PET-CT/MRI scans to ensure its effectiveness. Validation encompasses various metrics and evaluation techniques, ensuring that the proposed method can reliably detect cancer using CT or MRI images alone. This research has the potential to revolutionize cancer diagnosis by providing an alternative approach that eliminates the need for PET-CT/MRI scans in cases where CT or MRI alone fails to detect cancer. By finding common features, this work not only benefits the general population but also reduces the dependency on radiotracers and expensive imaging techniques.

ARTIFICIAL INTELLIGENCE FRAMEWORK FOR COVID19 patient triage

By Sandy Rihana

Holy Spirit University of Kaslik, Lebanon

Description: The fatalities of COVID-19 can be linked to the intensive care unit's lack of availability or saturation. Prioritizing patients for hospitalization and intensive care may be crucial in minimizing COVID-19 mortalities. This project aims to create a model that can predict whether a COVID-19 patient who has already been admitted to the hospital will be admitted to the ICU or not. This could be accomplished by taking his vital signs, consulting his blood tests, inquiring about his demographic records, and keeping track of him during his stay in the hospital. Results: Multiple models, including Artificial Neural Networks, Logistic Regression, Decision Trees, Random Forest, Gaussian Naive Bayes, Gradient Boosting, and Support Vector Machine, were developed using MATLAB and Python. It was noted that Random Forest, Extra Tree Classifier, and Gradient Boosting are examples of decision tree-based algorithms that outperform others.

Valuation of Biomedical Engineering Professional Practices in Bangladesh through Comprehensive Survey: a Dire Demand for Certification and Credentialing

By Md. Ashrafuzzaman; Tasnuba Tabassum Mourin; Rayesa Haque Rupanti; Nawrin Tasnim; Md Asadur Rahman

Saudi Bangladesh Institute of Biomedical Engineering & Technology, Military Institute of Science and Technology, Bangladesh

Description: We conducted a survey on the state of biomedical engineering education and professional practices in Bangladesh along with BioMedical Women Engineers in Bangladesh (BMWEB) and the Bangladesh Association of Clinical & BioMedical Engineering (BACBME). The objective of this survey was to gain insights into the present state of biomedical engineering education and professional practices in Bangladesh, with the aim of raising awareness among decision-makers in the government. The survey addressed several key questions to shed light on important issues within the field. Key findings

were gathered through particular questions that were asked of a wide spectrum of participants in the survey. A considerable representation of women in the sector was highlighted by the male-to-female ratio among respondents, which was found to be 59.5% to 40.5%. Nevertheless, 28% of respondents claimed that there was gender disparity in the workplace, despite their numbers. Only 40% of biomedical engineers believed that their employers had adequately evaluated them as such. Another important area of attention was the phenomenon of experts leaving the field of biomedical engineering after earning their BSc. The survey identified a lack of opportunities provided by the government and industries in Bangladesh, leading to feelings of insecurity among biomedical engineering students and professionals. Women frequently experience discrimination in both academic and professional settings, despite their large presence in the sector. The current situation of biomedical engineers must be improved, and that requires acknowledging the crucial role that this sizable community of female professionals plays. This study seeks to suggest alternative solutions based on a comparative analysis of the global situation in biomedical engineering in light of the survey's results. The objective is to encourage changes and create an atmosphere that is favorable for biomedical engineers across the nation by offering practical advice. Objectives:
•To obtain a comprehensive understanding of the current state of biomedical engineering education and professional practices in Bangladesh.
•Seek to raise awareness among government decision-makers about the existing conditions in the field, advocating for improvements and changes.
•Identify challenges and issues faced by biomedical engineering students and professionals, including employment opportunities, workplace evaluation, and career shifts.
•Propose potential solutions and recommendations to address the identified challenges, considering global best practices and the specific context of Bangladesh.
•Immediately implement the certification and credentialing of biomedical engineers of Bangladesh.
Potential outcomes:
•Providing detailed data insights on biomedical engineering education and professional practices in Bangladesh, covering demographics, gender dynamics, and employment status.
•Raising awareness about gender disparities in the biomedical engineering field, to promote gender equality and inclusivity.
•Identifying significant challenges, including a lack of employment opportunities, inadequate evaluation by employers, and professionals switching fields.
•Emphasizing the urgent need for policy interventions from the government and proactive measures from industries.
•Finally, capacity building through the certification and credentialing process will assist the young biomedical engineers to get their proper recognition for the well-being of HTM at national level.

Explaining the European Medical Device Regulatory Framework: Policies for Survival in the Jungle

By Federico Sternini; Noemi Conditi; Alice Ravizza; Filippo Molinari

InsideAI srl, Politecnico di Torino, Italy

Description: Recent developments in innovative technologies have prompted European legislators to define a set of regulations to ensure the safety and efficacy of AI-based devices, medical devices, and any system intended to process personal data. The resulting legal framework consists of the General Data Protection Regulation (Regulation 2016/679), the Medical Device Regulations (Regulation 2017/745 for MD and Regulation 2017/746 for IVD), and the AI Act (Proposal for a Regulation COM/2021/206 final). The definition of these new regulations poses new challenges for AI practitioners wishing to introduce an innovative device to the medical device market. In this context, the "Explanaiblity of AI (XAI)" could be used as a valuable tool to meet the general requirements of the regulations. At the same time, the same concept of explainability can take advantage of the techniques and approaches to be used in the regulatory path of AI medical devices. We propose a comprehensive method to adhere to regulatory requirements while promoting medical AI innovation. This approach emphasizes risk management and the AI software life cycle. It first identifies design inputs and verification activities, incorporating requirements derived from risk analysis. Notable international standards, such as ISO 24971 and ISO 24028, can assist in evaluating risks, though they don't provide risk mitigation recommendations. Results: Primary AI system risks include unforeseen and improper data processing which can be tackled via various risk control measures (RCMs). The design phase should consider "Safe by Design" RCMs, including privacy-focused policies, pseudonymisation, and strategies to ensure data representativity and unbiased AI training. Explainability techniques should be embedded in design and training to improve

interpretation by clinicians. Alarms and Protections RCMs should notify users about potential errors or deviations from the training data scope. The device should enable clinicians to evaluate the impact of uncertainty in their decisions. Instructions for safe use should provide clear, user-appropriate information on device operation, utilizing Explainable AI (XAI) techniques to help users understand data processing. Post-design, continuous learning and updating policies should be defined, ensuring consistent performance and quality in each device iteration. These policies should allow for regular checks on performance, incoming data, and the AI's working principles, promoting transparency for designers and users alike. Conclusions: The European regulatory framework, requiring safe and effective technologies, necessitates manufacturers to create extensive records of all design stages to ensure compliance. This regulatory demand inadvertently improves the explainability of AI systems. The explainability of AI becomes a beneficial tool, aiding designers in adhering more effectively to regulations. Our proposed approach promotes a cycle of improvements. The regulations demand traceability and explainability, which traditional techniques can partly satisfy. New AI explainability techniques can fill the remaining gaps, enhance traceability, and pave the way for significant technological advancements.

OXYLUCK a Device to for Evaluating the Quantity of Oxygen Delivered to Patients

By Hwenude Judicaëlle Chance Gountin

Department of Biomedical Engineering of the Ecole Polytechnique d'Abomey Calavi (EPAC), Benin

Description: My training has allowed me to acquire the knowledge required to ensure the maintenance of biomedical equipment, to be able to manage a fleet of equipment and acquire the essentials to adopt the ergonomics of the technician in a hospital environment. Following my end-of-training internship at the University and Hospital Centre for Mothers and Children in 2021 in Benin, I noticed that there is no standard way of billing the volume of oxygen administered to the patient. The evaluation of the amount of oxygen consumed by patients is a point on which hospitals cannot be fixed among themselves. In addition, the methods of billing oxygen to the patient are highly criticized by patients who complain of overbilling. This is a daily problem in our hospitals and finding a solution to it has become our concern. Results: Hospitals are complaining about oxygen loss and patients are complaining about excessive oxygen charges. To find a solution to this problem, I developed OXYLUCK, a device for evaluating the quantity of oxygen delivered to patients, to reinforce the hospital's capacity to manage and use oxygen rationally. The validation and acquisition of this module for evaluating the volume and cost of oxygen administered to a patient will not only strengthen the capacities of medical and administrative staff in the billing and rational use of oxygen but will also have a positive impact on the quality of patient care. My participation in a design thinking workshop allowed me to improve this device by prototyping software to monitor this oxygen consumption in the hospital. This work enabled me to win first place in the best technological innovation projects competition during a training course organized by the MTN Benin Foundation in March 2023. I also had the chance to work on research projects in collaboration with clinicians, engineers, and scientists in the specialized workshop of the Biomedical Engineering Department at the Polytechnic School of Abomey-Calavi from 2022 to the present day. Despite our many efforts to implement this project, there is always room for improvement. To achieve this goal, I decided to pursue my studies in engineering to better understand the subject.
I am passionate about science and technology for health and would like to specialize in the field of medical device design to become a biomedical engineer, specializing in scientific and technical systems related to health. To help doctors and biologists understand the problematic development of scientific and technical devices necessary for health. And to make it easy for doctors to diagnose, by designing tropicalized medical devices that are adapted to sub-Saharan realities.

Building Smart, Quality and Sustainable Healthcare Infrastructure as a Key to Improving Healthcare Delivery Outcomes

By Eng. Francine UMUTESI; Annick ISHIMWE

Rwanda Biomedical Centre, Rwanda

Introduction: The definition of health care infrastructure is one that involves the individuals, facilities, and buildings required to deliver world-class health care. This complex term includes the components comprising basic hospital delivery of services, including both structural and maintenance of facilities. In many communities, this has been looked at as only buildings, not accounting for the technologies that are comprised into those buildings to make them specialized and worthy to be used for

healthcare services delivery. Discussion:In Rwanda, healthcare facilities used to be built based on local development trends of constructions for homes, businesses, and other non-specialized infrastructure. Presently, about 85% healthcare facilities are built without clean rooms, no negative pressure, until 2020, hospitals were not required to have oxygen for their critical care settings nor neonatology departments, to name a few. In recent years, things have changed, and new strategies are being put in place to ensure that any healthcare facility project is conducted with a multi-disciplinary team, who include not only the architect and civil engineer, but principally biomedical engineer and clinical personnel who guide the process from the feasibility study, designing of a health facility, and its construction. Results: Defining the healthcare packages of the facility to be built, then designing its programming room by room has become a science. Then comes the technical requirements in terms of air flow, ventilation, electrical connections, communication tools, internet, water systems, all this to ensure that the equipment to be installed in the rooms will have facilities needed to operate. For instance, radiation protection is needed for radiology department, a faraday cage for the MRI room, water systems for the dental room, proper UPS to ensure uninterrupted power supply in some and all sensitive areas of the hospital. Most importantly, availing green and recreational spaces, considering for the patient's comfort in the designs is key. This requires a skilled workforce that includes architects, civil engineers, biomedical engineers, electromechanical engineers, electrical engineers, and IT so that all these requirements can be considered from the beginning of a project. Other countries have done this, built sustainable health infrastructure in terms of systems, construction and technologies; and Rwanda is on its way. One just need to learn from best practices and be able to tailor solutions that apply to their environment. Conclusions: Building green, smart, quality and sustainable infrastructure requires that one builds an ecosystem that helps along the whole process. Setting up a skilled workforce, proper guidelines and SOPs, conducting benchmarking missions to learn from best practices, and building sufficient capacity so that the engineers can implement projects based on evidence-based engineering and technology trends of the moment.

Planning and Coordination with Hospital Architecture

By Marcelo Horacio Lencina

National Technological University, San Nicolas, Argentina

Description: The purpose of this study is to demonstrate the importance of the CE participation when a construction and/or expansion project is planned in the health sector. A health project should be consider from its conception the variables that imply the incorporation of medical equipment, from the complementary facilities for its operation, entry and internal movement to the assembly and commissioning; to this the participation of Clinical Engineering (CE) is necessary. Its success depends on interdisciplinary work not only between architecture (design and project) and the different engineering (equipment and facilities), but also between professionals and technicians (future users). This project was the relocation of the Sterilization Unit in the Hospital "San Felipe" of San Nicolas city, belonging to the MoH of the BA Province. The intervention tries in general to respect the characteristics and existing structures of the building, increasing the current surface of the upper floor, with the construction of a mezzanine and roof of concrete slab with reinforcement. The Hospital CE Department, has an actively participation with the architecture and engineering professionals of the MoH, providing the necessary data to the project design and development. Results: The chosen location had the necessary pipes to supply electricity according to the power demanded by this unit. In addition to having the facilities to supply water, gas and effluents, that is, no extra supply facilities should be made. As this service was projected on the first floor, it contemplated the reinforcement of the slab in the place where the autoclaves, which are of heavy weight, would be installed. In addition, it was considered for the work progress program, that in the room where they would be installed, the wall to be built that overlooks the service patio would be done at the last minute, so that the autoclaves could be entered. This procedure would avoid the execution of rough work once assembled, increasing the risk of unintentional damage. The entrance and storage in a warehouse in front of the work was also considered, since they were going to arrive before the scheduled date for assembly. This condition occurred because the equipment´s purchase was not included in the tender, it was carried out separately and simultaneously. The service was projected on the first floor and adjacent to an easily accessible patio, this was so that a forklift could enter to locate them in the projected place. The CE Dartment also participated in the development of the project with regard to the circulation and treatment of ambient air corresponding to the area of the equipment exclusively, not air conditioning, since this room doesn´t contemplate it. The area corresponding to the autoclaves and stoves was designed with positive pressure and the area of the sterilizer by ethylene oxide with negative pressure with a system of trap doors for entry and exit. The air injection and extraction equipment with its corresponding filter boxes were mounted on the exterior ceiling.

Synthesis of Cardiac Signal Processing Methods for Telemedicine

By Cosme A. T. Dotonou; Dr Roland Houessouvo; Dr Patrick Sotindjo; Prof. Medenou Daton

Université d'Abomey-Calavi (UAC), Benin

Description: The monitoring of human health is becoming increasingly important these days, with the development of intelligent mobile objects that facilitate the acquisition of medical signals from the patient to assess the effectiveness of treatments and monitor sick patients. Mobile devices such as watches, phablets, cell phones, etc., are used to collect medical data without the assistance of a healthcare specialist. However, at a time when telemedicine is undergoing rapid development, the processing of data collected with these devices for remote, real-time medical monitoring of patients is still encountering difficulties. Results: The study of medical data treatments methods is therefore becoming an active area of research and development. The present work is part of this dynamic, and proposes, on the basis of a comparative study, a synthesis of treatments methods of cardiac sound or phonocardiograms (PCG) for telemedicine. The study is based on the ability of the transforms to detect the B1 and B2 heart sounds contained in the PCG, and to identify each sound by differentiating its intensity. The results obtained reveal simple, effective transforms that locate B1 and B2, and show a pronounced difference between their intensities in both healthy and diseased (pathological) PCG. These methods, with their negligible computing time, guarantee the use of mobile devices for telemedicine.

Pandemic Solutions followed at Omandurar Medical College Hospital, Chennai, Tamilnadu, India

By G Alfred Roger

Tamilnadu Biomedical Engineers Association; Government Medical College, Omandurar Estate, Chennai, India

Description: The Government Omandurar Medical College & Hospital is functioning as an exclusive hospital for the treatment of SARS CoV -2 since the 27th of March, 2020 under the direction and guidance from The Ministry of Health and Family Welfare State Government of Tamil Nadu. The conversion of the Government Medical College, Omandurar Government Estate, Chennai to tackle the COVID'19 pandemic was completed within a period of 7 days in March' 2020. Results: The author as an Assistant Engineer (Bio-Medical) in-charge, was instrumental in managing the successful installation of Ventilators, Bedside Monitors, pulse oximeters, ECG machines, RT-PCR Laboratory, Biochemistry and Haematology Laboratory Equipment, Horizontal Autoclaves, Fowler's and Semi-Fowler's Cots, Liquid Oxygen Plant, Pressure Swing Adsorption plants, and Oxygen Concentrators, etc. This hospital is capacitated with 575 inpatient beds with 11 isolation wards and 3 IMCU wards. Out of the total beds, 78 are equipped with ventilators and 322 oxygen beds. During the pandemic the oxygen consumption was managed effectively by increasing oxygen production through 2 numbers of PSA plants and also adjusting the delivered litres per minute to the patients as per clinical requirement and thereby excessive consumption was reduced. The Ventilators were running without any break leading to internal battery failure. A stock of internal batteries was maintained and replaced as and when required thereby managing risk and ensuring patient safety. This was a predictive maintenance measure thereby improving patient safety and reducing risk. As a predictive maintenance measure the ECG patient cables, SpO2 probes and NIBP cuffs of Bedside Monitors which were bound to fail were replaced immediately through the stock made available by us predicting the possible breakdowns of these devices. Reducing user errors is important in safe Healthcare delivery to the patients. The end user like Doctors, Nurses and Laboratory Technicians were adequately trained to avoid equipment breakdowns, this proved to be very successful during the pandemic. Daily Disinfection of Medical Devices were carried out in a safe and controlled manner thereby ensuring user safety and to avoid infection to those who come in contact with the medical device. An Important lesson learned during the pandemic was to uplift the propaganda for responsible Donations. Many Medical devices without local service / installation support and spare availability reached this hospital and we found it difficult to install and replace the defective spare parts for such items. Hence the need for responsible Donations has emerged and needs global attention.

Women-Baby Humanized Health Care Model

By Gloria Milena Cruz Velasquez, Ph.D.

Universidad ECCI, College of Engineering, Biomedical Engineering Program, Colombia

Description: Violence against women is identified as a serious public health problem, due to its dimension and the consequences it generates on physical and psychological well-being, including the family and the impact on the whole society, according to the World Health Organization. Pregnancy is an emotional and important time and brings changes in physical form, role and lifestyle. These changes can have an impact on the attitude, decision-making and behavior of the pregnant mother when assuming the social responsibility that comes with pregnancy and motherhood. Violence in pregnant women

also involves the health of the fetus. Therefore, to address these challenges, the need for social support, with a humanized approach is vital. Community-based models are paramount to improving maternal health outcomes and promoting equity. Results: Provide strong support considering a "Health: mom-baby-human-social" model to improve emotional and physical well-being, strengthen social relationships, and cope with the stress caused by the violence. Therefore, it is necessary to identify what is needed to establish care and follow-up models that minimize the social impact that can affect the development of a life and social integration with dignity. To address this problem, strategies based on different levels of prevention have been designed, according to the moment in which violence is intervened; however, from the health sector, the comprehensive approach is still stagnant or in its initial stage. Even diseases such as human immunodeficiency virus, sexually transmitted infections, malnutrition, complications during pregnancy and childbirth, and inadequate newborn and childcare can be addressed. Coordination of care can lead to important health benefits and improve later pregnancy outcomes and infant health. It is also important to highlight that the increase in live births comes from low-income women, victims of violence, women living on the streets and minors, who do not have the opportunity to undergo a medical check-up or check-up during pregnancy, causing illnesses in the newborn, where medical care in intensive care units would be involved. The problem is evident and also focuses on the lack of beds or sufficient health technology in pediatric and neonatal intensive care units, for the exclusive use of these patients who may present serious health difficulties. It is necessary to identify that the lack of care and opportunity directly affects the health of the mother and the baby. The coverage and the deficiencies of the health system does not contemplate or very little is achieved with a preventive, social and human approach.

251: Progress Towards an Open-Source Cloud Enabled CMMS for Low Resource Countries

By Akshay Puli; Bill Gentles; Martin Poulin; Edward Opoku-Agyemang

Ghana Medical Help, Ghana

Description: In many low resource countries, health technology management (HTM) tools are in limited use. One essential tool, a Computerized Maintenance Management System or CMMS, has seen limited adoption due to: 1. The cost of commercially available CMMS systems, both initial purchase cost and ongoing support costs are prohibitive in health systems with severely limited resources; 2. The additional work required to take an accurate inventory, which provides the foundational data to start using a CMMS, places an undue burden on staff who are already overworked; 3, Entering maintenance data into a CMMS after each maintenance intervention takes additional time compared to the default mode of not recording such data, and Staff who are overwhelmed with the task of just keeping things running often can't see the longer-term benefits of documentation. Results: With these obstacles in mind, a Pilot Project has been underway in Ghana with three goals: 1. Familiarize biomedical engineers with the advantages of using a CMMS; Collaborate with local engineers and administrators to develop requirements for features needed to support wide adoption of a CMMS tool, and Inform the design of a cloud-enabled open-source CMMS application. The Pilot Project developed a prototype CMMS application using Microsoft Access as a proof of concept to gather feedback from clinical engineers in Ghana. While deploying the prototype to select sites in Northern Ghana, the team worked through the hurdles of printing barcodes, tagging equipment, gathering equipment details, populating the CMMS prototype, and documenting maintenance activities. The lessons learned from this prototype informed the specifications for an open-source web-based application. An international team of Clinical Engineers included members based in Ghana, USA, and Canada, defined the features and requirements for the first release of the open-source CMMS project to address the limitations and lessons learnt from the Pilot Project prototype. The architecture and design of the open-source CMMS was influenced by the user requirements and guiding development principles: 1. Open-Source-At-Heart- to eliminate any financial burden for use; every aspect of the software development must use license free tools and applications; 2. Ease of Access- users can access and add to the asset inventory on a mobile device while on-location; 3. Simplified Development Framework- decrease the learning curve required to contribute to the project to encourage local participation, and; 4. Low-Resourced Deployment- the server application is able to be installed on limited IT hardware. Currently, a prototype with limited functionality such as the ability to create and view equipment information has been deployed on a web server. When fully implemented the open-source CMMS is expected to positively impact healthcare technology management in resource constrained countries. Healthcare institutions can enroll to access the CMMS with minimal or no financial commitments. Engineers at these sites have the flexibility to access inventory data and create new assets from any device with internet access. As the inventory data is stored centrally, administrators can generate reports based on assets from single or multiple sites.

Advances in Home Care Technology: Implications for Clinical Engineering

By Jorge Alarcon; Claudio Meirovich

Meirovich Consulting, Spain

Description: In recent years, the use of technology in the field of home healthcare has experienced significant growth. Technologies such as telemedicine and remote patient monitoring have shown positive impact in improving healthcare delivery and enhancing patients' quality of life. The increasing demand for home-based healthcare and the need to reduce costs associated with hospital care have driven the development and implementation of innovative technological solutions for home care.In this context, clinical engineering plays a crucial role in ensuring the integration and optimal functioning of these technologies in domestic settings. This paper focuses on exploring recent advances in home care technology and the fundamental role of clinical engineering in their successful implementation. Results: We will examine various technologies used in home care, including telemedicine, remote monitoring devices, emergency response systems, and medication administration devices, among others. Additionally, we will analyse the technical and operational challenges associated with the implementation of these technologies, such as interoperability, data security, and remote technical support. Furthermore, we will address the benefits and implications for patients, healthcare providers, and healthcare systems at large. We will discuss how these technologies can improve access to healthcare, promote self-management of health, reduce unnecessary hospital visits, and optimize the efficiency of home healthcare services. Ultimately, this study highlights the importance of clinical engineering in the development, implementation, and maintenance of technological solutions for home care. Key strategies to ensure safety, reliability, and effectiveness of these technologies will be explored, as well as future challenges and opportunities in this rapidly evolving field.

Implementation and Streamlining of the Medical Equipment Inventorying Process

By Aris Dermitzakis; Spilios Zisimopoulos; Nicolas Pallikarakis

Institute of Biomedical Technology (INBIT), Patras, Greece

Description: Modern medicine is highly dependent on healthcare technology. Hence, the efficient management of medical equipment (ME) is crucial for healthcare institutions in delivering high-quality patient care. The existence and maintenance of an accurate inventory is the cornerstone of any ME management system, (MEMS, also called CMMS) that is essential for the efficient management safe use of medical technology. The inventory provides a real-time clear image of the available equipment, facilitates strategic planning of new acquisitions, and is the basis of a hospital vigilance system, allowing easy localization of ME involved in adverse events and subjected to recalls. On the contrary, the lack of a systematic inventorying process can lead to inefficiencies, increased costs, and compromised patient safety. This work presents an overview of a ME inventorying process, its specifications regarding the information content, the general steps and procedures followed in creating and maintaining it, as well as the positive outcomes it brings to healthcare facilities. Results:The ME inventorying process is based on a thorough registration encompassing all ME across various departments and clinical areas. The procedure is performed by experienced biomedical engineers, on a room-by-room basis. Communication between the inventory team and the hospital staff is of paramount importance for the success of this phase. This onsite registry concerns data such as serial number, manufacturer, model, area of installation, functional state, acquisition method etc., as well as a photographic archive. Equipment labeling/tagging (i.e. QR - numerical code) is used to assure accurate identification and tracking of each device and its uniqueness in the database. At a second stage data accuracy is checked and each equipment is assigned to a medical device group according to a proper nomenclature and codifications system. The more well-known international systems are: the UMDNS, the GMDN and the more recent EU EMDN, based on the Italian CND. Appropriate mapping and cross reference between these systems is essential and WHO is working to resolve this critical issue. Continuous updates of the inventory are crucial to ensure data integrity. This includes implementing a strict process for adding new ME and tracking equipment movement within the facility, such as transfers, disposals, or replacements. Additionally, the accuracy of the inventory data can be assured with the use of catalogue fields instead of free text, the use of photographic archives and conducting periodic physical audits. Implementing a streamlined ME inventorying process yields numerous benefits to healthcare institutions. First and foremost, it provides an accurate picture of the available equipment, enables better financial planning, optimization of resource allocation, identification of areas requiring additional resources and in general allows informed decision-making regarding new equipment acquisition, replacement, or withdrawals. It is also the main prerequisite of any centralized database and ME management system, like the commercially available web-Praxis (https://www.web-praxis.gr/web/en/), developed by INBIT. Conclusions:A ME inventory is critical for every healthcare facility. By establishing a streamlined approach, healthcare institutions can enhance operational efficiency and optimize resource allocation. The benefits of an efficient inventorying process may positively impact productivity, financial planning, regulatory compliance, and ultimately patient care.

The Unsung Heroes-Role of Clinical Engineers in Ensuring Positive Patient Outcome Especially During COVID19 Pandemic

By Martin Manzi

Rwanda Association of Biomedical Engineering, Rwanda

Discussion: On March 16th, 2020, Rwanda was hit with the 1st case of the c19 pandemic. The world was in crisis, and Rwanda was not alone in feeling panicked. Fortunately, men and women from private and public institutions were called to support the GoR efforts.The Medical Technology Division of Rwanda Biomedical Center was called to provide technical support starting in January 2020 for preparedness. Planning for potential quarantine, isolation and treatment centres, establishing a preliminary list of needs in terms of medical and non-medical equipment and materials ranging from beds, bedsheets, bedside cabinets, hygiene products, to required PPEs and IPC materials, to medical devices needed to diagnose and treat positive cases. 26 oxygen PSA plants were procured and installed in the efforts to cater for respiratory care needs that were generated by c19 needs. The task to plan, acquire, manage and implement the c19 response activities was herculean, and the existing technical team was improved by numbers of experts that came to support from different government institutions, iNGOs, local NGOs and private companies. Results:The Rwanda Association of Medical Engineers provided over 30 Biomedical Technicians who joined the team and supported the efforts. Among them were 17 women, with 4 of them delivering during their volunteership at one the major C19 treatment centre in Kigali. Overall, over at least 39 quarantine sites were set up across the country, 56 isolation rooms were renovated and equipped in all hospitals, 5 major treatment centres were renovated, acquired (field hospital), and established, 26 medical oxygen PSA plants procured and installed, 10 existing PSA plants were renovated, oxygen piping systems were installed in all public hospitals (56), over 6000 standard beds as well as 550 ICU beds were procured and distributed in public hospitals, oxygen cylinder, oxygen concentrators, thousands oxygen accessories and consumables, and more. Capacity building was conducted for clinical staff in terms of safe utilization of oxygen equipment, biomedical technicians' skills were upgraded in terms of oxygen systems management from production, distribution and delivery to patients. Conclusions: Biomedical engineering or clinical engineering is a vibrant and rapidly expanding field in both content and opportunity. As technological infrastructure expands and fundamental knowledge in the life sciences reaches the basic molecular level, biomedical engineers continue to make major advances. But there is a major divide between the clinical providers and clinical engineers: Indeed, clinical engineers have been seen as technical support for several years, so much that there is a growing need to advocate and ensure that both contribution to the lives saved is highlighted. Covid19 pandemic showed the need for collaboration, and the importance of having a knowledgeable technician in our hospitals. Most healthcare facility settings in the world do not have a proper clinical engineering departments, but with the increased healthcare technologies including robotics and Artificial Intelligence, engineers are becoming more and more relevant to ensure smooth, quality and safe operations in healthcare facilities.

Reinventing clinical engineering education in the face of uncertainty

By Noel Camilo Castro; Vicente Zuccaro; Ricardo Silva

Universidad Simon Bolivar, Venezuela

Description: The Bolivarian Republic of Venezuela has experienced significant waves of emigration in recent years, leading to a large-scale exodus of its population. Macrotrends data reveals that the current net migration rate for Venezuela in 2023 is 10.853 per 1000 population, resulting in approximately 7 million inhabitants fleeing the country since 2015, which accounts for more than 20% of its total population. This mass emigration has had a profound impact on Venezuela, particularly in the field of academia, where the loss of highly skilled professionals, including university professors, has severely handicapped the academic system. Before 2015, several academic institutions in Venezuela had robust bioengineering programs, producing biomedical engineering technicians (BMET), biomedical engineers (BME), and clinical engineers (CE). Institutions such as the Universidad Nacional Experimental del Tachira (UNET), Universidad Experimental Politécnica Antonio José de Sucre (UNEXPO), Universidad de los Andes (ULA), Universidad de Carabobo (UC), Universidad Nacional Experimental Francisco de Miranda (UNEFM), and Universidad Simon Bolivar (USB) were known for their contributions in the field. Results:However, in the wake of the emigration crisis, only UNEFM and USB are currently partially active in the field. UNEFM has emerged as the primary provider of BMET and BME programs, while USB offers a master's programs in clinical and biomedical engineering (MCE and MBE). Both institutions have been compelled to transition to virtual or hybrid modalities due to the challenging circumstances. The recent offering of the MCE program at USB saw a limited enrollment of only 15 students, some of whom were located abroad alongside a portion of the faculty. To facilitate payments from students and faculty, USB, through its Foundation for Research and Development (FUNINDES), established an international account. While the program demonstrated promising outcomes, many students were unable to complete the curriculum due to various constraints. Furthermore, since the program is a full academic endeavor, these students were unable to obtain any degree upon their

departure. In response to this situation, USB is currently working on restructuring the MCE program by adopting a different approach. The program will be transformed into a series of stackable certificate programs, where at the end of each term, students will receive certificates for the credits earned. Upon successful completion of all the certificates and the graduate research, students will be accredited with the MCE degree. This innovative approach represents a bold move for academia, allowing institutions to adapt and survive in the face of uncertainty. Conclusions: The mass emigration from Venezuela has had a profound impact on the country's academic landscape, leading to the loss of top professionals and significantly affecting bioengineering programs. USB and UNEFM are among the few remaining institutions offering relevant programs, albeit in modified formats to accommodate the challenges posed by the emigration crisis. USB's initiative to promote the MCE program through stackable certificates showcases their resilience and determination to continue providing education and training opportunities despite the uncertain circumstances.

Network Building for Biomedical and Clinical Engineers in Africa

By Elisha Sanoussi

Global Alliance for Clinical Engineering Intern, USA; Biomedical Engineering Graduate Student, Niger

Healthcare Needs Assessment in Multi-lingual sub-Saharan Africa. The sharing of knowledge and information regarding healthcare technology management across the continent of Africa seems to be an ever-present need. Many of the access, maintenance, and regulatory issues concerning medical devices in the continent's clinical settings prove to be similar, which begs for further collaboration across national and regional societies. The main official languages through which such collaboration occurs are French and English. Current Biomedical Engineers (BME) and Clinical Engineers (CE) in Africa have received their training in one of these languages. Results: As a result, the dilemma of sharing information in a language other than one's official language makes it difficult to receive useful information for addressing technological needs. It is understood, for example, that there is high effectiveness in French-speaking (francophone) organization's ability to provide relevant health evaluations and solutions in francophone countries. A vital part in the role of a BME/CE is to produce qualitative and quantitative data of a healthcare professional's needs in their respective clinical settings to provide the proper technological solutions. However, there is a challenge when conducting healthcare needs assessments with clinicians working in sub-Saharan countries where the official language is not their professional training language. In other words, a francophone healthcare tech organization may have difficulty performing a proper needs assessment with English-speaking clinicians working in francophone Africa. Thus, it is critical that all African countries and their national societies increase efforts to increase the accuracy of healthcare needs assessment in countries where their formal language is minimally represented. In summer 2023, the Global Clinical Engineering Alliance (GCEA) adopted the use of a built-in software in Zoom that provides simultaneous translation functionality. This simple, yet effective software provides a virtual solution that could be effective in assisting medical professionals and BMEs/CEs performing health needs assessments regardless of the country's formal language. Like most software, it can be inferred that an increased use of this technology will increase its preciseness. Another effective solution is for national biomedical societies to increase internship roles for young and aspiring health professionals who have bilingual or multi-lingual fluency in Africa's formal languages. There is high value in developing their cross-cultural networking skills, but more importantly their knowledge of healthcare needs. Promoting the need for linguistic abilities is critical for building a strong African network of BME and CE organizations.

Biomedical/Clinical Engineering & Health Technology Management Profession: The Nigeria Perspective

By Bukola Esan

Former Head, CE-HTM Programme Federal Ministry of Health, Abuja, Nigeria

Description: From Year 2002, the biomedical/clinical engineering and health technology management (CEHTM) profession had begun to gain prominence in Nigeria; at which time, the government of the Federal Republic of Nigeria first approved the '' Modernisation and Reequipping of Eight (8) Federal Teaching Hospitals. The contract was awarded on a turn-key basis with direct procurement to the CPL Medical Group, together with its technical partner, VAMED Engineering GmBH & Co of Vienna, Austria. Prior to the above, the situation of medical devices was in a state of disrepair, dilapidated and weak healthcare infrastructure, hence inadequate delivery of health service in Nigeria. Results: The goals of the project is to improve access to save and quality health service to all Nigerians by providing state-of-the-art- medical equipment. The ongoing project has been an eye opener indicating the greater relevance of medical devices in the contemporary healthcare

system in Nigeria. As at today, several training institutions (including technical colleges, monotechnics/polytechnics and universities) had sprung up delivering teaching, research and service in the field of biomedical/clinical engineering and health technology management in Nigeria in line with global best practices. Presently, the country had continued producing critical mass of biomedical equipment technicians (BMETs) and clinical engineers (CEs) with approved schemes of service for their enhanced career progression gaining recognition both within the public and private healthcare service in Nigeria.

Health Technology Supports and Informs Health Equity: A Case for Leveraging a Critical Lens to Health Data, Analytics and AI Ethics

By Amanda Fronk, MHSA; Jennifer DeFrancesco Oyler, DHA, FACHE

Cincinnati Children's Hospital Medical Center; Dayton VA Medical Center, USA

Description: This presentation will discuss how health technology management professionals impact health equity. The ethical collection, management and analysis of various healthcare data could be leveraged to further health equity, but organizations often struggle to extrapolate this to their population which leads to potential health disparities. The reasons for this are multi-faceted, but a key challenge is that organizations unknowingly make implicit value judgements that ultimately lead to variation in interpretation and decision-making. Machine learning and artificial intelligence transparency and opacity will also be discussed via the lens of supporting health technology management professionals with tools to support health equity within their organization. Goals:
•Understand Health Equity and Social Determinants of Health through the lens of the WHO SDGs.
•Discuss data collection, management and analysis potential short-falls.
•Case Study- Electronic Health Record Race Designation
•Discuss implicit value judgements in measuring disparities.
•Discuss machine learning and artificial intelligence transparency and opacity and potential ethical implications of implementing or not implementing in the healthcare environment.
•Explore learning for healthcare technology management professionals to help support their organization's health equity goals.
Results: Authors will share data related to health disparities from peer reviewed sources.

Still "Swinging" After All These Years…Working Together For a Common Goal

By Eric Rosow

CEO, Conduce Health New York, NY, USA

Description: As a longtime oarsman, rowing coach and entrepreneur, I've always considered the sport of rowing to be a metaphor for life. Whether building a company or rowing a race, the core principles of teamwork, strategy, commitment, trust, empowerment, balance and execution are essential attributes to successful outcomes and achieving a team's mission. This past fall, I competed in my 25th Head of the Charles Regatta, which is the largest 2-day regatta in the world, with 11,000 athletes rowing in over 1,900 boats in 61 events. This year's event was extra special in that it marked the first time in 31 years, that our 1987 Pan Am gold medal lightweight 4- came back together to once again race as a crew. Preparing for this race, reuniting with my fellow oarsmen and reflecting on this wonderful sport, inspired me to write a somewhat personal blog and reflection on the many similarities between crew and new venture creation. Results:In the world of rowing, there is a term called "swing". Swing is an elusive feeling of near-perfection and synchrony among a crew. It is a state in which all rowers in a boat are in a "symphony of motion" and there is no wasted energy. It's not how hard you work, it's how hard you work together.A rowing team – and a successful business – need more than a vision, mission, resources and talented people. They need those team members in the right seats, working together and doing the jobs they're most suited to do. If we apply this analogy to an eight-oared shell, we can correlate the specific roles of each seat in a shell as follows: 1. The Coxswain: This position can be analogous to the CEO, the leadership team and/or the board. The key elements of this position are to set strategy, "steer the boat" and clearly communicate tactics to the team. 2. The Stern Pair (the "Stroke" and the "7-Seat"): This combination needs to be both competitive and highly skilled. These positions set the pace for success, anticipate timing, respond to external conditions and provide an example for the rest of the team. 3. The Engine Room" (seats 6 through 3): The middle of the boat is referred to as "the engine room". It consists of the strong, dependable, and focused team members who provide the core power, products and services that drive the business's success. 4.The "Bow Pair" (seats 2 and 1): Seats One and Two are referred to as the Bow Pair. They are responsible for the boat's "set" and stability. Conclusions: Finding Swing…In order to create swing, everyone must work together to balance the boat and have exact timing.

Your hands must be at exactly the right height as you slide up to the catch. Each oar has to drop into the water at the exact same time. Everyone needs to pull with equal pressure. All the blades need to come out of the water and release in unison. Any deviation disrupts and slows the boat. This is a great model for how members of Clinical Engineering Departments, members of national and global CE societies can best work together as teams with each individual with different skill sets finding their best way to participate.

Capitalization Development Guidance in the Laos Health System

By Peter Heimann

Luxembourg Development Cooperation Agency (LuxDev) Vientiane, Laos (Lao PDR)

Description: Laos is committed to attaining universal health coverage (UHC) by 2025 as stated in the 8th National Socio-economic Development Plan. Within the current context, the Laos Health Sector Reform (HSR) Framework recognizes that inadequate domestic resources are allocated to health to achieve targets and outcomes associated with UHC.Over the past three decades, Laos has struggled to achieve health financing and service delivery outputs and has required significant support from development partners. Traditionally, most support from development partners has been "off-budget", meaning expenditure not funded through the government. This financing arrangement engendered a culture of siloed support and donor contributions to Laos without more sophisticated consideration for necessary governance and finance arrangements which would encourage the Laos to achieve stated HSR. Results:Framework goals. Given these experiences of the past decade, the evolving challenge and question to be addressed for Luxembourg and other development partners is: How should Luxembourg and other development partners engage with the Lao MoH so that the Government responsibly finances, governs, and supervises the delivery of quality RMNCH services to the Lao population while maximizing the efficient use of government and donor financing? LuxDev intervention of the Joint Participatory Mechanism (JPM) aims to build upon successes of the past and current support programmes in health while further targeting support of key public administration reform initiatives related to stewardship and governance, finance, and monitoring and oversight while delivering maternal, new-born and child health services. Supported by the JPM National Council (JPMNC) and the JPM Secretariat (JPMS), the JPM serves as a mechanism to disperse "multiplier funds" provided by Luxembourg to the three target provinces from a central level account to jointly-cover the costs of delivering reproductive, maternal, new-born, and child health (RMNCH) services and activities. Under the JPM, Provincial Health Authorities plan and budget RMNCH activities under the guidance of MoH priorities and within the context of the Laos Health Sector Reform. Funding is directed at operational costs only. The intent is to maximize the allocation and efficiency of donor and Government financing for RMNCH and to align donor support with the Government budget planning and execution process each year. For four consecutive years, all Luxembourg target provinces achieved the JPM milestone triggers including submitting a concept note and letter of intent, delivering a full JPM technical and costed proposal, and government funds deposited into the provincial JPM imprest account. The conditions which were set to provide the institutional, legal, economic, and environmental framework required for successful implementation of the JPM include trust, engagement and diplomacy, foundational agreements and decrees, the application of the multiplier financing model, stewardship of the JPMNC, and supervision by the JPMS. These achievements lay the groundwork for further expansion and application of the JPM, moving steps closer to "on-budget" support in the health sector. In future, the JPM could potentially be advanced to address more complex investments related to infrastructure and equipment, actioning engagement with other donors into the JPM mechanism, and application of the JPM to the Teaching Complex concept.

Pandemic Solutions in the Fight against COVID-19 in Thailand

By Dr. Wongwit Senavongse

Thai Biomedical Engineering Association and Instrumentation, BME accreditation for Council of Engineers of Thailand

Description: As the COVID-19 pandemic swept across the globe since early 2020, Thailand faced significant challenges in its healthcare system. This report aims to outline the background, goals, benefits to patients, results, and concluding remarks of the pandemic solutions applied in Thailand during this critical period. Key challenges included the scarcity of traditional medical devices, limited training in dealing with such an infectious disease, ensuring access to medical oxygen for severe cases, enhancing diagnostic capabilities, integrating digital tools for data management, and providing adequate personnel protection to safeguard healthcare workers. Goals and Benefits of this Study: Resource Optimization;Enhanced Training;-Improved Diagnostics;Personnel Protection.

Patients and healthcare workers on the front lines benefited from these pandemic solutions. Results: The efforts and implementation of the pandemic solutions yielded significant results in Thailand: 1. Decreased Transmission Rate: The strict implementation of infection control measures led to a decline in the rate of COVID-19 transmission.2. Enhanced Patient Outcomes: With improved training and resource optimization, patient outcomes showed positive trends, with better recovery rates and reduced hospital stays.3. Efficient Diagnostics: The integration of digital tools with diagnostic systems improved testing capacities, leading to faster and more accurate results. 4. Healthcare Infrastructure Resilience: The experience gained during the pandemic resulted in a more robust healthcare system prepared to handle future challenges effectively.

AI to Enable Clinical Engineering (CE) Global Equipment Support: Proposal for the Development of a Domain Specific Large Language Model (DSLLM) via ChatGPT

By Fred Hosea, Ph.D.; Ricardo Silva, Ph.D.

Global Clinical Engineering Digital Health Professors & Experts, Ecuador

Rationale:In the realm of medical technology and healthcare, a Domain Specific Large Language Model (DSLLM) – aka ChatCPT - tailored to the field of Clinical Engineering holds the promise of transforming how medical equipment is managed, troubleshot, maintained, and repaired. Unlike generalized language models, a DSLLM is designed to offer highly accurate and specialized solutions within a specific domain. The aim of this proposal is to seek partners and funding to develop and implement a DSLLM specifically for Clinical Engineering. Methodology:The DSLLM development methodology involves extensive training with domain-specific data. This data serves as the foundation to immerse the model in the intricacies and knowledge peculiar to the clinical engineering sector. Two strategies exist: fine-tuning a pre-trained LLM with domain-specific data or building a new LLM from scratch using this data. The former approach, despite its specialization, retains the advantage of quicker convergence and often superior performance. Addressing LMIC Challenges:Clinical engineers in Low and Middle-Income Countries (LMICs) face significant challenges in managing medical equipment due to limited resources, training, and access to expert knowledge. A DSLLM for Clinical Engineering could provide a multitude of benefits: 1. Accessibility to Expert Knowledge: The DSLLM can be accessed from anywhere with an internet connection, providing clinical engineers in remote areas access to a repository of medical device information. 2. Cost-Efficiency: DSLLM serves as a cost-effective alternative to expensive textbooks, manuals, or training resources. 3. Real-time Troubleshooting Assistance: Clinical engineers can use the DSLLM for quick solutions in the event of device malfunctions. 4. Training and Skill Development: DSLLM can act as a training tool for budding clinical engineers to practice problem-solving and learn about various devices. 5. Standardization of Knowledge: DSLLM ensures standardized, accurate, and updated information is accessible to everyone. 6. Multilingual Support: DSLLM can break language barriers by offering information in local languages.7. Supplemental Tutorials: Clinical engineers can receive step-by-step procedures for device maintenance and repairs. Challenges and Mitigation: 1. Data Challenges: Obtaining medical device-specific literature requires agreements with manufacturers, ensuring data integrity, privacy, and protection through anonymization measures.; 2. Technical Challenges: Addressing architecture, training, assessment, and validation necessitates specialized knowledge in machine learning and natural language processing. 3. Ethical Challenges: Robust content moderation mechanisms are crucial to prevent biases and inappropriate content generated by DSLLM.4. Resource Challenges: The project requires substantial computational resources, specialized skills in machine learning, NLP, and software engineering.5.Implementation Challenges: Successful implementation requires training for clinical engineers and integration with local resources. Conclusions: Developing a DSLLM for Clinical Engineering holds tremendous potential to revolutionize medical equipment management in LMICs. With the right partnerships, funding, and a strategic approach, we can create a tool that empowers clinical engineers, enhances healthcare delivery, and contributes to bridging the knowledge gap in medical technology across the globe. This initiative aligns with the mission of leveraging advanced technology for the betterment of healthcare and medical equipment management.

A Definitive Framework for the Effective Implementation of Health Technology Management

By Hemanth kumar Revalli

Biontrics MedTech(OPC) PVT Ltd, India

Health Technology implementation is the key to effective healthcare delivery and outcomes for every healthcare provider across the globe to optimize patient care and services through the focus on the selection, implementation, and management

of medical technology. Effective HTM implementation requires a high level of organizational commitment and involvement across the healthcare organizational structure. Effective Implementation requires a systematic approach that focuses on the assessment, procurement, maintenance, and training of HTM Professionals This paper presents an overview of the key principles and practices of HTM and highlights the importance of an effective HTM framework to ensure successful implementation of medical technology. The paper discusses the various components of an HTM framework including the challenges encountered during the HTM process, such as budgetary constraints, lack of standardization, and inadequate training. Additionally, the paper outlines the benefits of an effective HTM framework including improved quality of care, increased patient satisfaction, and reduced healthcare costs. A Definite framework for the Implementation of HTM consists of as following: 1. WHO'S HTM Framework. 2. The clinical Engineering Framework 3. IT services management Framework 4. The Healthcare Delivery Framework 5. Quality Systems Management Framework 6. Baldrige Performance Excellence Framework. The implementation of a suitable HTM framework can also foster innovation and drive progress, leading to better healthcare outcomes. In conclusion, an effective HTM framework is essential to optimize the use of medical technology for improved patient care and cost-effective healthcare delivery. Effective implementation requires a systematic approach that focuses on the assessment, procurement, maintenance, and training of healthcare technologies and professionals.

A Paradigm for Risk Management of Medical Laboratory Equipment

By Neven Saleh

Biomedical Engineering Dept., Higher Institute of Engineering, El-Shorouk Academy, Egypt

One important tool for diagnosing a patient in healthcare institutions is medical laboratory equipment (MLE). Since clinical laboratory testing is essential for making medical choices, it must be dependable and precise. In the study, a method for lowering the risks connected to the management of MLE is presented. Failure Mode and Effects Analysis, or FMEA, was the methodology's cornerstone. To address the limitations of conventional FMEA, a technique called TOPSIS (Technique for Order of Preference by Similarity to Ideal Solution) was implemented. A risk priority number (RPN) was given to each MLE component under evaluation to indicate the level of risk. By using the RPN values that were acquired, maintenance tasks may be prioritized and equipment performance can be enhanced. Goals: (1) Reduce risks associated with poor management of medical laboratory equipment. (2) Maximize the use of medical laboratory equipment. Users: Healthcare providers. Clinical engineers. Results: This work has been applied to real laboratory data from 15 different hospitals in Egypt utilizing a data set of 150 MLE, taking the haematology analyzer, the chemistry analyzer, and the centrifuge into consideration. New RPN values were obtained to rank the MLE risk by employing the TOPSIS approach. In comparison to the conventional FMEA, the TOPSIS technique has been validated for its robustness in prioritizing the risk value of MLE. In order to decide on the best incoming maintenance and scrapping procedures, a prioritized list of MLE was established.

Empowering Excellence: A Comprehensive Overview of the Competency Program for Medical Device Management in Healthcare Delivery Organizations

By Thangavelu Sasikala

Policy, Code & Standard Division, Medical Device Authority, Malaysia

This article provides a comprehensive outline of the Competency Program developed for technical personnel engaged in the installation, commissioning, testing and maintenance of medical devices within Healthcare Delivery Organizations. The program furnishes insights into the competency framework, encompassing four main categories of medical devices, along with corresponding proficiency levels for each device listed in the category and product specialist. Furthermore, it delineates potential career trajectories for biomedical engineers and technologists within the healthcare sector. Additionally, the program extends its reach to non-biomedical engineers aspiring to specialize in the installation, commissioning, testing, maintenance, and disposal of medical devices within Healthcare Delivery Organizations, outlining their career pathways and prerequisites. A notable aspect of the program is the establishment of a special grandparenting initiative, tailored to assess and certify existing technical personnel engaged in medical device management and related activities. The article underscores the meticulous structure of the training regimen, incorporating compulsory modules, medical technology training, assessment and certification, and Continuing Professional Development (CPD) endeavors. The versatility of this competency program enables its seamless integration and customization, aligning with the policies and specific needs of medical device regulatory requirements, Healthcare Delivery Organizations and Health Ministries.

Establishing and Implementing a Comprehensive Medical Device Maintenance Program in Healthcare Institutions: A Focus on MS2058:2018 Standards in Malaysia

By Thangavelu Sasikala, Dzatul Ithri Binti

Policy, Code & Standard Division, Medical Device Authority, Malaysia / Engineering Services Division, Ministry of Health Malaysia

Medical devices play a crucial role as essential components in providing high-quality healthcare services. It is imperative that these devices function effectively, safely, and in accordance with their intended purpose throughout their operational lifespan. Maintenance activities are pivotal in ensuring the continuous and optimal performance of these devices. This challenge is particularly pronounced in healthcare institutions, gaining paramount significance in low to medium-income and developing nations. Thus, this article underscores the imperative of establishing, upholding, and executing a comprehensive medical device maintenance program across all devices within healthcare establishments. The paper delineates the development and implementation of a maintenance management program based on the MS2058:2018 standard and international norms within a healthcare institution operating under the purview of the Ministry of Health, Malaysia.

Role of Clinical Pharmacist in Risk Management of Adverse Drug Events in Healthcare Technology

By N. V. Rama Rao, SK. Baajirahamtulla, K. Ramakrisnareddy, Rama Rao Nadendla

Chalapathi institute of pharmaceutical sciences, India

Adverse drug reactions contribute significantly to the healthcare burden. However, they are largely preventable through appropriate management processes. This review aims to identify quality indicators that should be considered for routine monitoring of processes within hospital ADR management systems. It also examines the potential reasons behind variation in ADR management practices amongst HCPs, and explores possible solutions, to improve both the quality and quantity indicators of ADR management processes. Improving the quality of life of patients is a key concern in public health. In the context of improving therapeutic compliance, quality of life of patients. We conducted this review to support risk minimization actions. ADR risk increases with age-related changes in pharmacokinetics and pharmacodynamics, increasing burden of comorbidity, polypharmacy, inappropriate prescribing and suboptimal monitoring of drugs. ADRs are a preventable cause of harm to patients and an unnecessary waste of healthcare resources. Several ADR risk tools exist but none has sufficient predictive value for clinical practice. Good clinical practice for detecting and predicting ADRs in vulnerable patients includes detailed documentation and regular review of prescribed and over-the-counter medications through standardized medication reconciliation. New medications should be prescribed cautiously with clear therapeutic goals and recognition of the impact a drug can have on multiple organ systems. Prescribers should regularly review medication efficacy and be vigilant for ADRs and their contributory risk level when drugs are no longer efficacious or beneficial or when safer alternatives exist. Inappropriate prescribing and unnecessary polypharmacy should be minimized. As a result, there is now an added focus on safety and risk assessment after a product has received regulatory approval when it is placed on the market and prescribed to large populations. Although there is no international standard that dictates the components of an adequate pharmacovigilance system or the processes to be engaged in risk management, there is a consensus among the major regulators that pharmacovigilance is necessary and important in the development and commercialization of medicinal products. Therefore it is essential in building capacity for clinical trials to understand the components, the functions, and the processes required for full and effective pharmacovigilance and risk management.CONCLUSION: The focus of ADR management in hospitals should be to promote patient safety through comprehensive assessment, risk communication and safe prescribing. There is a need to develop a system to define, measure and monitor the quality of ADR management. With health technology. Educational strategies may help improve the quality of ADR management processes. By using strategies like ADR alert card, making patients adhere to the medication with the help of health technology tools like issuing ADR alert card, voice message systems, short message systems, and continuous follow-up to report ADR and any other complications related to drug or devices to minimize the risk of adverse drug reactions and events so that we can generate a signal to recall the medication affecting the society to recall specific medication to minimize the adverse effects.

Addressing the Biggest Challenge Faced by Biomedical Personnel in East African Health Facilities, Accepting the Status Quo

By Deborah Aloyo

Gould Family Foundation, Uganda

An effective HTM framework is essential to optimize the use of medical technology for improved patient care and cost-effective healthcare delivery. Effective implementation requires a systematic approach that focuses on the assessment, procurement, maintenance, and training of healthcare technologies and professionals. troubleshot, maintained, and repaired. Unlike generalized language models, a DSLLM is designed to offer highly accurate and specialized solutions within a specific domain. The aim of this proposal is to seek partners and funding to develop and implement a DSLLM specifically for Clinical Engineering. Methodology: The DSLLM development methodology involves extensive training with domain-specific data. This data serves as the foundation to immerse the model in the intricacies and knowledge peculiar to the clinical engineering sector. Two strategies exist: fine-tuning a pre-trained LLM with domain-specific data or building a new LLM from scratch using this data. The former approach, despite its specialization, retains the advantage of quicker convergence and often superior performance. Addressing LMIC Challenges: Clinical engineers in Low and Middle-Income Countries (LMICs) face significant challenges in managing medical equipment due to limited resources, training, and access to expert knowledge. A DSLLM for Clinical Engineering could provide a multitude of benefits: 1. Accessibility to Expert Knowledge: The DSLLM can be accessed from anywhere with an internet connection, providing clinical engineers in remote areas access to a repository of medical device information. 2. Cost-Efficiency: DSLLM serves as a cost-effective alternative to expensive textbooks, manuals, or training resources. 3. Real-time Troubleshooting Assistance: Clinical engineers can use the DSLLM for quick solutions in the event of device malfunctions. 4. Training and Skill Development: DSLLM can act as a training tool for budding clinical engineers to practice problem-solving and learn about various devices. 5. Standardization of Knowledge: DSLLM ensures standardized, accurate, and updated information is accessible to everyone. 6. Multilingual Support: DSLLM can break language barriers by offering information in local languages.7. Supplemental Tutorials: Clinical engineers can receive step-by-step procedures for device maintenance and repairs. Challenges and Mitigation: 1. Data Challenges: Obtaining medical device-specific literature requires agreements with manufacturers, ensuring data integrity, privacy, and protection through anonymization measures.; 2. Technical Challenges: Addressing architecture, training, assessment, and validation necessitates specialized knowledge in machine learning and natural language processing. 3. Ethical Challenges: Robust content moderation mechanisms are crucial to prevent biases and inappropriate content generated by DSLLM.4. Resource Challenges: The project requires substantial computational resources, specialized skills in machine learning, NLP, and software engineering.5.Implementation Challenges: Successful implementation requires training for clinical engineers and integration with local resources. Conclusions: Developing a DSLLM for Clinical Engineering holds tremendous potential to revolutionize medical equipment management in LMICs. With the right partnerships, funding, and a strategic approach, we can create a tool that empowers clinical engineers, enhances healthcare delivery, and contributes to bridging the knowledge gap in medical technology across the globe. This initiative aligns with the mission of leveraging advanced technology for the betterment of healthcare and medical equipment management.

Introduction of a new asset management system at Amsterdam UMC

By Kitty Siemerink

Amsterdam UMC, the Netherlands

In Dutch hospitals, the importance of well-managed medical equipment is highly prioritized. Legislation and regulations require that equipment be safe, handled by trained users, and situated in an environment conducive to safe usage. Medical equipment is managed through asset management systems, which register all equipment and plan and execute tasks according to protocols.

In 2023, Amsterdam UMC, an academic hospital, implemented the Ultimo asset management system. This system supports the medical technology department by facilitating equipment management, work request and reporting, equipment lending, purchase requests, contract management, and project management. Implementing a unified asset management system is a crucial step in the merger of two locations within Amsterdam UMC.

In addition to the standard requirements of an asset management system, the hospital had the following objectives:

1. Streamlining the reporting and recording of tasks through a self-service portal and a mobile app.

2. Harmonizing the risk management model for prioritizing maintenance issues
3. Support for contract management, equipment replacement, and cost control/allocation.
4. Simplification of registration by utilizing Eudamed data.
5. Facilitation of decision-making through PowerBI by providing management information.
6. Integration with external applications, including:
- ERP systems of both locations.
- ProtocolManager for automatic generation and linking of service reports.
- DocBuster for automatic linking of service reports from external parties.
- OK-net for equipment localization (an internally developed Track & Trace system).
- ServiceNow for linking assets to the CMDB/IT infrastructure.

By merging to a single system, both medical technology departments at Amsterdam UMC are taking an important step towards merging into a unified department. This allows for unified management of both locations and ensures the safe use of medical technology in a consistent manner. This project served as a catalyst in the merging process of these departments. Additionally, significant progress has been made in efficiently and effectively utilizing, maintaining, and managing the medical equipment inventory.