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3rd ICEHTMC PROCEEDINGS

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INTERNATIONAL
CLINICAL ENGINEERING
AND HEALTH TECHNOLOGY
MANAGEMENT CONGRESS



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associazione
italiana
ingegneri clinici

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Editor's Corner

Dear 3rd ICEHTMC Congress Participants,

On behalf of the organizers and sponsors of the 3rd International Clinical Engineering and Health Technology Management Congress (ICEHTMC) it is our honor to offer this publication that contains all of the accepted abstracts for the oral and poster sessions. With the amazing support from the Scientific Program Committee, consisting of several dozen reviewers from all over the world, all the submissions were subjected to strict peer review and the event has broken all previous CE congresses' records for quality and quantity.

Major recognition must be given to the Italian Clinical Engineers Association (AIIC) and IFMBE/Clinical Engineering Division (CED) for hosting and collaborating on the organization of this event and for engaging early on practitioners around the world to respond to the Call for Papers and vendors to exhibit their ware.

This is also the first time that the Congress's proceedings are published and available in print and on-line (GlobalCE.org). The Global Clinical Engineering Journal's commitment to the promotion and sharing of knowledge is evident by committing to and the timely accomplishment of this major task.

Rome, Italy is a unique location to engage in professional development, networking, meeting friends, enjoy Italian cuisine, and visit historic sites. We wish you success and hope that you will take advantage of all of these opportunities to carrying with you many special life-long memories from Rome.

Ciao a tutti e buon lavoro!

Yadin David

Editor-in-Chief of GlobalCE Journal



Stefano Bergamasco

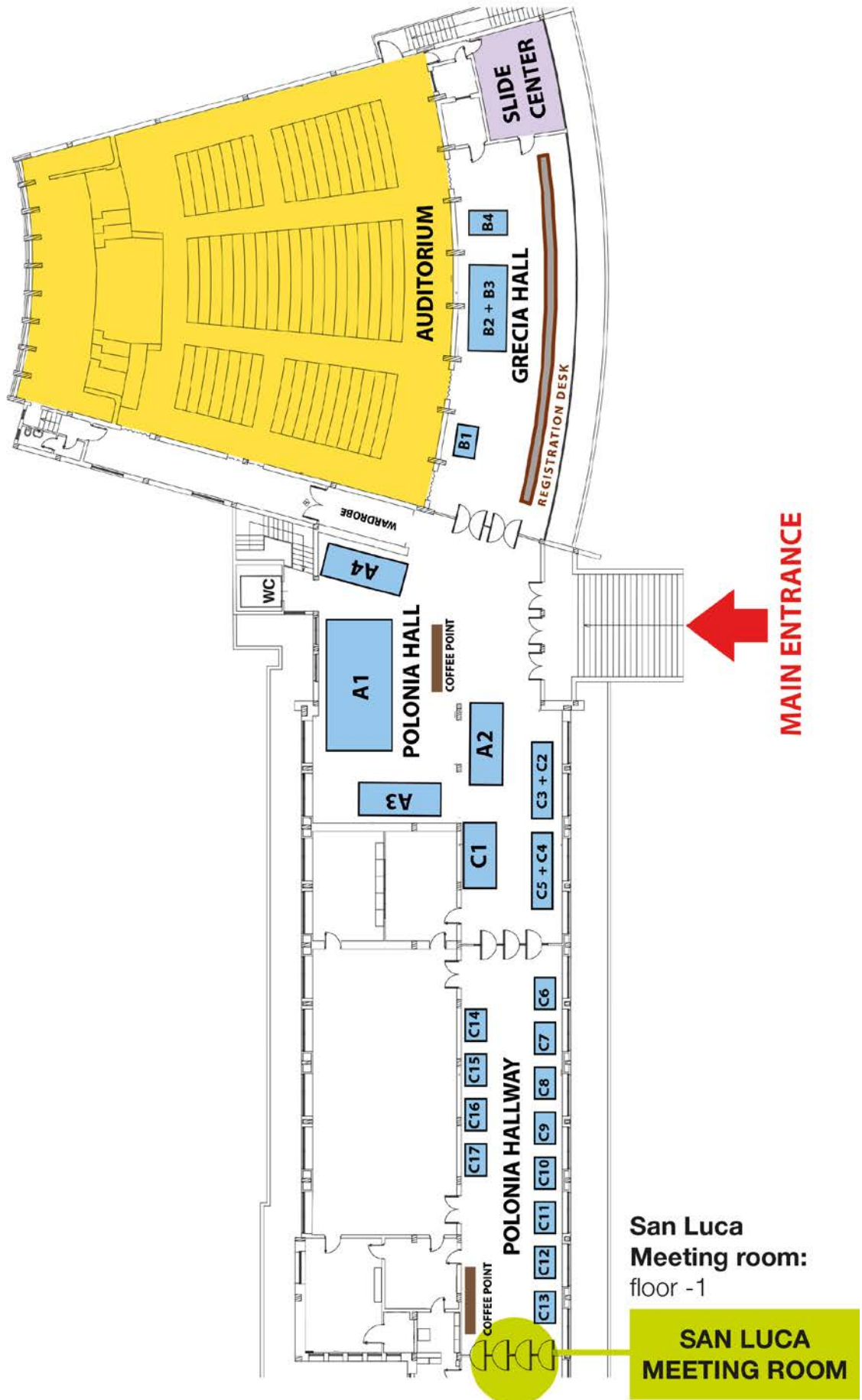
Chair III ICEHTMC



Together we can make it better!

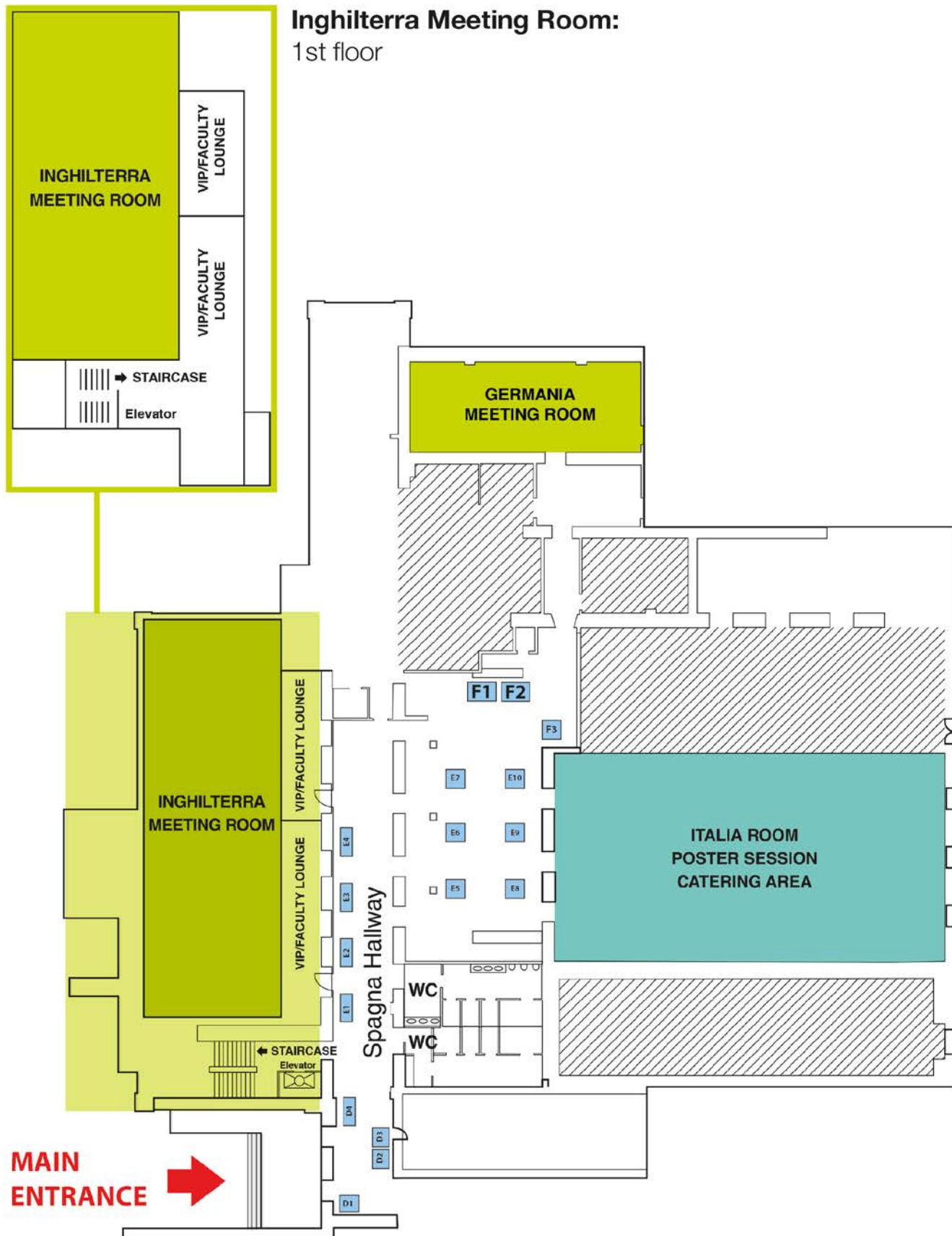
FLOOR PLAN

AUDITORIUM



FLOOR PLAN

CENTRO CONGRESSI



MONDAY, 21ST OCTOBER 2019

	Auditorium	Room Inghilterra	Room San Luca	Room Italia	Room Germania
09:00 10:30	Opening ceremony				
10:30 10:45	Networking and Refreshment Break • Exhibition				
10:45 12:30	Parallel session Medical equipment management in hospitals	Parallel session Artificial Intelligence, Big Data	Parallel session Technologies for home care	Poster sessions & Exhibitions	Workshop IUPESM A
12:30 14:00	Networking and Lunch Exhibition				
14:00 15:50	Plenary session - HTM Medical Equipment Management in Hospitals			Poster sessions & Exhibitions	Workshop IUPESM B
15:50 16:00	Networking and Refreshment Break • Exhibition				
16:00 17:45	Parallel session Health Technology Assessment	Parallel session ICT and medical informatics	Parallel session Health Operations - Project Management	Poster sessions & Exhibitions	Workshop ENProjectMedicali High disinfection devices
17:45 19:15	Plenary session IFMBE Global BME & CE Education status - Education				
20:30 23:00	Social dinner CED HT Challenge awards				

TUESDAY, 22ND OCTOBER 2019

	Auditorium	Room Inghilterra	Room San Luca	Room Italia	Room Germania
08:00 09:00		Breakfast session AAMI 2020 Global Track discussion			Breakfast session Significant Developments in CE-HTM in last 10 years
09:00 10:30	Plenary session and round table Policy				Workshop ERBE High frequency electrosurgery
10:30 10:45	Networking and Refreshment Break • Exhibition				
10:45 12:30	Parallel session Development of innovative devices	Parallel session Global challenges, sustainable development	Parallel session Education, certification, training	Poster sessions & Exhibitions	Luncheon Symposium CISA MD sterilization
12:30 14:00	Networking and Lunch Exhibition				
					Luncheon Workshop ASP MD reprocessing
14:00 15:30	Plenary session and round table - HTA Health Technology Assessment			Poster sessions & Exhibitions	Workshop Althea Managed Equipment Services/PPP
15:30 15:45	Networking and Refreshment Break • Exhibition				
15:45 17:30	Parallel session Design of health facilities - Health Technology Management in hospitals	Parallel session Clinical risk management, safety, emerge. prep	Parallel session International standards and regulations	Poster sessions & Exhibitions	Workshop HIMSS/IHE
17:30 18:30	Closing ceremony				

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01. Health Technology Assessment

PARAMETERS OPTIMAL SELECTION DURING PEDIATRIC 18F-FDG PETCT EXAMINATION

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Objective: Up to now, pediatric 18F-FDG dose and acquisition durations are generally based on coarse extrapolation from adult guidelines. This study sought to determine whether shorter acquisition durations or a lower 18F-FDG injected activity could be used during pediatric 18F-FDG PET/CT examinations while maintaining diagnostic utility. **Methods:** 36 whole-body 18F-FDG PET/CT examinations were performed on 36 patients (weight, 13–89 kg; 46.51 ± 5.63 kg, age range, 3–14 y, 9.22 ± 3.16) with a weight-based injected activity (5.3 MBq/kg [0.144 mCi/kg]), fixed acquisition durations 180 S/FOV, Vip record acquisition mode using Discovery STE. For each examination, the Vip-mode data were truncated to form multiple datasets with shorter acquisition durations down to a minimum of 60 S/FOV (i.e., 60, 80, 100, 120, 140, 160 S/FOV data were formed from single 180 S/FOV acquisition). 168 image volumes were generated, randomized, and reviewed in a masked manner with corresponding CT image volumes by 6 radiologists. Overall, subjective adequacy and objective lesion detection accuracy by body region were evaluated. **Results:** All examinations with maximum acquisition duration were graded as adequate and were used as the reference standard for detection accuracy. For patients more than 30 kg, when acquisition duration was more than 120 S/FOV, all PET/CT examinations was graded as adequate for clinical tasks, whereas, acquisition duration was reduced less than 120 S/FOV, lesion detection became less accurate. For patients less than 30 kg, Lesion detection accuracy was perfect for acquisition times between 140 S/FOV and 180 S/FOV for all regions of the body. However, lesion detection became less accurate when imaging acquisition time was reduced less than 140 S/FOV. **Conclusion:** When GE Discovery STE PET/CT was applied during Pediatric PET/CT examination, Using decreased acquisition times as a surrogate for 18F-FDG dose, 18F-FDG dose can be reduced by approximately 33.33%, when patients larger than 30 kg were scanned for 180 S/FOV, for patients less than 30 kg, 18F-FDG dose can be reduced by approximately 22.22% without a loss of diagnostic utility. Reduction of overall scan time potentially reduces motion artifacts, improves patient comfort, and decreases length of sedation. Alternatively, decreased 18F-FDG dose minimizes radiation risk. Therefore, the HTA report highlights the several benefits related to the making of the new hybrid operating room, proving that the hybrid technique can be integrated in the care offer of the university hospital.

01. Health Technology Assessment

A DECISION-MAKING SUPPORT ALGORITHM FOR ACTIVE IMPLANTABLE MEDICAL DEVICE EVALUATION

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Objectives: The management of active implantable medical devices (AIMD) has been becoming a pivotal topic due to their significant economic value and to the high levels of safety and clinical effectiveness, which AIMDs have to guarantee. Moreover, the scientific literature, does not still offer a standard method supporting decision makers in AIMD evaluation. The aim of this work was to develop a rigorous and reliable decision-making support algorithm for AIMD assessment, including the definition of the evaluation criteria and of the most suitable methods for collecting evidence, in order to evaluate the AIMDs' performances and to finally select the most suitable and patient-specific AIMD model. **Methods:** The pilot study was conducted taking into account only one type of AIMDs' products: Implantable cardiac pacemakers (PM). Firstly, a scientific literature review was carried out together with the analysis of manufacturers' user manuals and data sheets in order to define the evaluation criteria and the performance indicators able to distinguish between different PMs' models. Following the health technology assessment (HTA) approach, a decisional hierarchy structure including all the safety, clinical, economic and organizational PM related aspects was built, in order to classify all the parameters identified within the related domains singled out by the EunetHTA Core Model. After that, a decision-support algorithm was developed and designed through a flow-chart, which included a number of questions not only on patient clinical information but also on safety, effectiveness and other PMs' parameters, supporting and guiding decision-making process. **Results & Conclusions:** The assessment process supported by the algorithm based tool, resulted to be a helpful instrument in selecting the most suitable patient-specific model. At the end of the process, only a limited number of technical specifications were considered. The "perfect" PM containing all together the most appropriate technical characteristics does not seem to exist on the market. For this reason, the integration of the HTA process within the multi-criteria decision analysis represents a clear and reliable solution. A weight and a performance score will be associated to each technical characteristic previously defined and the PM model resulting with the highest performances' score will represent the one that includes the highest number of specifications reflecting the most suitable PM for the specific case.

01. Health Technology Assessment

IMPLEMENTING ELECTRONIC HEALTH RECORD IN A CHILDREN'S HOSPITAL: A HTA PROCESS

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Introduction: The adoption of electronic health record (EHR), which contain large volumes of aggregated longitudinal clinical data, guarantees substantial benefits. Its implementation seems to lead to significant improvements in the quality of care and in safety issues as well as to a drop in the number of clinical related risks. However, it is also associated with significant costs and large technical and organizational impacts. For these reasons, it is important to conduct a comprehensive evaluation of health care delivery outcomes. The purpose of the study is to gather evidence on safety and overall effectiveness of EHR implementation at Bambino Gesù Children's Hospital.

Methods: Decision-oriented HTA method was applied to assess the technology on clinical, technical, organizational, economic, legal, ethical and safety domains. It is a new implementation of the EunetHTA CoreModel integrated with the Analytic Hierarchy Process. It allows defining an evaluation structure represented by a hierarchical decision tree filled by indicators of technology's performances, to each of which was attributed a weight proportional to the impact that this criterion provides to achieve the purpose of the decision problem. Finally, the alternatives' ranking was defined. A subgroup of these indicators has been included in a checklist form for the evaluation of six EHR implementation projects. This checklist was used as a tool by each involved professional during demo sessions.

Results: The assessment took into consideration all the recommendations about the benefits and drawbacks of HER implementation. In particular, EHR seems to offer many benefits in terms of safety and clinical effectiveness improving the continuity and the quality of care and increasing the accessibility of clinical data. Its implementation resulted in significant organizational outcomes such as EHR configuration, learning curve and training. Usability was the main technical characteristics of the technology taken into account. Finally, legal aspects on privacy and data security assumed a key role.

Conclusions: A detailed technology's evaluation has permitted hospital's decision-makers to knowingly assess its introduction in the hospital.

01. Health Technology Assessment

PROJECT AND DEVELOPMENT OF THE NEW HYBRID OPERATING ROOM OF THE FEDERICO II UNIVERSITY HOSPITAL ACCORDING TO HOSPITAL-BASED HTA TECHNIQUES

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Despite of big progresses obtained in diagnostic and therapeutic fields, the cardiovascular diseases are the first death cause in the industrialized countries. The significant increase of the average life in the next years will give origin to an older population, unavoidably composed by a large number of cardiac patients affected by more complex diseases. The hybrid surgery technique develops in this context. This surgery technique allows the execution of interventions which put together the traditional surgery technique and the endovascular technique, increasing the complexity of interventions but at the same time reducing the invasivity for patients. A new hybrid operating room must be installed to allow this kind of interventions. This operating room is a multifunctional room which assumes at the same time the function of a catheterization laboratory and of a conventional operating room.

The project consists in providing a technology assessment report on the cardiovascular hybrid operating room, written through the Health Technology Assessment (HTA) approach. Within the study of feasibility of the making of the hybrid room of the Federico II University Hospital, the assessment report provides to decision makers useful information, important for decisional processes, to establish if the making of the new hybrid room is appropriate and sustainable.

From the analysis several advantages are emerged by the making of a hybrid operating room, which can be used by different kind of medical doctors of the surgical specialties of Cardiology, Cardio surgery and Vascular Surgery. Obviously, all these benefits require a big and important economic investment. The technology assessment proved that the hybrid technology brings a reduction of time of fluoroscopy and of surgery time. This reduction of times bring to an economic saving in doing interventions in hybrid operating room. Doing the activity plane of the hybrid operating room, the costs for structural modifications and for the leasing of electromedical devices can be covered.

Therefore, the HTA report highlights the several benefits related to the making of the new hybrid operating room, proving that the hybrid technique can be integrated in the care offer of the university hospital.

01. Health Technology Assessment

COST-BENEFIT ANALYSIS OF RESPIRATORY HUMIDIFIERS RENTAL IN A SECONDARY CARE PRIVATE HOSPITAL OF MEXICO CITY

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The cost-benefit analysis presented in this work was carried out in a secondary care private Hospital with 77 beds located in Mexico City. The Hospital offers the Respiratory Medicine Service (RMS) where techniques and procedures are applied for the management of respiratory diseases that contribute to the strengthening and restoration of pulmonary function, using respiratory humidifiers for the administration of inhaled humidified medicines. The RMS treats adult, pediatric and neonatal patients, as well as hospitalized and outpatients. Currently the RMS has seven humidifiers that are property of the Hospital but they are only used with mechanical ventilators. This means that there is no equipment available for caring patients who only require respiratory therapy. That is why the Hospital must rent the necessary humidifiers in order to meet these patients demand.

The objective of this work was to make a cost-benefit analysis of the respiratory humidifiers by calculating the profitability for three acquisition modalities: rental, purchase and comodato. Rent, consists of paying for the temporary use of the equipment during a defined period. Purchase, consists of paying the cost of the equipment so that it is property of the Hospital. In this modality it is necessary to consider operational costs such as accessories, consumables and maintenance for the operation of the equipment throughout its useful life. Comodato, is that the company provide the medical equipment with the requirement to buy a fixed amount of consumables and /or accessories, defined by the company. These three cost-benefit analysis considered the demand of patients who required these medical devices in 2016 and 2017. On the other hand, another cost-benefit analysis was made due to the non-effective use of the humidifiers. It is the hypothetical case that the Hospital purchases these devices and does not have the patient demand to use them all. The income that the Hospital would not receive due to this cause was calculated.

The results of this study showed that the most convenient modality of acquisition for the Hospital is to buy the humidifiers. This acquisition modality provides a much greater gain than the one through the devices rental. Finally, it is important to highlight that this cost-benefit analysis can be applied to any type of medical equipment and is very useful for planning medical equipment acquisition.

01. Health Technology Assessment

IDENTIFICATION OF MEDICAL EQUIPMENT GAPS AT THE NATIONAL INSTITUTE OF PEDIATRICS FROM MEXICO

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Pediatrics is a tertiary care public institution with 22 specialties for attending patients under the age of 18, who reside mainly in eight states of the Mexican Republic and eight municipalities in Mexico City. In 2017, the Institute attended a total of 5,705 patients with a hospital stay average of 11 days. This requires the constant updating of medical care and the consequent renewal of its technological capacity. Therefore, it is necessary to identify the gaps of medical equipment in order to prioritize their acquisition and, therefore, make a rational investment that optimizes the budget of the Institute and maximizes the impact of medical technology for the patients benefit.

The objective of this work was to develop a methodology to identify the medical equipment gaps, considering information on the epidemiology of the population, the demand for medical care services and the installed technological capacity.

Initially, it was considered the main cause of consultation in 2017, which was "congenital malformations, deformities and chromosomal abnormalities" in which 2,323 patients were attended. Within these five causes were chosen: congenital cataracts, malformations of the urinary tract, non-syndromic craniosynostosis, malformations of the lip and/or palate and Wilms' tumor. In order to identify the medical equipment that should be used in the diagnosis and/or the treatment of these diseases, the clinical practice guidelines developed by the Mexican Center of Technological Excellence were analyzed. Subsequently, a comparative analysis was made between the clinical practice guide and the corresponding clinical procedure performed at the Institute. The medical equipment that is not available was identified and this translated into a new need for medical equipment for the Institute. The identification of the new needs of medical equipment was made through an Availability Matrix, which is a methodology proposed by the World Health Organization to map medical devices to high-burden diseases.

01. Health Technology Assessment

MINI-HTA FOR MEDICAL DEVICE (MD) PURCHASE. BETWEEN EFFICIENCY AND EFFECTIVENESS

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Introduction: In the last few years mini-HTA has been combined with MCDA for the purchase of MD; nowadays the main criticisms are three. In primis, the criteria are specific on the device to buy. Hence, each time it is necessary to propose and validate the new proposed criteria and measurement scales and this makes the MCDA ineffective. Vice versa, generic criteria are proposed without differentiating MD on power, invasiveness, risk, lifecycle. Another critical issue regards the choice of the MCDA technique. Often the choice is in favour of AHP that is not able to manage the vagueness and imprecision which are typical when selecting a medical device. Another problem is the aggregation of the judgments of the decision makers regarding i) the MD on the basis of the criteria and ii) the weights to be assigned to the other decision makers. The combination of judgments on criteria (i) quite often uses expensive methods. Regarding (ii), the assignment of weights to decision makers by a super-decision maker can generate distortion. **Objectives:** Our main objective is to propose a mini-HTA tool that, by classifying MD, overcomes the three above critical issues by:

- providing different criteria for the four MD classes with possible modifications when needed
- using MCDA techniques capable of managing objective and subjective information, precise or imprecise values
- allowing that the weights to decision makers are assigned according to a peer-based procedure

A peer-based IF-TOPSIS technique will be used that, while managing subjectivity, inaccuracy, and vagueness, avoids the centralized assignment of weights to decision makers. **Methodology:** There are two phases (the second is still not implemented):

1. MD criteria identification for all the four classes, based on literature and on clinical/manager's advice to ensure its validity
2. Data collection and peer-based-IF-TOPSIS implementation to classify the MD supporting patients in a locked-in state.

Contribution: This mini-HTA tool departs the limits of the extant tools in order to reach efficiency and efficacy. The criteria structured according to MD classes make this tool immediately useable, avoiding to waste resources for putting forward other criteria. The tool aggregates the judgments of decision makers without time-consuming methods. The tool efficiency facilitates its use even for supporting purchases of non-high-value MD, for which state-of-the-art MCDA techniques are prohibitive. This ensures transparency on a larger number of purchase processes.

01. Health Technology Assessment

WE SPEAK METATAG SO YOU DON'T HAVE TO! HOW INFORMATION PROFESSIONALS SUPPORT AND STREAMLINE THE HEALTH TECHNOLOGY ASSESSMENT PROCESS

By Erinoff E.

ECRI Institute, Plymouth Meeting, United States of America

Just as there's science and methodology behind how to review evidence, there is methodology about how to best to search for evidence. This presentation will not create expert searchers. It will help analysts involved with health technology assessment find and assess existing search strategies, craft strategies using controlled vocabulary and keywords, better use tools available in different search platforms, and decide which resources to include for different types of projects. Topics addressed include the balance between precision and recall, search protocols, caveats, and real world examples of tricky searches.

01. Health Technology Assessment

STRATEGIES TO INCREASE AVAILABILITY OF SURGICAL EQUIPMENT IN KENYA, CASE STUDY, NAIROBI CITY COUNTY

By Mwaura S.

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Objective: The need for surgery is currently not met in Sub Saharan Africa, this requires workforce but equally important surgical equipment. Currently there is a gap in the availability of surgical equipment which limits the provision of safe surgery. This study aims to identify the different phases surgical equipment goes through during its lifespan and to identify barriers that are perceived by stakeholders. **Introduction:** Access to surgery is lacking in many low-and-middle income countries. Of all major surgical procedures that are performed worldwide, only 3.5% are received by the poorest one third of the world's population. There is a large unmet need since currently more people die from surgically treatable conditions than from infectious diseases. Surgical equipment is currently designed, manufactured and sold with a main focus on HICs. The market in many LMICs, such as Kenya, is currently not exploited. Surgery requires human resources, equipment, medicines and an organized infrastructure. To understand the barriers to functioning surgical equipment, I used Nairobi County as a case study.

Background of health services in Kenya: According to the Kenya Health Policy 2014-2030, a document issued by the government of Kenya in 2014, health services are provided in over 4700 facilities across Kenya. Approximately half of them are public hospitals and the others are private or mission. Its public health system can be divided in 6 levels. The four level 6 hospitals are the Kenyatta National Hospital, Moi Referral and Teaching Hospital, Mathari Teaching and Referral Hospital and Spinal Injury Hospital. A new constitution of Kenya in 2010 introduced a devolved system of government. This system provides for one national government and 47 county governments and a centralized Ministry Of Health. The health services up to level 5 are managed by the county governments. **Identified barriers:** Lack of spare parts, specialised training, policy, Bureaucracy, Bad management of equipment, High cost/lack of finances, No guidelines on preventive maintenance, Rapid change of technology, Increased workload, Delays in procurement and Misuse of equipment. **Conclusions:**

- Medical device companies should provide training and ensuring spare part delivery
- Policies on donations, quality of surgical equipment should be developed
- More BMETs should be trained

01. Health Technology Assessment

DESIGN AND IMPLEMENTATION OF MEDICAL ENDOSCOPE SERVICE EVALUATION SYSTEM BASED ON APP&WEB TECHNOLOGY

By Zheng J., Lou L., Li J., Chen S., Feng J.

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Background: Medical endoscopy is an important medical device, which widely used in medical examination, surgical treatment and other fields of minimally invasive. Medical endoscopes have many product categories, wide application range, lots of manufacturers, and wide product distribution, resulting in uneven service capabilities of medical endoscopes, which is inconvenient for manufacturers to improve services and demand for services. Currently, there are no methods and software for evaluating medical endoscope service capabilities on the market. **Objective:** This study has established a medical endoscope evaluation index system, and developed a medical endoscope service evaluation system to provide a complete set of data solution for the regional implementation of medical endoscopy life cycle service evaluation. **Methods:** Based on APP&WEB technology, in the three business levels of user management, data collection, data analysis, layered according to the characteristics of medical endoscopy evaluation, the front end used vue2.0 technology, built by vue-cli independent front-end project; the background was written in java language, the framework used spring boot and the database used relational database mysql. For the purpose of business optimization, the medical endoscope evaluation index system was established as the basic big data framework, and other technical solutions such as Log adaptation were used to complete the design and development of the medical endoscope service evaluation system. **Results:** This paper completed the medical endoscope service evaluation software based on the data portal platform of APP and WEB, which included seven modules: installation service, maintenance service, warranty service, complaint service, annual evaluation, expert evaluation and baseline investigation. Using the medical endoscope service evaluation system, the business contacts of 127 hospitals and grassroots hospitals were established, and a data evaluation team of about 200 people was formed. Collected 1,500 evaluation data and conducted data collection for brands such as Olympus, Storz, Mindray, Kaili, Aohua, Chengyun, Tiansong and Shenda, at the same time, software testing and validation of medical endoscopy service evaluation system were completed. **Conclusion:** The system provides a complete, feasible and effective solution for the improvement of the level of medical endoscope service and the choice of medical institutions for medical endoscope services.

01. Health Technology Assessment

EVALUATION OF IN-SERVICE PERFORMANCE OF DIFFERENT BRANDS OF MRI DEVICES IN 1.5T

By Wang L., Chu C., Jin W., Zheng Y., Jiang R., Li B.

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Purpose: To investigate the in-service performance of different brands of 1.5T MRI in China, 45 MRI devices of 6 brand models in 20 provinces of China were detected. The testing results reflect the performance of 1.5T MRI device of different brands to a certain extent.

Methods: The 6 brand models of 1.5T MRI device were chosen to do the evaluation. Five items include signal-to-noise ratio(SNR), uniformity, geometric distortion rate, slice thickness and high contrast resolution were detected using single image methods. The sequence used is T1W SE(TR 500ms, TE 30ms, FOV 25cm, slice thickness 5mm, matrix 256*256, NSA 2). The phantom used is SMR170, which is produced by American phantom Laboratory. The images were acquired using the head coil and abdomen coil respectively. 45 devices were detected to do the comparison and evaluation.

Results: Using head coil, the mean SNR of Signa HDx, MAGNETOM Avanto, uMR560, NSM-15P, Centauri/Echo star and SuperVova is 508.5, 938.2, 741.12, 469.8, 446.19 and 558.88 respectively. The uniformity is 93.99%, 96.32%, 93.86%, 94.10%, 93.56% and 84.28%. The geometric distortion rate is 0.58%, 1.19%, 1.55%, 0.72%, 0.98% and 2.18%. The slice thickness error is 0.22mm, 0.13mm, 0.21mm, 0.28mm, 0.38mm and 0.7mm. The high contrast resolution is 4.5lp/cm, 5lp/cm, 4.89lp/cm, 4.83lp/cm, 5lp/cm and 4.75lp/cm. Using abdomen coil, the mean SNR of six models is 271.73, 494.91, 1055.37, 283.32, 594.46 and 292.88 respectively. The uniformity is 93.99%, 96.32%, 93.86%, 94.10%, 93.56% and 84.28%. The geometric distortion rate is 0.58%, 1.19%, 1.55%, 0.72%, 0.98% and 2.18%. The slice thickness error is 0.22mm, 0.13mm, 0.21mm, 0.28mm, 0.38mm and 0.7mm. The high contrast resolution is 4.5lp/cm, 5lp/cm, 4.89lp/cm, 4.83lp/cm, 5lp/cm and 4.75lp/cm.

Conclusion: This MRI sampling detecting work covers hospitals of different levels in different regions of China. It can be seen that the basic performance of MRI of some Chinese brands is similar to that of European and American brands, and even surpasses some parameters. Although more than 80% of detected MRI devices are qualified according to the existing industry standards in China, it can be seen that the testing value of some equipment is still very low. So it is suggested that the industry standards should be improved accordingly and regular performance detecting of in-service MRI devices should be carried out to ensure the quality of imaging.

01. Health Technology Assessment

TOOLS FOR INTEGRATED MANAGEMENT OF CHILDHOOD ILLNESS

By Gupta K.

PATH, New Delhi, India

An estimated 5.6 million children under five years old died in 2016 due to preventable or treatable causes. Most of these deaths were due to pneumonia (24%), diarrhea (15%), and malaria (9%). Many low- and middle-income countries (LMICs) lack comprehensive policies and broad access to tools to help health care workers (HCWs) more effectively diagnose and manage sick children who present at the primary health care (PHC) level, especially those with severe illness. The project is a global effort to accelerate availability, adoption, and scale-up of tools to identify severe illness and decrease mortality in children under five years of age.

The main goals are- to improve PHC workers' ability to diagnose severe disease by equipping them with pulse oximeter (POX) and decision support tools; to accelerate the development and market entry of non-invasive devices that augment the features of standard POX with one or more additional vital sign measurements.

To achieve the goals, the project will collaborate with country stakeholders at national and sub-national level, to co-create programs to integrate POX into each country's Integrated Management of Childhood Illness (IMCI) guidelines and with Swiss TPH to adapt their electronic point-of-care tool (ePOCT) testing algorithm (one form of an eCDST) in conjunction with POX and local guidelines and ensure interoperability with existing local digital platforms.

The programs will measure health impact, cost-effectiveness, and operational factors. This will include training HCWs to use the devices, implementing the program, and providing ongoing supportive supervision; working with local civil society organizations to encourage care-seeking behavior when children are sick.

Thus, this will help the project- to support LMICs in establishment of POX and electronic decision support tools into PHC settings; to inform global-level decisions to update guidelines, policy, or recommendations regarding the use of POX and eCDSTs in PHC settings; to provide an optimized approach and facilitate an efficient and successful introduction of devices. The project will co-generate national scale-up strategies and finance plans; build capacity for procurement, budgeting, and maintenance; facilitate South-to-South learning exchange; and catalyze scale-up of POX by elevating country successes and making the case for POX as essential technologies that reduce child morbidity and mortality associated with fever, cough, and difficult breathing.

01. Health Technology Assessment

SEPSIS AND MORTALITY PREDICTIVE MODELS USING DEEP LEARNING: A PROGRESSIVE LEARNING ANALYSIS

By **Camacho J., Bonet I.**

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Sepsis is one of the leading causes of death among intensive care units' patients. As sepsis progresses, it causes organ dysfunction, and the mortality rate increases substantially in hospitals. The European Society of Intensive Care Medicine/Society of Critical Care Medicine Third International Consensus Definitions for Sepsis and Septic Shock task force (the Sepsis-3 task force) recently defined sepsis as a "life-threatening organ dysfunction caused by a dysregulated host response to infection" Most recent studies have focused on patients with existing sepsis using electronic medical records, biomedical signals from monitors and laboratory results to predict status changes as sepsis progresses or analyze the mortality of sepsis patients. The data analysis methods have made possible the recent successful applications of Artificial Intelligence in health.

In this research, we analyzed the data stored in the free database MIMIC-III, which contains information of patients admitted to the intensive care unit of The Beth Israel Deaconess Medical Center in Boston, Massachusetts. A series of clinical variables of the patients were used, which were passed through hard rules that generate a numerical value or probability that is related to the severity of the condition. The chosen variables correspond to those used in the mentioned indicators in order to predict the existence or not of sepsis and the mortality of patients. This study aimed to develop an analysis of three models to predict sepsis, mortality and length of stay in ICU patients using Deep learning. The best model consists in a 3 hidden layer neural networks. It was designed in Python and tensorflow, using collaborative platform from Google.

The procedure carried out was based on the CRISP-DM methodology, where the data was obtained, an analysis of their quality was done, the variables of the aforementioned indicators were selected (31), a cleaning of the data was performed, and a single view was obtained which was used to develop the model. The results (AUC = 0.90 and accuracy = 96) indicated that the models of deep learning implemented, are able to equal and even improve the predictions of hard rule models, breaking the paradigms and serving as a support in the decision making of health professionals.

01. Health Technology Assessment

DISTRIBUTION AND USE OF HIGH VALUE CAPITAL MEDICAL IMAGING EQUIPMENT IN GREECE

By **Dermitzakis A., Pallikarakis N.**

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Modern medicine is strongly dependent on technology. Health technology as a term, according to World Health Organization (WHO), refers to the application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of lives. Therefore, Medical Devices (MDs) belong to the Health Technologies, and High Value Capital Medical Technologies are an important subgroup of them. The term High Value Capital Equipment refers to high-tech medical devices that are considered costly both in terms of initial investment and operation, requiring specially trained personnel for its use and needs regular quality control, preventive maintenance and management procedures, to function properly and safely. The present study focuses on the High Value Capital Medical Imaging Equipment (HVCMI) which according to the Global Medical Device Nomenclature (GMDN) are the following groups:

- MRI: Magnetic Resonance Imaging
- CT: Computed Tomography Imaging
- PET/CT: Positron Emission Tomography / Computed Tomography
- γ -Camera/SPECT: Single Photon Emission Computed Tomography
- MMU: Mammography Unit

The present study aims to:

- Assess the sufficiency and equity in the distribution of HVCMI and its use in Greece
- Identify eventual inequalities in terms of geographical coverage, specific needs and lack of HVCMI
- Estimate the costs for the use of HVCMI: Since a country-wide medical equipment inventory for Greece does not exist, various sources were used and compared including OECD, WHO, EEA and Scientific Societies

In terms of number of units, from 2009 to 2017 the per million population number of MMUs, CT, MRI, PET and SPECT rose by 30%, 19%, 28%, and 175%, while γ -Camera/SPECT were kept stable. In terms of their usage, a very pronounced decline of the CT and MRI exams between 2008 and 2013 is noticed. Data available from 2013 and on, for the number of mammograms show also a reduction, while PET exams remained stable between 2013 and 2016, are expected to increase in 2017, based on the number of new PET scanners that are in process of installation during 2017. The study revealed that in Greece, there are quite pronounced inequalities in terms of availability of some of these technologies in different regions of the country. Long term strategic planning is needed based on evidence, such as updated inventory of MDs, usage statics and costs, which are unfortunately lacking in Greece.

01. Health Technology Assessment

METHODOLOGICAL ASSESSMENT TOOL MEDICAL DEVICES INCORPORATION FOR HEALTHCARE INSTITUTIONS

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In Colombia, Health technology assessments (HTAs) in hospital context are difficult to conduct because of the decisive procedures of the HTA algorithm, which are often complex and not easy to apply. Thus, their use is not always convenient or possible for the assessment of technical requests requiring a multidisciplinary approach. For this reason, a new web site methodological tool for HTA was developed and implemented to support and enhance the decision-making process for Medellín's healthcare institutions. Named ETESDispHosp, use as core technique the systematic review from the most important HTA agencies in different countries, identifying the best methods applied. They are characterized and selected so that each of the evaluation criteria were more similar and adaptable to the clinical needs of a municipal hospital. The ETESDispHosp methodological tool comprises four criteria: Security, effectiveness, economical, and social factors. The final report is made based on these criteria and through the analysis of evidence medicine-based reports, sanitary alerts analysis and the implementation of a hierarchical analysis to contribute in the decision-making process. Additionally, a web site software was designed as an assessment platform services, in which the health institutions and professionals related can perform a remote evaluation of technologies. As a test of its usefulness, the ETESDispHosp was validated to three medical devices of priority interest for Hospitals in Colombia. The final recommendation was (I = Incorporate or NI = Not Incorporate), MR system = I, drug-eluting stent = I and the robotic assisted system Da Vinci = NI. This validation was developed by a group of national and international clinical engineering experts' group. A statistical analysis was implemented to measure the level of reliability and variance of the outcomes obtained throughout the implementation of the Cronbach α coefficient. For the method it was set $\alpha = 0.70$ as a minimum of tolerance. The α for the evaluation of the software was $\alpha = 0.76730$ that indicates a good grade of reliability and correlation. For the methodological document the results were $\alpha = 0.88983$ which demonstrates a high grade of reliability and correlation with the expert's feedback. Feedback from participating decision-makers about the ETESDispHosp tool was very positive. The tool could help to promote a more structured and transparent approach to HTA decision-making in Medellín hospitals.

01. Health Technology Assessment

AUTOMATED PREPARATION OF CHEMOTHERAPY IN PIEMONTE (ITALY): A RAPID HTA EVALUATION

By Bellelli S.^[1], Buffa E.^[2], Cattel F.^[2], Fruttero C.^[3], Pagano E.^[4], Pisterna A.^[5], Rivoiro C.^[1], Romano V.^[1], Scelfo B.^[1]

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INTRODUCTION In Piemonte (Italy) the planning procedure for medical equipment procurement has been reviewed in 2017 with DGR n. 82-5513. A regional HTA committee was established with the aim to evaluate the introduction of biomedical technologies in public setting. In order to support the decisions of the HTA committee about the new introduction of the automated preparation of chemotherapy (APC) in the Pharmacy Units of three Hospitals, the HTA research group of IRES Piemonte conducted a rapid HTA evaluation on the preparation of cytotoxic drugs by comparing the robotic method vs the manual procedure.

METHODS Research questions included safety and efficacy, organizational impact and economic evaluation of the APC. Policy question included guidelines of local and regional planning. A systematic literature review was conducted by formulating the PICO and searching articles in MEDLINE PubMed and Embase. The economic evaluation was conducted to estimate the mean unit cost of manual preparation of chemotherapy vs robotic procedure. Costs have been collected by a questionnaire using the bottom-up and micro-costing approaches. Cost items included personnel, cost of disposables used, acquisition and management of facilities, systems and robot. A conservative and prudent approach in respect to APC was adopted.

RESULTS The literature shows that APC is more accurate and safe than the manual method, in terms of single dose tracking, with benefits for patients and operators. Heterogeneous results about the workflow emerged from literature. Preparation time is higher using the APC and there are no savings about the full time equivalent workers involved. Respect to the manual procedure, the economic analyses show different results depending on the overall number of preparation and the percentage of preparations switched from manual to automatic setting. In case of 65,000 preparations with 30% made by the robot, a slight reduction of costs was observed; the saving were improved with an increase of the number of preparations: up to -12.1% for 75,000 preparations. In cases with preparations < 25,000 and 65% made by the robot, costs increased from +9.1% to + 13.4%. **RESULTS** The rapid HTA report supported the decision of the HTA committee for implementing the APC in the three settings. The HTA committee suggested the users to monitor the quality, safety and the organizational and economic impacts of the new technology, in order to produce and increase the evidence of APC.

01. Health Technology Assessment

TOWARDS THE DESIGN OF AN HTA STUDY ON ALTERNATIVE TECHNOLOGIES IN MAMMOGRAPHY

By Giansanti D.^[1], Greco R.^[2], Gulino R.A.^[2], Amato S.M.^[3]

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Introduction: Traditional mammography is a diagnostic radiological technique that allows early detection of breast lesions. The careful study of the udders also allows the identification of small anomalies, such as microcalcifications. For this reason, its diagnostic effectiveness is superior to the clinical palpation. An early diagnosis is essential because it allows to safeguard the health of the woman and the integrity of the breast. It is estimated that over 97% of breast cancers diagnosed at an early stage resolve positively in the following 5 years. If, on the other hand, the discovery takes place at a later stage, the possibilities for treatment and healing are much more limited. Therefore, mammography must first of all have a preventive character and must not be seen by the patient as a simple diagnostic tool. Its repetition at regular time intervals is essential to prevent and defeat the most common malignancy in incidence and mortality in the female population.

However, it is necessary to keep in mind the so-called health detriment of the female population due to the exposure of ionizing radiation of the radiographic system: a certain number of women will get cancer just because of the diagnostic-preventive medical practice. For years we have been looking for new diagnostic methods not based on ionizing radiation to eliminate the consequent health detriment.

Goals and final users: The study has three main polarities. The first polarity faces:

- Generalities on traditional mammography with analogical and digital techniques (Mammography as a prevention and monitoring tool)
- The health detriment of the female population due to the diagnostic practice referred to in points (a) and (b).

The second polarity consists on the design of a survey based on an electronic methodology to investigate on women (a) their relationship with mammography diagnosis; (b) awareness on radiation risks; (c) opinion on alternate to traditional methodologies. This polarity is propaedeutic to the final polarity; providing basic information on the introduction of alternative methodologies. The third polarity (a) investigates the alternative technologies available in mammography and (b) set-up an HTA study. The final users are the citizens (women and familiars); health care operators and stake-holders.

Results: At the moment we have terminated the first two polarities and the first part of the third. The electronic survey based on Forms provided a good basis for all the study.

01. Health Technology Assessment

SINGLE-USE ENDOSCOPY: EVALUATION BY HB-HTA APPROACH AND COMPARISON WITH REPROCESSABLE DEVICES

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The growing's population and the improving life expectancy require a constant technological improvement to guarantee workflow efficiency and, at the same time, the patient's security, while taking into account available economic resources. Nowadays, this appears to be the most important challenge for the health sector, and the HTA analysis is a valid instrument to support it. In this work we have developed a HB-HTA analysis which supports decision-makers in the choice between innovative technologies, and technologies that are already available in the market. The method that has been implemented is the DoAHP, and it is based on the translation of the domain proposed in the HTA (Core model of the EUnetHTA), in a numerical evaluation. Each of these domains represent an element of evaluation. The expression of this numerical evaluation will allow the inclusion of technology in three different bands (high, intermediate, low), and they indicate how the introduction of this new technology will bring improvements to the health sector. The analysis that has been carried out is based on a weighted sum: it is a combination between normalised weights, and scorings assigned to each of the domains. These weights have been calculated by applying the Analytic Hierarchy Process (AHP) multicriteria method, to create a hierarchy of domains. This method, tested and implemented in the ASUI of Udine, has allowed to establish the advantages of the introduction of single-use endoscopic devices in a comparison between reprocessable bronchoscopes and single-use bronchoscopes. The results have shown the convenience of a coexistence between these single-use and reprocessable technologies, as single-used bronchoscopes might not be reliable for all bronchoscopic procedures. Moreover, the single-use procedure costs about twice compared to the reprocessable technologies. In conclusion, we can assert that the proposed HB-HTA method is applicable and adaptable to different healthcare contexts. Valorising the comparison in numerical terms can foster a more objective decision-making in terms of purchase and utilization on behalf of decision-makers.

01. Health Technology Assessment

DIABETES TECHNOLOGIES: EVOLUTION, MODELING AND EVALUATION OF PERSPECTIVES THROUGH NEW METHODS OF HTA

By Giansanti D.^[1], Ferrante U.^[2], Gulino R.A.^[2]

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The project: We designed, developed and implemented a new HTA method concerning technologies for antidiabetic therapy. This method is based on 3 different questionnaires and a evaluation module, managed electronically and structured to reflect the opinions of the main stakeholders involved.

Moreover, a cost-effectiveness analysis of two different diabetes therapies was designed. They are Continuous Glucose Monitoring (CGM) and home monitoring (HM) with glucometer, both joined with multi-infusion using pre-filled insulin pens. The comparison was carried out using data from the clinical trial registered on ClinicalTrials.gov with code NCT02282397. For this, the therapeutic cycles were evaluated over a period of 24 weeks and the quantities were calibrated for it. The trial showed a 1% decrease in glycated hemoglobin (HbA1c) with CGM therapy, compared to 0.4% in HM.

Objective: - To investigate the knowledge and expectations of society about diabetes medical devices.

- To assess the impact of a new treatment on the community.
- To build a bridge between the technical-scientific world and the decision makers'one.

This same methodology can evaluate other technologies, remodelling it according to devices to be examined. It is useful to government that deals with planning responsibilities, regarding national or international health policies.

Results: - The questionnaires involved 68 people (citizens, health professionals)

- Artificial Pancreas (AP) cannot completely replace traditional diabetes therapies.

- The main problems for the spread of the APDS are costs and complexity of use.

- The smartphone is the most appropriate management tool for AP.

- Diabetic children and athletes could obtain the greatest benefits using ADPS.

- The evaluation form returned positive feedbacks.

- Total costs for CGM, HM and hospitalization for a diabetic patient was estimated according to the Regional Social Health Agency and the Hospital information System. The American Diabetes Association associated a 1% decrease in HbA1c with a 35% reduction in the risk of immediate patient's hospitalization and it was applied to calculate the cost of the two treatments. This analysis led to estimate the two costs in 8225.1€ for CGM and in 8066.28€ for HM. Although the difference is minimal, HM is more convenient. However, the excellent results of effectiveness and technological progress can lead to the growing diffusion of CGM, creating a competitive market, with a consequent decrease in price.

01. Health Technology Assessment

HTA IN THE ACCURACY OF SELF-MONITORING BLOOD GLUCOSE FOR DIABETES MELLITUS TYPE 2 FOR PRIMARY CARE SCENARIO

By García R.^[1], García F.^[1], Avelar P.^[1], Martins J.^[1], Félix M.^[2]

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Self-Monitoring Blood Glucose (SMBG) is currently a technology in the Primary Care and Homecare scenario that have great impact on the population. A follow-up of their safety and accuracy based on technical norms is rarely performed and the lack of this information can directly affect the treatment of the patient. The context of this study is post-incorporation equipment distributed in the Primary health Care for the control of diabetes by patients in homecare. The health technologies assessment (HTA) assists in identifying a potential mediator for these demands analyzing the risks, benefits, costs and impacts, the study technology. The methodology of this research is based on the methodological guideline for the evaluation of medical equipment that addressing its main fields of Admissibility, Clinical, Technical, Operational and Economic in order to verify the accuracy and safety of the SMBG in comparison to other glucose measurement technology. Systematic Reviews, Randomized Clinical Trials, ATS Guides and technical documents on the equipment were selected and the inclusion and exclusion criteria were determined according to the key specific issue of this study. SMBG showed a minimum acceptable accuracy due to their bias when associated with minimal patient risk, however, this bias has a significant effect on medication in severe hypoglycemia events. A similar difference, although not statistically significant, was shown to the use of SMBG in patients with training compared to the group without training. Few evidences report an evaluation of their inputs and interpretation of the results by the patient, since they may directly affect the reliability of the technology. These results challenge Clinical Engineering in the generation of new technical evidences with the use of metrology for a program to follow the technology and programs of patient-oriented training to improve technology control through post-marketing performance in the Primary Care network.

01. Health Technology Assessment

REAL WORLD DATA, REAL WORLD EVIDENCE AND SENTIMENT ANALYSIS IN HTA

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The main objective of HTA is to provide evidence to respond appropriately to the growing demand for healthcare and to the continuous availability of new technologies, against a background of limited economic resources. For this reason, in recent years, the Real World Data (RWD) have been playing a crucial role; these are data collected outside randomized controlled Trials (RCTs), such as those obtained from electronic health records (EHR), records of reports, data generated by the patient and then collected from all those sources that can inform about a clinical condition. Final RWD analysis is the clinical evidence related to the use and potential benefits or risks of a health technology, namely Real World Evidence (RWE). The real challenge in using RWD to generate reliable evidence, in order to guide decisions, lies in our ability to address these issues with appropriate tools. One possible solution is to consider social media as a new way to capture patients' comments. Social data are publicly available and can be analysed relatively easily, overcoming many logistical obstacles associated with traditional approaches and enabling fast and cost-effective data collection. Studies have shown that these data can provide a reliable insight into the patient experience. Linking social media to electronic health records offers a significant opportunity to collect patients' opinions to improve health services and patient care. The aim of this project is to achieve HTA decisions through a sentimental analysis of RWDs. Considering some machine learning techniques, it is possible to implement algorithms that are able to extract opinions and concepts from the texts of patients' comments, obtained from different platforms, to evaluate needs and make decisions on different technologies in the area of health care.

01. Health Technology Assessment

NON-CONTACT INFRA-RED THERMOMETERS: IS THERE SUFFICIENT EVIDENCE TO SUPPORT THEIR USE IN SECONDARY CARE?

By Clark D.^[1], Bolton S.^[2], Latimer L.^[2]

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Background: Body temperature measurement is a key part of routine patient observations in all healthcare settings including secondary care. Temperature monitoring can influence important decisions regarding tests, diagnosis and treatment it is therefore crucial that thermometers are accurate, reliable and easy to use as since inaccurate results may lead to a failure in identifying patient deterioration and compromise patient safety. The most accurate measure of body temperature comes from invasive "core" thermometry options such as pulmonary artery but also bladder, nasopharynx or oesophageal thermistors. However, these methods are invasive, potentially high risk and restricted to patients undergoing specific procedures and not suitable for everyday use in all care settings. There are a range of non-invasive thermometers for obtaining temperatures from peripheral body sites including the tympanic membrane, the mouth or the axilla. There is currently fresh interest in temporal artery thermometers (TAT) and non-contact infrared thermometers (NCIT) as they show promise in terms of their convenience, ease of use and patient acceptability. We wished to consider if there was sufficient evidence to consider TAT and NCIT as a replacement for our standard temperature measurement techniques in hospital.

Method: A literature search and data review was undertaken. Each paper was reviewed and summarised in terms of populations, setting, devices used, outcomes and detection of hypo/hyperthermia (febrile) patients. The conclusion of the authors regarding whether the device was clinically acceptable or not was recorded.

Discussion:

- TAT and NCIT offer promise of improved ease of measurement and patient acceptability
- Current evidence base is quite large but ill-defined
- Evidence inconclusive but certainly not supportive

Conclusion:

- Literature search and data review for both TAT and NCIT indicates that neither is currently suitable as a replacement for tympanic IR ear thermometry in clinical practice
- In particular, evidence suggests these techniques are not suitable for detecting temperatures outside the normothermic range.

01. Health Technology Assessment

BRAZILIAN NATIONAL HTA GUIDELINES APPLICABILITY TO LOCAL CONTEXT ASSESMENT OF MEDICAL DEVICES

By De Vilhena Garcia E., Alvarenga Sampaio De Souza G.

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BACKGROUND: Brazilian Ministry of Health has issued many guidelines on several aspects of Health Technology Assessment (HTA). Among others, there are publications about systematic reviews and meta-analysis, rapid reviews, risk-of-bias assessment; GRADE system; medical devices evaluation. All guidelines are from a nationwide viewpoint, with no consideration to the local context of managerial decisions as related to Hospital-Based HTA. This work presents a critical review of the current national guidelines in the light of the AdHopHTA Handbook (Adopting Hospital Based HTA) and their applicability for local context evaluation of medical devices.

METHODS: We made pointwise comparisons among the multiple domains of AdHopHTA Handbook and the sections of the medical device evaluation guideline in order to highlight similarities and differences. Later, we evaluated a volumetric infusion pump model, from a medium-sized hospital in Brasilia, accordingly with the Brazilian guideline or, whenever it was not applicable, in accordance with the AdHopHTA Handbook.

RESULTS: In contrast to the 10 domains of the AdHopHTA Handbook, the Brazilian guideline on medical device evaluation has 6 domains: clinical, admissibility, technical, economical, operational, innovation. Overall, their correlate well in a domain-wise comparison. The exception in the Innovation Domain, with no surrogate in the Handbook. For the Ministry of Health, Innovation Domains is about research and development feasibility of the evaluated technology by Brazilian industries. These aspects were not considered relevant in a local context and were replaced by MTBF (mean time between failure) as a proxy indicator of technology obsolescence degree. Specifically, about volumetric infusion pump, PICO and TICO acronyms were considered not much effective for search building about clinical effectiveness and safety due to the several technology indications and related populations. We propose that the Unit where the infusion pump is located – instead of Intervention or Indication – may be more useful for local context assessment.

01. Health Technology Assessment

HEALTH TECHNOLOGY ASSESSMENT OF LABORATORY MEDICINE: THE OPBG EXPERIENCE

By Ritrovato M.^[1], Faggiano F.C.^[1], De Vivo L.^[2], Pireddu M.^[2], Andellini M.^[1], Nacca A.^[1], Derrico P.^[3]

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Objective: Recent studies have been sustaining the re-organization and automation of a Laboratory medicine as a challenge for the hospital in terms of reduction of costs, turnaround time and workload, optimization of human and technological resources and improvement of safety. The purpose of this study was to conduct an HTA evaluation process about the possibility to re-organize and automate the Laboratory medicine of Bambino Gesù Children's Hospital.

Methods: Decision-oriented HTA (Do-HTA) method was applied to assess the best technology solution involving the integration of the EUnetHTA CoreModel and the Analytic Hierarchy Process. It is an analytical instrument for the identification of the main evaluation criteria leading to the attribution of their performances.

Twenty-one professionals have been involved to define tender specifications related to the adaptation works of the new dedicated rooms and to the automatic technologies and organizational solutions for the new Laboratory Medicine. Finally, two manufactures' companies were took into consideration.

Results: The study was focused, through DoHTA method, only on the laboratory technologies while the infrastructure evaluation was conducted by the Engineer and Logistic Units of the hospital. Results showed that the total performance score of the first proposal was slightly higher (2,5%) than the second one, proving the comparable high qualitative level of both manufactures' technologies. After an accurate analysis, evaluating all aspects (safety, clinical efficacy, cost, organization & technical criteria) and integrating the infrastructure evaluation, the decision has fallen upon the first classified company offer.

Conclusion: This HTA project allowed to examine in depth all technological and organizational solutions proposed. Thanks to DoHTA method, producing and developing data and all needed information, it was possible to guide and assist the decision makers on the choice between the two technical solutions compared.

01. Health Technology Assessment

HEALTH TECHNOLOGY ASSESSMENT OF CARDIOVASCULAR MAGNETIC RESONANCE (CMR) IN THE HEALTH SYSTEM IN SARDINIA

By Mura F., Marcias M., Podda B.

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DESCRIPTION: This project evaluates the request of medical specialists about 2 issues: technological upgrade of a CMR located in SS Trinità Hospital in Cagliari on the one side and acquisition of additional CMR for San Francesco Hospital in Nuoro on the other side. The aim of the Specialists is to reduce waiting time in the health care list and also improve the quality of health care related to cardiac pathologies. This report adapts EUnetHTA models to Health Italian System also through Age.Na.S. manual and HTA Lombardy Region framework.

GOALS OF THE PROJECT: The goal of the assessment is to evaluate 4 aspects related to the implementation of CMRs to respond to cardio vascular disease: epidemiology; supply (interest of patient, association and Governance); availability, safety and efficacy; economic and organizational. The results of the last 2 points are compared to competitors' values. Cardiovascular pathologies are one of the most frequently cause of death in the developed countries involving men and women from 35 to 65 years of age.

RESULTS: Positive outsides of CMR implementation are: to prevent cardiac pathology; to assess critical events; to grant morphological and vital information about cardiac system of each patient compared to competitors; minimal collateral events; to reduce passive mobility (patients traveling to other Regions health centres residents' movement to hospitals outside the region or private centres); to reduce waiting list in the total number of CMR exam is enhanced; no economic impact if the total number of RM exam will be kept constant; to align Medical Specialist skills to the same European levels through specific training; potential European accreditation of both Medical Specialist and Clinical Centre. Negative outsides concern above all economic aspects. These are due to: recruitment of more Clinical Specialist personnel to increase total number of MR exams; attend specific training; reach European accreditation (some requirements for accreditation refer to a high number of various cases studied, and training exams conducted).

02. Medical equipment management in hospitals

CLINICAL ENGINEERING BENCHMARKING COMPARISON BETWEEN BEIJING AND AMERICAN HOSPITALS

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The first Clinical Engineering (CE) benchmarking between Chinese and American hospitals was performed in 2014. At that time only data from Zhejiang province was available. A new comparison was completed in 2018 with data collected from 11 hospitals from the capital city of Beijing. These data were compared to those from 270 acute-care hospitals in USA. The benchmarking comparison was made in three categories: (A) Operations, (B) Finance, and (C) Productivity. Within the Operations category, the following metrics were compared: inventory size/operating beds, annual repairs/inventory size, and annual scheduled maintenance/inventory size. Within the Finance category, the following metrics were compared: total CE expense/total hospital expense, total CE expense/operating beds, and total CE expense/cost of equipment inventory. Within the Productivity category, the following metrics were compared: total CE full-time equivalent (FTE)/inventory size, total CE FTE/operating beds, and total CE FTE/total hospital expense. These comparisons showed that: (1) While still a bit lower than USA, Beijing hospitals have higher inventory than Zhejiang but slightly lower amount of repairs and scheduled maintenance per equipment; (2) The total CE expense/total hospital expense ratio is around 1% in both USA and Beijing, slightly above Zhejiang; however, the total CE expense/operating beds and total CE expense/cost of equipment inventory are still lower in Beijing and Zhejiang than USA.; (3) The CE FTE amount is higher in Beijing than Zhejiang and closer to USA relative to both inventory size and total hospital operating expense, but still a bit lower than USA relative to the number of operating beds. Some of the differences detected are likely caused by the same factors found in the prior study of Zhejiang hospitals, namely, higher length of stay in China than USA, lower labor and living costs in China, and different healthcare management methods in these countries. The differences found between Beijing and Zhejiang cannot be explained solely by inflation (~2%/year) or even higher cost of living in the Capital but likely due to more advanced medical practice. Overall, these results confirm the outstanding progress of CE in China.

02. Medical equipment management in hospitals

DESIGN AND APPLICATION OF MEDICAL ENDOSCOPE SERVICE EVALUATION SYSTEM BASED ON APP&WEB TECHNOLOGY

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Background: Medical endoscopy is an important medical device, which have many product categories, wide application range, lots of manufacturers, and wide product distribution, resulting in uneven service capabilities of medical endoscopes, which is inconvenient for manufacturers to improve services and demand for services. Currently, there are no methods and software for evaluating medical endoscope service capabilities on the market.

Objective: This study has established a medical endoscope evaluation index system and developed a medical endoscope service evaluation system to provide a complete set of data solution for the regional implementation of medical endoscopy life cycle service evaluation.

Methods: Based on APP&WEB technology, in the three business levels of user management, data collection, data analysis, layered according to the characteristics of medical endoscopy evaluation, the front end used vue2.0 technology, built by vue-cli independent front-end project; the background was written in java language, the framework used spring boot and the database used relational database mysql. For the purpose of business optimization, the medical endoscope evaluation index system was established as the basic big data framework, and other technical solutions were used to complete the design and development of the medical endoscope service evaluation system.

Results: This paper completed the medical endoscope service evaluation software based on the data portal platform of APP and WEB, which included seven modules: installation service, maintenance service, warranty service, complaint service, annual evaluation, expert evaluation and baseline investigation. Using the medical endoscope service evaluation system, the business contacts of about 100 hospitals in China. Collected 1,500 evaluation data and conducted data collection for brands such as Olympus, Storz, Mindray, Kaili, Aohua, Chengyun, Tiansong and Shenda, at the same time, software testing and validation of medical endoscopy service evaluation system were completed.

Conclusion: It has been verified that the system can operate normally, data acquisition and analysis is reliable, and it has the characteristics of practicability, scalability and security. The system provides a complete, feasible and effective solution for the improvement of the level of medical endoscope service and the choice of medical institutions for medical endoscope services.

02. Medical equipment management in hospitals

CAUSES AND FAILURES OF RIGID ENDOSCOPES

By Knob Souza W., Marciano M.

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The minimally invasive techniques, such as the video surgery bring numerous benefits for both physicians and patients, when compared to conventional surgeries. For a video surgery could happen it is essential to use an optical instrument (rigid endoscope). They are fragile equipment because they are made of glass. Using a software program to control and management of rigid endoscopes, we propose to submit: the percentage of two surgical procedures with greater use of optics; the percentage of repair by type of surgical procedure; the total number of maintenances by type of optics; the number of maintenances by type of defect. It is important that additional to the care with the quality of the instruments to be purchased, if you followed all the steps in the flow of use and processing of the optic of video surgery. How they are handled since cleaning up the medical use, are crucial to prevent the causes of faults are operational failure.

02. Medical equipment management in hospitals

COMPARISON BETWEEN HIGH AND LOW OXYGEN FLOW FOR THE TREATMENT OF PACIENTES ADMITTED IN AN INTENSIVE CARE UNIT

By Borges P., Marciano M.

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There are two concepts that are still confused as dependents in ventilation: air flow and oxygen concentration. In other words, there are understandings that to obtain a high oxygen concentration is necessary a high inspiratory flow. A measurement-based study was used to demonstrate independence in this correlation, focusing on low fluxes (less than or equal to 3 LPM) as it is directed at use in neonatal patients.

The objective is to demonstrate that when using flows from 1 LPM, any concentration of oxygen that is selected in a gas mixer is obtained. As a method was used a high flow oxygen therapy circuit connected to a calibrated gas flow analyzer. The result meets the goal.

02. Medical equipment management in hospitals

ANALYSIS OF THE INDICATION OF REPLACEMENT OF MEDICAL EQUIPMENT: MULTIPARAMETRIC METHOD APPLICATION OF OBSOLESCENCE EVALUATION

By Knob Souza W., Antunes Marciano M.

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For the Hospital Equipment (HE) or Biomedical Equipment (BE) to contribute in an effective way and for the health organizations to use them in the most productive manner; there is the need to do a management of their life cycles. A decisive factor in this life cycle is to know when a HE must be replaced. The replacement evaluation is crucial to base the hospital direction in investments definition, since that one of the inputs of incorporation in the one of obsolescence replacement. Therefore, the purpose 1 of this project is to compare the list of medical equipment replaced by the hospital, in relation to the equipment list that the multiparametric method (of assistance to the replacement by obsolescence) indicated to replace in the following year, having as a reference 3 consecutive years. The objective 2 is to compare the diversity, quantity of equipment and the decisive multi-parametric methods, that the method indicated to the replacement in the years of 2016, 2017, and 2018. It was possible to compare the list of medical equipment replaced by the hospital, in relation to the list of equipment that the replacement multi-parametric method indicated to substitute, having as reference 3 consecutive years, as well as, comparing the diversity, quantity of equipment and the decisive multi-parametric criteria, that the method indicated to replace in the years of 2016, 2017 and 2018. Some of the main shocking factors of the replacement indications, were the corrective maintenance cost, the user preference (changing the equipment to new ones), increase of standardization of new model, the age of the equipment and the manufacturer support.

02. Medical equipment management in hospitals

WHICH AMERICAN CLINICAL ENGINEERING PRACTICES SHOULD YOU ADOPT?

By Wang B.

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Most countries -with the notable exception of Japan- have replicated the American Clinical Engineering (CE) model and adopted its practices for several decades. While many of these practices have been proven effective in keeping equipment safe and reliable, some of them are actually misconceptions. It is not uncommon for pioneers to make mistakes because there is no other way for them to learn and improve. However, it is not justifiable for others to follow the same path and repeat the identical errors. Therefore, it is essential for CE professionals in other countries to examine critically American CE practices before adopting them. To help foreign CE professionals distinguish proven practices (“real news”) from myths and legends (“fake news”), at least a dozen American CE practices will be presented for discussion. The validity of each practice will be supported or rebuffed with concrete evidence. Examples of practices to be discussed include routine electrical safety tests, value of preventive maintenance (PM), PM completion rate, staff productivity measures, risk-based maintenance planning and scheduling, cost-of-service ratio as an efficiency benchmark, patient harm caused by use errors, routine defibrillator testing, and following manufacturers’ service recommendations. At this session attendees will learn how to review critically their own practices to see if they are simply adopting Americans without justification or they are indeed using their limited resources in the most effective and cost-efficient manner to ensure patient safety and high-quality care.

02. Medical equipment management in hospitals

MEDICAL EQUIPMENT MANAGEMENT IN HOSPITALS

By Ulak P.

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Medical equipment (ME) is the medical device that is used for the specific preventive, diagnostic, treatment or rehabilitation procedures carried out in most health care facilities. It ranges from simple devices such as thermometer to complex devices such as C-arm. ME benefits patients by helping health care providers diagnose and treat patients and helping overcome sickness, improving their quality of life. Significant potential for hazards are inherent when using a ME and thus ME must be proved safe and effective with reasonable assurance. It is, therefore, importance that hospitals manage their assets to ensure the quality of healthcare delivery. This area is often referred to as clinical engineering or medical equipment management. The Medical Equipment Management (MEM) begins with understanding the needs of the facility and ends with decommissioning. In between, the process consists of good procurement practices, appropriate donation solicitation and provision, logistics of delivery and installation, inventory management, maintenance, safe use and training, and measurement of clinical effectiveness.

But what about the MEM on the least developing country like Nepal. In spite of the hard work of the World Health Organization (WHO) health policies and guidance and the effort of ministry of health in every country, there are many challenges faced in managing the ME, most especially in the developing countries. Problems like longer downtime of equipment, hospital administrator’s inadequate knowledge on maintenance and service, absence or little budgetary support for maintenance, lack of the framework for auditing system, lack of knowledge and innovative ways of using new equipment, delayed fault reporting, difficulty in obtaining spare parts, failure to provide technical training to operators, obsolete equipment left unattended in maintenance room and wards, absence of information system on medical equipment’s for decision making.

Conclusion: ME provides many valuable services to support and enhance patient care, but its use is never without risk. While appreciating the benefits that ME can provide, healthcare providers and staff also should remain cognizant of potential safety issues. Medical equipment management strategies can help healthcare personnel proactively manage medical equipment.

02. Medical equipment management in hospitals

DESIGNING A MEDICAL EQUIPMENT DATABASE MANAGEMENT SYSTEM

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Objectives: The implementation of the design will efficiently improve the operations of health facilities, management of equipment immediately and continuously. The information can be used to increase health care facility profitability, improve audit accuracy, reviewing upcoming maintenance of medical equipment, and eliminate errors in manual processing (paper work) and hence improving the healthcare delivery to the public and hence the World Health Organisation (WHO) goal of having a healthy and happy population is achieved.

Methods: Equipment management is a very important issue for safety and cost in hospital operation. The use of an effective and efficient information system effectively improves the managing performance. The design of a Medical Equipment Database Management System (MEDBMS) used for better equipment management. The design incorporates the use of Local Area Network (LAN), internet or wireless network and consists of work order management, contract management, hospital equipment inventory management, equipment life-cycle management, breakdown maintenance and preventive maintenance (PM) among others. A user friendly web interface is available for secure and easy access to the system.

Results: The MEDBMS is used for improving on medical equipment management.

Lessons learnt: Medical equipment is a very important component of modern health services, but the related management or maintenance is particularly weak in the health centers. The growth in capabilities to manage or maintain medical equipment has lagged far behind the rate of deployment of equipment. In addition to the traditional operation performance in cost/efficient analysis and control are the important issues for using medical equipment in hospital. A medical equipment database management system has been designed to help the hospital technicians and health service providers early to confront the potential risks.

02. Medical equipment management in hospitals

A STUDY ON THE PROCUREMENT CLASSIFICATION OF MEDICAL EQUIPMENT BASED ON KRALJIC MODEL

By Zheng C., Zheng K., Shen Y., Wang L., Su C., Wu Y.

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At present, most hospitals still exercise extensive passive management of their procurement, lacking systematic procurement strategy. Procurement needs are not accurately assessed, and procurement is done at low efficiency as procurement decisions are mostly based on the purchase price while no systematic and individualized supervision is exercised over supplies and suppliers. To address those problems, this paper intends to establish a procurement classification model of medical equipment based on Kraljic model, which enables the purchasing personnel to adopt corresponding purchasing strategies according to different classification. Based on the profit impact dimension and the supply risk dimension of Kraljic model with the characteristics of medical equipment, the profit impact dimension can be divided into five assessment indicators which are purchase price, quantity of purchase, proportion of cost for consumables in the total purchase price, use rate and ratio of whole-life-cycle cost (for maintenance and repair) over the purchase price, while the supply risk dimension can be divided into four assessment indicators which are the number of potential suppliers, technical complexity, production capacity guarantee and time of delivery, then establishing the criteria system and determining the weight coefficient of each indicator by using the analytic hierarchy process, at this point the procurement classification model of medical equipment was established successfully. Finally, we selected 10 kinds of medical equipment to verify the effectiveness of the model. The result suggests the model can be applied to other medical equipment procurement, but more tests need to be conducted in real life.

02. Medical equipment management in hospitals

APPLICATION OF THE AHP METHOD IN THE PRIORITIZATION OF THE SELECTION CRITERIA OF THE CALIBRATION SERVICE PROVIDER

By Alves Dos Santos A., Souza W., Marciano M.

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To enable the validation of the consistency of the weights and measures of the selection criteria. Contribute so that the best qualified company performs the equipment calibration services. Maximize patient safety. The main objective is to choose the best service provider; that is, the most qualified to perform the calibration services of the medical-hospital equipment. Considering that the selection criteria and their weights will serve as reference for choosing the company that obtains the best score, the specific objectives are to prioritize, give weight and validate consistency of evaluation criteria (considering importance and relevance) for selection of service providers calibration of medical-hospital equipment. The method used was the AHP.

02. Medical equipment management in hospitals

PROPOSAL OF DIMENSIONING OF CLINICAL ENGINEERING TEAM OF THE HOSPITALS OF THE FEDERAL UNIVERSITY

By Frota Oliveira E., Valadares Oliveira E.J.

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To perform medical equipment management is necessary a technical and administrative team adequately sized to perform the services with quality. In the hospital environment, the Clinical Engineering is responsible for performing this management, and it is necessary to structure the team in a way that is appropriate to the reality of the institution. Considering the characteristics of public hospitals in Brazil, there is an environment that requires a different control by the Clinical Engineering because it is inserted in the scope of public contracting, which causes an increase of activities to be considered in the scope of the service. In this work, a sizing model was proposed that uses a calculation tool to carry out the personnel sizing for the Clinical Engineering team in University Public Hospitals of the Ebserh Company (Brazil), both to plan the structuring of new services and to evaluate if the services are properly sized to perform the activities defined in the scope. The proposed instrument was elaborated, taking into account the estimate of the demand of each activity assigned to the Clinical Engineering team and the estimated time to execute the activity. For this, some items were suggested to define the scope of the Clinical Engineering service and the processes related to the scope were mapped, which served as a reference to describe the main activities of responsibility of the Clinical Engineering team. Then, each activity was assigned to a team position and the time required to perform this activity was estimated, allowing the calculation of the required number of professionals for each position, taking into account the estimated time demand for its execution. The proposed model uses some variables that are linked to each of the activities in order to optimize the performance of the calculations, besides presenting a table with the reference parameters for estimating the quantity of service demand and estimating the time for execution of each activity. Thus, the construction of the instrument and the presentation of reference data will guide the professionals in the dimensioning of the team. With this, it is intended to base the Clinical Engineering professionals and managers with information necessary for the adequate planning of the team, avoiding a scenario that may result in inadequate contracting, causing damages to the quality of the services rendered and excessive expenses.

02. Medical equipment management in hospitals

AUTOMATIC DETECTION AND EVALUATION RESEARCH OF CT IMAGE PERFORMANCE BASED ON REMOTE QUALITY CONTROL

By Zhong Y.^[1], Liu J.^[2], Liu S.^[3], Jiao L.^[3], Yu X.^[3]

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Objective: The widely used detection method for CT image quality control is that human observers carry CT detection phantoms, and the quality of CT scan images was evaluated by subjective observation. This method usually brings artificial error. It is difficult to use for remote quality control and management of CT equipment and mutual recognition of CT images. In order to overcome the above disadvantages, and simplify the burdensome process of CT image detection, the paper studies automatic detection and remote assessment methods for CT image quality.

Method: The quality control phantom was scanned to automatically detect the CT value (water), noise, uniformity and low contrast resolution of the CT image, and compared with the traditional detection method. Among them, in the process of low contrast detectability (LCD) detection, because of the extremely close trend between noise and low contrast resolution, we analyzed and measured the low contrast resolution according to the noise. A method based on statistics was used to detect LCD automatically.

Results: According to experimental results, automatic detection methods of CT quality control indexes in this paper conform to conventional detection results.

Conclusion: Based on automatic measurement on CT image performance indexes, it is feasible to conduct more objective and accurate assessment on CT devices, reduce artificial errors and greatly enhance the work efficiency of CT quality control, and it provided a technical basis for remote quality control of CT images.

02. Medical equipment management in hospitals

DASHBOARD FOR QUALITY AND SAFETY ASSURANCE IN MULTIDISCIPLINARY LIFE CYCLE MANAGEMENT OF MEDICAL EQUIPMENT IN A HOSPITAL

By Kruis N.

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Assurance of quality and safe use of medical equipment should be performed through multidisciplinary life cycle management. Such multidisciplinary collaboration and risk-based medical equipment management in hospitals is relatively new. As a result, an overview of the state of health care technology infrastructure is missing, which limits the quality and safety while using medical equipment. The need for a multidisciplinary dashboard with clear information of the state of medical technology infrastructure has only grown since the government of The Netherlands introduced the covenant "safe use of medical technology in hospitals". Our aim is to determine which information about medical equipment is desirable for multidisciplinary life cycle management and to develop a dashboard based on that desired information.

To design information structures and visualize them in the dashboard, stakeholders were interviewed, current processes analysed and (potentially) available information of the medical equipment was listed. First results showed that the medical equipment management should indeed be more multidisciplinary than previously executed. Additionally, more information than currently available was desired to perform risk-based lifecycle management. Above all the available information had to be presented more clearly and be easier to access. This was made even more apparent during the first experiences with the dashboard.

Our multidisciplinary dashboard provides a clear overview of information about the state of medical equipment. The process of development was valuable in awareness of quality and safety assurance for medical equipment. Additionally, stakeholders became more aware of their responsibilities and are being reminded about it every time the dashboard is used. Therefore, development of such a dashboard contributes to the quality and safety assurance and awareness of medical equipment.

02. Medical equipment management in hospitals

IMPROVING WAREHOUSE EFFICIENCY VIA A QUANTITY MANAGEMENT SYSTEM OF SURGICAL SUPPLIES

By Wang H., Huang J., Huang W., Jin B., Yang S.

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The upgrading of surgical supplies has enhanced healthcare provider's ability and patients' outcomes. However, the locations of surgical instruments can be stored are limited and need associated costs, and the amounts to be purchased are often based on the surgeon's experience, rather than optimization methods based on accessed data. This means that there is a high risk of low service, insufficient safety stocks, stock-outs and high costs in hospital. In this research, we have classified the surgical supplies by the consumption data to determine how to stock and developed a qualitative and quantitative model to make the inventory decision. The main contributions of this study are: (1) Inventory ways were addressed heavily depending on the real-world data about different surgical instruments. (2) We provide a framework to solve the proposed artificial estimation uncertainty. (3) When the inventory decisions are based on this model, there were monthly RMB 200, 000 stock cost-savings. Meanwhile, the relative increase in clinician satisfaction was 3.08% and about fifteen percent monthly space-savings.

02. Medical equipment management in hospitals

IMPACTS OF ACTIVE COLLECTION FOR EQUIPMENT IN FULFILLMENT OF CALIBRATION AND PREVENTIVE MAINTENANCE SCHEDULES

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Perform preventive maintenance and calibration of medical equipment are practices that contribute to minimizing the probability of failure of equipment, but also contributes to increase the safety and effectiveness of the technologies used for diagnosis, treatment and therapy of patients in the hospital environment. Complying with the schedules of preventive maintenance and calibration are tasks not so simple, that among the variables are: the difficulties of finding the equipment, of liberation, of logistics (search and return of medical equipment), etc. Due to this scenario, this article demonstrates the proposal of the implementation of a logistic flow, carried out by an administrative professional, who collects and delivers the medical equipment according to the calibration and preventive maintenance schedules elaborated by the Clinical Engineering. With the purpose of proposing an evolution in the process, minimize the time of medical equipment stoppage, identify procedural obstructions, optimize the proposed schedule and promote social inclusion. The main objective of the work is to propose the implementation of an active search logistics flow of medical equipment, to enable compliance with the calibration schedule, preventive maintenance and minimize the downtime of medical equipment. And thus, as specific objectives: a) To expedite the transport of electromedical equipment for PM, Lime and even corrective maintenance; b) Centralize in a professional the logistics service of collection and delivery of equipment and materials by Clinical Engineering; c) Free the technicians of the demand of displacement to stay focused on the activities of maintenance and evaluation of equipment performance; d) Carry out the social inclusion of a professional with a disability (which has permanent limitations). From the preventive maintenance and calibration schedule, a detailed schedule was modelled to make possible a quick itinerary for the realization of the rounds, in the schedule add-ons were added as the place where the equipment is allocated.

02. Medical equipment management in hospitals

INSPECTION OF LEAD APRONS: PRACTICAL EXPERIENCE UNDER JCI STANDARDS

By Zhang J., Zhu F., Chu Y., Wang Z.

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Due to standards set forth by the Joint Commission, health care organizations must perform annual inspections on medical equipment lead aprons. We introduce standard operating procedure of inspecting lead aprons in our hospital. In order to reduce the failure rate of lead apron inspection and increase the service life of lead aprons, we give recommendations to both the manufactures and clinical users. In addition, we have proposed an electronic inspection system for lead apron, which can store the X-ray images and judges the conformity of lead aprons automatically.

02. Medical equipment management in hospitals

RESEARCH ON THE STATUS QUO OF TIME SYNCHRONIZATION OF MEDICAL EQUIPMENT AND SOLUTION TO THE PROBLEM

By Zhang J.

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Various problems caused by the unsynchronized time (clock) of medical equipment occur from time to time in medical behavior and have caused different degrees effects on medical activities .In particular , medical equipment related to life support and important diagnosis and treatment, problems due to asynchronization of time, can lead to errors in medical information exchange ,but more importantly ,it may lead to medical accidents, causes the patient to be disabled even the life threat and irreparable result. There is no specification and requirement for clock synchronization of medical devices. At present, domestic hospitals do not have a serious understanding of hospital clock synchronization generally, so there is no management process and norms for clock synchronization of medical equipment, and there is also a lack of solutions and equipment for this problem. This report is mainly aimed at the current situation of the medical device clocks in domestic hospitals and how to synchronize the clocks of medical devices.

Method 1: NTP time service server is used to time the equipment in the network through the hospital internal network. The premise of obtaining a standard clock on the Internet is that all devices to be calibrated need to be connected to the Internet. Because the hospital network belongs to the local area network, it is physically isolated from the Internet and the internal data inventory has a large number of sensitive private information of patients, so it is not appropriate to directly connect to the clock source outside the hospital for security reasons.

Method 2: Use the radio clock to unify the internal clock system of the hospital, and the clock system also can be synchronized by manual proofreading according to the management system.

Hospitals should select suitable schemes for implementation and assessment according to their own conditions and actual states. It also calls on the state administrative departments to promulgate policies and regulations in this regard, so that all hospitals could have laws and regulations to follow and implement. We will do a good job in every detail of medical services to ensure the safety of medical quality and protect the health of the people.

02. Medical equipment management in hospitals

RESEARCH ON MAINTENANCE MANAGEMENT OF EQUIPMENT OF MAGNETIC RESONANCE IMAGING BASED ON RAM

By **Chu C., Li B.**

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Purpose: To optimize the maintenance quality management of MRI equipment and ensure the quality and safety of its clinical use.

Approach: The data of failure time and repair time of an MRI equipment in three years were collected by magnetic resonance repair report system, developed by us, and then the Reliability, Availability and Maintainability (RAM) were studied and analyzed. Firstly, the trend test was carried out on the failure occurrence time and failure repair time data to verify whether these data were evenly distributed. Then, the optimal fitting distribution was carried out on the failure occurrence time and failure repair time data. Finally, the effectiveness of the preventive maintenance strategy was evaluated through the simulation of the actual system.

Findings: The results of reliability analysis show that the communication module is the key subsystem of the MRI equipment. The results of usability analysis show that RF module is a key subsystem of MRI equipment. Maintainability results showed that the proportion of the MRI equipment not fully utilized due to maintenance-related problems was 2.58%. In order to improve the availability of MRI equipment, the maintenance time of MRI equipment should be shortened. Value RAM-based analysis of MRI equipment can help hospital equipment managers to carry out the work of operation optimization, maintenance strategy formulation and safety management of MRI equipment.

02. Medical equipment management in hospitals

INVESTIGATION AND ANALYSIS OF GFIL INTERLOCK ON TRILOGY OF VARIAN MEDICAL LINEAR ACCELERATOR

By **Lu Q.**

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Objective: This paper attempts to measure the impact of the GFIL Interlock on daily operation of the Medical Linear Accelerator.

Methods: During the research on the GFIL Interlock of Varian Medical Linear Accelerator for over one year, the clinical medical Engineers were the main crew that conducted the research. And the experience sum-up method was adopted as the main method of this research. This research checked the 12 major categories of error information in the maintenance manual for details, reporting and analyzing the errors according to the data. Clinical medical engineers have a certain understanding of the working principle and schematic diagram of the equipment, and they can also give professional judgment on the status of the equipment. The main processing procedure is divided into two parts: the first part (fault analysis): estimate the status of the equipment, analyzing the cause of the failure; the second part (fault handling): carry out methods to deal with the fault in case of emergency and bring the fault under permanent control. Reviewing the whole process, although the study only recorded a single fault, in the course of more than one year of recording, some data information worth studying was found.

Results: This study found that the GFIL Interlock caused by the Hot Deck error message accounted for the majority, while the Gun Deck Fatal Error message did not appear or caused any down event. Throughout the whole research, the biggest challenge was about the limitations of the PCB board circuit diagram. Although the manufacturer provided the maintenance manual, some detailed circuit diagrams could not be obtained. The significance of this research is to improve the quality control management of medical equipment, reduce the equipment failure rate, and ensure that the equipment operates in an optimal state.

02. Medical equipment management in hospitals

RFID FOR CLINICAL ENGINEERING: EQUIPMENT MANAGEMENT OF A.O.U FEDERICO II

By **Matano M., D'Agostino G., Cantone A., Perrone A.**

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The project consists of a management and geolocation software of electromedical equipment in hospital facilities. The electromedicals are managed by the use of labels that incorporate a microchip. Through authentication on the SW, each user can access the information of an electromedical device (serial number, inventory number, model, functional and safety checks, maintenance). The labels affixed to the equipment have a memory microchip and a miniaturized antenna which transmit information about the equipment and their position to the SW. These can be programmed, storing the desired information within the microchip. From the equipment data inventoried in the SW it is possible to obtain the maintenance priority according to an index called EQUIPMENT MANAGEMENT. The index is obtained by considering 3 important factors such as function, risk factor and required maintenance of each machine, according to the following formula:

$EM = \text{Function} + \text{Risk} + \text{Maintenance}$.

The function of the equipment is divided into 4 categories: therapeutic, diagnostic, analytical and support. Each is assigned a number that expresses the risk for the patient connected to the use of the equipment. Assigned scores to therapy devices: support for life = 10, support for surgery = 9, treatment and physical therapy = 8; diagnosis devices: monitoring for surgery and intensive care = 7, physiological and diagnostic monitoring = 6; analysis devices: chemical-clinical analysis equipment = 5, laboratory accessories = 4; support devices: computer = 3, other = 2.

The physical risk is given by all the possible consequences for the patient or the operator as a result of an inconvenience or a malfunction of the equipment. The more serious the risk, the higher the value. Assigned scores to risk: patient death = 5, patient/operator damage = 4, incorrect diagnosis = 3, incorrect therapy = 2, not significant risk = 1. The required maintenance is spread over several levels, with the relative scores: high = 3, average = 2, minimum = 1.

The information in the SW is also necessary for the evaluation of the obsolescence of the machinery and for the programming of purchases and disposal operations. The SW also provides for the creation of a report on the costs related to the maintenance, purchase and disposal of the machines, to guarantee the traceability of the funds used and to have useful data for the General Management.

02. Medical equipment management in hospitals

QUALITY ASSESMENT OF THERAPEUTIC ULTRASOUNDS: RESULTS OF LEGAL METROLOGY FRAMEWORK FOR MEDICAL DEVICES

By **Gurbeta Pokvic L., Spahic L., Badnjevic A.**

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Prominent use of medical devices in health care demands them to be fit for purpose and in their best functioning capacity throughout the entire implementation lifespan. Biomedical engineers inspect and verify the functionality of all medical devices, those used for diagnosis and disease treatment. Emphasis in safety aspect is put on medical devices used for treatment, such as therapeutic ultrasounds. Therapeutic ultrasounds emit ultrasonic waves of varying intensity depending on the therapeutic purpose and utilization of these waves in medicine varies from muscle stimulation and tissue regeneration to cancer cell eradication. The constant development and widening of the usage scope of these devices requires an effective mechanism for their quality assessment. The legal metrology framework designed, implemented and tested in Bosnia and Herzegovina has proven itself as an effective mechanism for both quality insurance and cost-effective maintenance of therapeutic ultrasounds. Since the first year of implementation of the framework, the amount of inspected therapeutic ultrasounds is constantly increasing and the ration between accurate and faulty devices is in constant decline which proves the effectiveness of this method.

02. Medical equipment management in hospitals

A MULTI-PLATFORM INFORMATION MANAGEMENT SYSTEM OF TOTAL LIFE CYCLE FOR MEDICAL EQUIPMENT

By Huang E., Xie W.

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Objective: To establish a total life cycle information management system for medical equipment based on the actual situation of our hospital. **Methods:** In accordance with the definition of the total life cycle for the medical equipment, the function modules were designed and distributed according to different staff posts, and then implemented on the WeChat public account-a series of APIs and services to develop custom features, mobile App and computer web browser. **Results:** After the implementation of the system, it can cover a series of management stages of the whole life cycle for medical equipment, and the information exchange among various stages. The relevant staff in different posts can operate the medical equipment management information on three platforms. **Conclusion:** After the implementation of the system, staffs in various posts setting about medical equipment management are facilitated, the efficiency of management has been improved, and medical behaviors and patient safety are guaranteed.

02. Medical equipment management in hospitals

IMPLEMENTING A PROGRAM TO SHARE USER EXPERIENCE DATA FOR MEDICAL DEVICES

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ECRI Institute developed a program to repeatedly produce usability and maintenance data to add depth to health technology product evaluations. We surveyed clinicians and Health Technology Management (HTM) professionals who use specific products and graphically communicate aggregated responses, providing additional information to help readers make data-based purchasing decisions.

This presentation summarizes the process we used to create and implement our user experience data collection program. Since different stakeholders have different perspectives and priorities given their distinct roles, we developed different surveys to solicit information from clinical end-users and health technology management (HTM) personnel. We also established procedures to process results and generate graphics to display the information. In addition to sharing our design goals and outlining our approach to quality control, we will share some of the lessons we learned, which may be useful for human factors practitioners who are interested in gathering usability and technology management data about other products.

Our main objective was to develop a program that would repeatedly produce usability and maintenance data that would add depth to our health technology product evaluations. Our concept was to gather feedback from people who had interacted with specific products and graphically communicate aggregated responses, providing additional information to help readers make data-based purchasing decisions. We had three high-level goals for this program: 1) ensuring users could provide feedback quickly and easily, 2) presenting response data using simple, intuitive graphics, and 3) establishing a reusable framework that makes it easy to collect and report user experience data for different types of health technologies. These high-level goals were broken down into three sets of program design sub-goals, which were refined over the course of developing our program.

02. Medical equipment management in hospitals

PERFORMANCE EVALUATION OF CES: IDENTIFICATION AND MEASUREMENT OF KPIS WITH PARETO DIAGRAMS

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In recent times the approach to health care has been mostly influenced by the growing number of biomedical equipment used in hospitals which needs the presence of the Clinical Engineering Service (CES). The aim of this work is to provide a performance evaluation of the CES that works within the UCBM University Hospital through the application of Pareto Diagrams. This evaluation is done by focusing on the use of KPIs, key performance indicators that represent a quantifiable measure of achieving goals set by an organization. In this study 5 KPIs are considered: Uptime, MTTR (mean time to repairs), MTBF (mean time between failures), PPM (percentage preventive maintenance) and the COSR (cost of service ratio). The first four indicators express the measure of CES's efficiency in ensuring regular maintenance; the COSR is an economic indicator.

The first step consists in the extrapolation of the data related to work orders for the years 2015-2016 on a total of 6000 installed devices, carried out by a management software, called Infohealth. Starting from Excel data extrapolated by Infohealth, the second step is to get the results through the use of an environment for numerical calculation and statistical analysis, called Matlab. In order to identify the critical issues that may be present, the first three indicators (Uptime, MTTR and MTBF) are analyzed by applying the Pareto principle. It shows that 20% of the causes produce 80% of the effects. Considering the totality of medical equipment, therefore, it is possible to concentrate on only 20% of them in order to focus on a small group of medical devices to understand the correlations between them. Identifying these characteristics means identifying the main critical issues that are present, on which action must be taken, and which affect 80% of the overall behavior. The COSR and PPM indicators, instead, suggest distribution models that allow to focus attention on the most critical devices.

In conclusion, the key issue in successful management of outsourcing contract is to measure the performance of outsourcing service provider's, to ensure that all the agreed outcomes are achieved. The way to analyze the results obtained is, when possible, using Pareto diagrams. We will be able to find the real reasons of failure and improve performance. The achievement of these results could allow the standardization of the method used, enabling it to be applied to any healthcare system.

02. Medical equipment management in hospitals

BENCHMARKING FOR THE CONTRACTING OF MEDICAL EQUIPMENT MAINTENANCE SERVICES IN EBSERH'S FEDERAL UNIVERSITY HOSPITALS

By **Valadares Oliveira E.J.^[1]**, **Vieira Frondana F.^[2]**, **Lima D.^[3]**, **Amorin V.^[4]**, **Pimentel E.^[5]**, **Zucchi R.^[6]**, **Ferreira Filho J.A.^[7]**, **De Castro Vivas G.^[8]**

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The Brazilian Company of Hospital Services (Ebserh), is responsible for the management of 40 Federal University Hospitals (HUF). When it took over the control of these hospitals, the number of professionals trained in clinical engineering was incipient. Thus, with the creation of this public company, clinical engineers were added to the HUF staff.

Since most HUFs do not have medical equipment maintenance technicians, test instruments, and spare parts management systems, it has become necessary to develop an approach capable of allowing an adequate execution of maintenance program. This approach consisted of hiring medical equipment maintenance companies to operate within hospitals under the supervision of its Clinical Engineering. To do so, it began with the collection of information on maintenance contracts already existing at Ebserh's hospitals. Then, based on the contracting documentation: terms of reference, legal assessment, and requests for information in the bids, the definition of the best practices for hiring these services was attempted. Thus, from the 15 existing contracts, two were selected considering the highest values and one the lowest value.

After the analysis in the light of the best hiring practices, it was established a model for contracting of medical equipment maintenance services. The most significant difficulties in the elaboration of the instrument lie in the definition of parameters such as the composition of costs; indirect expenses; metrological requirements, adequate financial reserve value.

Preliminary data from one of Ebserh's hospitals, the Clinical Hospital of the Federal University of Minas Gerais, indicate that a clear definition of contracting parameters has the potential to promote cost reduction of 30% per year. Besides the financial and qualitative gain, the establishment of a robust instrument will allow to qualify the market and align the best practices of Clinical Engineering to the conformity regulations of the Federal Public Administration.

02. Medical equipment management in hospitals

CLINICAL ENGINEERING PROCESS AND OPERATION MANUAL: BEST PRACTICES AT EBSEERH

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The Brazilian Company of Hospital Services (Ebserh), is responsible for the management of 40 federal university hospitals (HUF). When it took over the control of these hospitals, the number of clinical engineers was incipient. One of the challenges of the modernization process of management in clinical engineering is the development of methodologies and work procedures that promote a higher quality of medical technology management without increasing current expenditures or, preferably, reducing them.

The lack of definition of operational standards and indicators that allow monitoring the performance of clinical engineering actions stimulated the creation of the “Process and practice manual in clinical engineering.” To ensure the quality of this work and the achievement of relevant results for the HUF, we sought: sponsorship of HUF governance; commitment of direct managers and their superiors; involvement of the multidisciplinary team (actors, clients, and stakeholders).

The development of the project took place in four stages. The first one was the modelling and development of the manual, considering the best clinical engineering practices developed at Ebserh HUF. The second stage was the implementation of the pilot in four HUF. Lastly, was the replication of the model in other hospitals of Ebserh HUF network. Up to December 2018, we achieved the following results:

1. The conception of the Best Practice Manual;
2. Definition of 35 indicators for CE operation in the FUH;
3. Description of Ebserh’s CE Dashboard for the collection, integration, analysis, and presentation of business information (CE – Dashboard).

As preliminary operational results, we were able to observe in the first five FUH, significant improvement in their operational processes, as well as optimization of public spending:

1. Optimization of federal expenditure by optimizing the installation process of 120 boxed medical equipment (estimated value of US \$ 2 million) – 5 FUH;
2. Improvement in the acquisition processes allowing the five initial FUH, save up to of US\$ 2.5 million;
3. Quantify and value CE efforts and empirically demonstrate to the stakeholders its importance for the FUH.

Thus, the implementation of HUF clinical engineering best practices can optimize the application of hospital resources, improve patient health care, and empirically demonstrate the importance of clinical engineering in the HUF.

02. Medical equipment management in hospitals

INVESTIGATION OF CLINICAL ENGINEERING SERVICES IN SOUTH AFRICA USING AAMI & CMBES GUIDELINES. (CASE STUDY ON KWA-ZULU NATAL PROVINCE, SOUTH AFRICA)

By Mulhanga F.^[1], Khalaf A.^[2]

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The growing complexity of healthcare organizations’ diverse equipment needs, rapid technology development, and organization-wide use of patient care equipment have made this expanding role for clinical engineering/health technology management both inevitable and necessary. The equipment-related “Environment of Care” standards of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) emphasize the importance of an effective technology management program, which can be cost-effectively implemented and managed by a comprehensive clinical engineering program. Standards in the Joint Commission’s 1995 Accreditation Manual for Hospitals require that a hospital’s equipment management program include provisions for user training, equipment-inclusion criteria, incident analysis, scheduled maintenance procedures, incoming inspections, equipment emergency plans, and assessments of the program’s overall effectiveness. This work aims to measure the degree of compliance with the AAMI/CMBES guidelines with emphasis on maintenance of medical equipment in Kwa-Zulu Natal (KZN) province in South Africa.

02. Medical equipment management in hospitals

DISCUSSION OF CHARGED MEDICAL CONSUMABLES MANAGEMENT IN OUR HOSPITAL

By **Chen C.**

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Purpose: Against problems with charged medical consumables, this paper explored the management mode of medical consumables under the new medical reform. **Method:** The paper expounded the management process of charged medical consumables in our hospital, from dictionary maintenance, warehouse management, clinic use and reimbursement charges. And some problems of management were discussed. **Results:** Combined the problems in the management of consumables, countermeasures were formulated in terms of business learning, management systems, policies and regulations, etc. **Conclusion:** Charged medical consumables were the focus of consumables management. In order to better serve the clinical, it is necessary to multi-sector cooperate and strengthen management level.

02. Medical equipment management in hospitals

EVALUATION RESEARCH ON THE DEPLOYMENT AND UTILIZATION OF EMERGENCY EQUIPMENT IN HOSPITAL

By **Zheng Y.^[1], Luo L.^[1], Chen Y.^[2]**

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Objective: Describe and evaluate the status of emergency devices deployment in city municipal hospitals by collecting the data of emergency devices equipped in hospitals. Based on the exploration of emergency equipment usage condition collection method, it develops more scientific and reasonable resource allocation method. **Methods:** Issued questionnaires to the emergency department management team and equipment management department team of 33 Level 2A and above hospitals in Shanghai. The effective return-rate was 84.8%. Obtained the equipping data of 12 types of emergency equipment including invasive respiration, infusion pump, ECMO, etc. At the same time, the Internet of things technology was used to select 40 ventilators from 5 city municipal hospitals of different levels in Shanghai to build a system platform, initiated the utilization rate data collection ventilators, and conduct real-time statistics and analysis on the operation process and equipment status of ventilators. 20 ventilators and monitors were sampled from 14 hospitals by leveraging Shanghai medical equipment quality control platform. The field application of emergency equipment was investigated to obtain the equipment maintenance status. **Results:** The aging rate analysis of emergency devices was found that invasive ventilator and monitor were used for a longer time. The ones of women's and children's hospitals is relatively old. The emergency devices of hospital emergency room is relatively old by comparing with the ones in EICU. The working hours of ventilators in general hospitals are longer than those in Level 2 hospitals and Level 3 suburban hospitals. The annual maintenance report of emergency equipment provided by some medical equipment maintenance service institutions to hospitals needs to be improved. **Conclusions:** Increasing financial investment on the emergency equipment such as ventilator and monitor and enhance the organic integration of the clinical engineering and information technology, building up the emergency medical equipment Internet of things in hospitals and united hospitals, to keep the premise of ensuring safe and effective, and monitoring emergency equipment operation, so as to achieve the purpose of the efficient use of financial funds and the post-performance evaluation and management.

02. Medical equipment management in hospitals

FEASIBILITY STUDY OF A COLLABORATIVE MEDICAL DEVICE NON-CRITICAL SPARE-PARTS DATABASE

By Gaudiard T.

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In the context where medical devices suppliers and manufacturers don't always have satisfactory solutions in many maintenance cases involving spare parts (such as: no more after-sales service with still operating old MD, sale of complete kits instead of single spare parts, overpricing spare parts...), and considering also the constraints of maintenance workshop in hospitals such as limited storage capacity and lengthy delivery times, 3Dprinting for MD spare parts seems to be a valuable solution for biomedical maintenance teams.

Many biomedical maintenance workshops in hospitals already use this technology but in a stand-alone way and have built or adapted several non-critical spare parts from their own with 3D printers. Considering that hospitals have common suppliers, and thus common maintenance issues, the main idea of this project is to analyze the feasibility to launch a collaborative 3D models database for non-critical spare parts that every biomedical workshop can use and develop as a registered user regarding mostly an analysis of the technical needs, the risk management, and legal aspects exploring regulatory loopholes. In 2018, the French Association of Biomedical Engineers (AFIB) started to finance internships for engineering students aiming to develop projects and tools in order to enhance the profession. This project was selected and financed because of its transversality with every one of the hospital biomedical maintenance issues.

Guillaume Bols, material student engineer is spending his 6 months engineering internship in Aix-en-Provence Hospital and is mentored by senior biomedical engineers, Joël Delode and Thomas Gaudiard. The study relies on AFIB's network and the results will lead to a publication in the scientific IRBM News review, and hopefully to the decision of launching the collaborative database.

In addition to the database feasibility, this study also explores the aspects of the online database ergonomics, and the integration of 3D spare parts modelling and printing functions in biomedical maintenance teams. 3D models may be obtained from CT scanner pictures, from online services provided to users and from MD manufacturers that could sell their original spare parts 3D models online.

This project is currently led in France but if the success is obtained, we could easily imagine spreading it worldwide and especially where equipment inventory is mainly obsolete and heterogeneous.

02. Medical equipment management in hospitals

SCHEDULED MAINTENANCE OF ELECTRO-MEDICAL EQUIPMENT

By Marchi D., Iadanza E.

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The Misericordia di Firenze is the oldest private humanitarian no profit voluntary organization in the world (founded in 1244); nowadays it offers specialized healthcare services, including ambulance emergency services and private assistance during surgeries. The internal preventive and corrective maintenance program is assigned to an external company, that carries out various activities including: Clinical Engineering services, Risk Management support, Health Technology Assessment (HTA), training and many others. Regular scheduled inspections, preventive maintenance and calibration of diagnostic and therapeutic devices as well as of other equipment are performed. The company carries on verification activities through a detailed program of the adopted methods and tools (planning of management activities, presence of calibrated and certified measurement tools, activity monitoring) and an equally specific list of tests carried on with clear indications about results, the so-called Functional protocol. So far, general Description functional protocols have been drawn up, relating to an entire equipment type, without taking into account potential specific requirements coming from the manufacturer for the maintenance one specific device model compared to others, because not all instrumentation is equipped with manuals. The goal was to fill this gap to ensure a more complete maintenance and to provide accurate checks even when information is not exhaustive. The method used was the following: design functional protocols for those electro-medical devices lacking technical documentation, taking into account that some models were provided with complete documentation (User and Service Manuals), while others just owned User Manual or had nothing at all. The final result was therefore to implement functional checks of these devices, thus helping to ensure an increasingly global and at the same time specific prevention system. This also ensures a higher safety and continuous efficiency over time, providing a benefit both to technical staff and to operators, but especially to the patients.

02. Medical equipment management in hospitals

ADVANTAGES OF A REGIONAL CLINICAL ENGINEERING SERVICE MODEL

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In the late 90s the Clinical Engineering (CE) department at the Children Hospital of Eastern Ontario (CHEO), in Ottawa, Ontario, Canada was only composed of six staff including the department head. This team was responsible for the maintenance of the general clinical equipment at the hospital and in five other community health centers. No Clinical Engineers were on staff to help the medical equipment acquisition process and there was limited support for high end technology used in Medical Imaging and the Laboratories. In Canada, few regions have sufficient population density to demand large sized healthcare facilities that can support comprehensive Clinical Engineering Service. CE Departments in community hospitals are often comprised of only 1 or 2 technologists. CHEO's CE services were marketed within the Eastern Ontario region, resulting in 13 healthcare facilities opting for shared CE service which created a revenue generating opportunity. Offering regional services provided a win-win situation where smaller community hospitals didn't need to manage 1 to 2-person departments or manage a large number of service contracts. The service offered competitive rates charging more than an in-house person, but substantially less than Original Equipment Manufacturer (OEM) contract pricing. Revenue generation enabled investment in staff and equipment to group its service offering to its clinical partners in the region. CHEO's clinical engineering service now provides services to 18 hospitals at 25 sites within its catchment area of 19,205 sq. km. and now boasts a staff of 5 clinical engineers including its Director and 25 Biomedical Engineering Technologists. They now are also able to offer CE professional support and specialized technical support for Medical Imaging, Anaesthesia and Laboratories throughout the region. All of these medium to small healthcare facilities now benefit from this resource normally only seen at larger acute care hospitals. Other collateral benefits that have resulted from the development of this regional model include support mechanisms to two local university Biomedical Engineering programs, the creation of a local graduate CE program and academic research activities resulting from the synergies of the involvement of CE with the two local universities.

02. Medical equipment management in hospitals

THE SPECIAL INFLUENCES OF LOCAL ATMOSPHERIC FACTORS IN TIBET ON THE USE AND MANAGEMENT OF MEDICAL INSTRUMENTS

By Xu X.^[1], Zheng Y.^[1], Pingcuo Z.^[2], Ma X.^[2]

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Background: It has been found that in Tibet some medical instruments are never used after procurement or serve much shorter than the designed life due to the influences of the local atmospheric factors.

Goals: This research was designed and conducted to 1) investigate and survey medical instruments affected by local atmospheric in Tibet; 2) summarize the special influences of atmospheric factors in Tibet on the use and management of medical instruments; 3) give suggestions and countermeasures to eliminate the influences. Hospitals in Tibet will benefit from the research by avoiding waste of medical resources via selecting applicable medical instruments and achieving better use and management, while the manufactures will also benefit by designing and producing medical instruments applicable in Tibet.

Methods: A questionnaire is designed to collect medical instruments affected by local atmospheric factors and the consequences result from the influences. Then according to the analysis of the collected data, we concluded and classified the influences, and gave the suggestions and took countermeasures to eliminate the influences.

Conclusions:

1. The atmospheric factors including low atmospheric pressure, low oxygen partial pressure and low gas density in Tibet have impacts on the use and management of various medical instruments such as ventilator, negative pressure aspirator, oxygen generator, air compressor, etc.
2. The impact of the atmospheric factor on the medical devices can be eliminated or avoided through reasonable product design.
3. In order to adapt to local patients' physiological conditions, the parameter settings are different from that working in low-altitude areas.

Suggestions and countermeasures:

1. When selecting medical equipment, hospitals in Tibet should fully consider the influences of local factors. Corresponding clauses are added in bidding document and contract to avoid purchasing instruments inapplicable.
2. Manufacturers should be required to provide specific training suitable for local service staff and patients, and adjust the parameter settings to status more suitable for local conditions. A corresponding part has been added to inspection and training documents.
3. Manufacturers of medical instruments should cooperate with Tibetan hospitals to fully consider various local factors during the design and production of products.

02. Medical equipment management in hospitals

ROLE OF REGIONAL QC CENTER IN MEDICAL EQUIPMENT MANAGEMENT QUALITY

By Li B., Zheng Y., Wang L.

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Purpose: The project is to introduce the system and achievement of Shanghai Medical Equipment Management Quality Control Center (MDMQCC). MDMQCC's goal is to improve the management of hospital MD in Shanghai, to enhance safety & effectiveness of MD, and to enhance CE academic status.

Methods: Shanghai Medical Equipment Management Quality Control Center (MDMQCC) was setup by Shanghai MOH in 2005. It is responsible to supervise MD management of 122 top hospitals in Shanghai. It is the first QC center for MD management in China. The 19 committee members and more than 40 CE experts of the MDQCC come from the CE dept. of 18 top hospitals in Shanghai. The MDMQCC team have setup 2-level QC network, 12 MD management demonstrating hospitals, 240 QC administrators among over 122 hospitals. Our duties include standards establishing, training, on-site inspection, evaluation of CT and MR, website building, communication among hospitals, manufactures and government etc.

One of our important innovations was to start an investigation of after-sale Service Quality of MD Manufacturers in Shanghai area in 2007. The investigation covered 17 categories and more than 50 brands of medical equipment after-sales service. According to the satisfaction survey results of each manufacturer's service, MDMQCC makes annual ranking and awards for them. The project for 11 years, has achieved National Hospital Technology Innovation awards in 2011. At present, the project has been extended to more than 20 provinces in China, and has made outstanding contributions in improving the quality of MD after-sales service.

Results: After 14 years of concerted efforts by MDMQCC, the management level of hospitals at all levels has been improved, and the safety and effectiveness of the use of medical devices have been improved. The standard contract has been adopted by over 95% hospitals in Shanghai. The 240 QC administrators share, communicate and consult on this platform. Numerous data are uploaded to our website. The MDQCC mode is being adopted by 15 provinces in China in recent year.

Conclusions: MD management QC center plays an important role for hospitals, manufactures and government.

MD management QC center can do the assessment of service and MD product of manufactures and collect market information for the local health bureau.

02. Medical equipment management in hospitals

CLINICAL ENGINEERS ROLE IN SAUDI HOSPITALS

By Alharbi N.

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What does a clinical engineer (medical equipment management) do in hospitals? It is known that medical engineering is a link between medicine and engineering, an emerging science that arose because of its need. The presence of medical engineering is vital and necessary in the health institution and hospitals, because the medical and systemic techniques in the development of permanent and continuous and surrounds the patient and medical staff from all sides, which requires awareness to use and maintain it, and monitor the safety and quality, and because it cost institutions and governments amounts of money is an experience Doctor, engineer and administrative alike to deal with. The medical engineer in the hospital has different responsibilities in the companies. In the hospital, he is required to know all the medical devices and techniques in terms of operation and maintenance. In the companies, he is required to know the devices that are marketing them and sell them only, not all of them. However, in the hospital, medical engineers are divided into several sections, for example, an engineer in charge of laboratory equipment, another engineer in charge of operating room equipment, and a third engineer in charge of the emergency equipment. In this regard, I would like to clarify what he is doing in the hospital.

1. Periodic follow-up to ensure the quality and functioning of medical devices in the hospital (PPM): The medical engineer has a list of dates and times for all the devices to be inspected in his hands. The periodic inspection method, PPM = Preventive Protective Maintenance, is used to inspect the equipment in all the departments responsible for it, with other measuring instruments and equipment called Test Equipment. Some devices are checked once a year, and some devices are checked twice a year. Some devices are checked monthly and some are weekly and some must be checked daily. There are several things that determine the number of times the test, including the number of times the use of important devices, which examine patients daily is checked every day, for example, user manual and manufacturer decides the number of times the annual inspection of the devices to ensure the quality of its work. In the event that the method of detecting the devices revealed an actual defect, there are ways to deal with them in the attached file.

02. Medical equipment management in hospitals

CONTRIBUTING TO THE DEVELOPMENT OF CE IN PERU - SUCCESS CASE IN AUNA

By Vidal M.^[1], Prietto M.D.R.^[2], Mochcco J.^[1], Ramos S.^[1]

^[1] AUNA - ASPIC, LIMA, Peru, ^[2] Peru

Contributing to the development of Clinical Engineering in Peru: Success case in AUNA Peru, located in the continent of South America, has a population of 32 million inhabitants. It has 22,000 public and private healthcare facilities; the last ones represent the 60% (13,230) and are managed by corporate groups or single companies. One of the most important private groups is AUNA, founded in 2010. AUNA is a Group of medical center and private hospitals which main purpose is to transform the healthcare experience. Currently, it has 6 private hospitals and 7 medical centers. In its beginnings, the C- suite's main needs related to medical equipment were to develop an area that:

- develops the guidelines, standards for the control of the medical equipment (Evaluation, Planning, Acquisition, Reception and Maintenance) and to ensure that all the medical equipment were available and in their optimal operating parameters for patient care,
- manage CAPEX and OPEX cost efficient and with advantageous conditions over the competitors (savings),
- guarantees the success of the Projects (design and implementation of medical centers and clinics),
- complies with regulatory bodies.

To cover those needs, it was created the Clinical Engineering area with the following mission: to manage Medical Equipment Technology through the Evaluation, Planning, Acquisition, Reception and Maintenance process in order to ensure quality care at reasonable costs in all Business Units and Projects of AUNA. Nowadays it counts with 15 people and manage \$35 million USD in medical equipment. In almost 9 years it has achieved:

- Being a key support and strategic area, a source of relevant information for decision making (C-Suite),
- To have a structure, processes and people that meet and understand AUNA's needs (patient safety, profitability and future),
- Strengthening the service level of medical equipment suppliers in Peru which contributes with development of other CE areas.
- Raise the CE profession.

In order to contribute with the development of CE Peru (not only in the private sector), some of the members of the CE area decided to create the Peruvian Association of Clinical Engineers (ASPIC) by the end of 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 presented.

02. Medical equipment management in hospitals

AN ASSESSMENT MODEL FOR REASONABLE QUANTITY EVALUATION OF EMERGENCY EQUIPMENT IN A HOSPITAL

By Sun J., Wen X., Zhang Q., Feng J.

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Purpose: Due to the lack of an assessment model for reasonable quantity evaluation of emergency equipment in hospitals, a contradiction occurs especially when supply in the Emergency Equipment Supply Center (EESC) cannot satisfy clinical departments. This study aims to establish an assessment model for reasonable quantity evaluation of emergency equipment in our hospital based on historical data. **Methods:** Data of the ECG monitor over 2011 to 2017 was analyzed to acquire the compound annual growth rate (CAGR) values of the ECG monitor quantity in the EESC and clinical departments, the maximum lease quantity, the maximum need quantity and ECG monitor quantity in the whole hospital. The equation we adopted is: $CAGR \text{ value } (\alpha) = \left(\frac{\text{the ECG monitor quantity in year } n-1}{\text{the ECG monitor quantity in 2011}} \right)^{\frac{1}{n-2011}} - 1$. The assessment model for reasonable quantity evaluation of emergency equipment was then established based on the CAGR values. The number of ECG monitor in the nth year \approx (the number in 2011) * $(1 + \alpha)^{(n-2011)}$. We verified the model's effectiveness by comparing the actual values and predictive values of ECG monitor quantity in 2018. Predictive values of ECG monitor quantity in 2019 were then obtained. **Results:** The CAGR values of ECG monitor quantity in the EESC and clinical departments, the maximum lease quantity, the maximum need quantity and ECG monitor quantity in the whole hospital are 17.7%, 5.4%, 5.5%, 5.5%, and 8.7%, respectively. Predictive values of ECG monitor quantity in 2018 were 417, 688, 681, 1369 and 1095, respectively, indicating good relevance with actual values. Predictive values of those in 2019 were then obtained as 468, 748, 740, 1488 and 1205, respectively. **Discussions:** The assessment model for reasonable quantity evaluation of emergency equipment can facilitate the budget-making of ECG monitors, and provide decision-making basis for rational allocation of other medical equipment. Application of this model can benefit hospitals of cost control and circulation efficiency improvement of medical equipment, finally improving the work efficiency of clinical departments. The assessment

02. Medical equipment management in hospitals

MGTB: A NEW QUALITY AND SUSTAINABILITY HTM MODEL FOR MIDDLE INCOME COUNTRIES HOSPITALS

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There are a variety of accreditation systems in the world, focuses on facilitating sustainable improvements in health service for the patient's safety and quality care. Medical equipment has a important role in this system. The Colombian quality system is new and includes several methodological elements to assess the quality. Nonetheless, is difficult for hospitals to achieve the accreditation due to the lack of appropriate medical technology management models. The aim of this project is to develop MGTB model, a new quality and sustainability healthcare technology management (HTM) model for middle income country hospitals. MGTB model include characteristics and process that it becomes a dynamic tool allowing an improvement in the medical equipment management in terms of quality and safety. MGTB was designed based on the identification of the best practices in HTM. The model includes as a novelty a corporate and technological strategies, an hospital intelligence process and an internal-external technological surveillance tools. It also incorporates technology assessment tools evidence based, a cost-analysis and technological benchmarking tools, quality indicators and others elements. MGTB model was validated through the acquisition process of high-cost medical equipment in a Pediatric Hospital in Medellín city. An operating microscope for surgical procedures of otolaryngology and pediatric neurosurgery was selected to test the model during six months. The results achieved show that the model served as a tool for the incorporation new technologies, from planning to use with patients. Before MGTB Model, the budget allocated was \$ US 250.000. As a result of the implementation allowed the execution of this project in \$ US 130.000, reaching a savings of approximately \$ US 120.000, showing a significant contribution to financial sustainability. The result of this validation is compared with the evaluation parameters specified by the ICONTEC (Colombia Accreditation Institute) for the HTM standards. Thus, according to the scoring for accreditation in Colombia, which is set on a scale from one to five, the model qualifies for a scoring of four; hence, it can be stated that the hospital's biomedical technology management will be improved. The implementation of the MGTB model showed that it is a novel and appropriate tool to improve the quality, safety and sustainability hospitals that are in accreditation processes in middle income countries.

02. Medical equipment management in hospitals

DESIGN OF A MANAGEMENT MODEL FOR THE PRIORITIZATION OF BIOMEDICAL TECHNOLOGICAL INVESTMENTS AND FOR THE TRANSFER OF CLINICAL ACTIVITIES INSIDE A NEW HOSPITAL

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Hospital realities are more often characterised by a huge and complex set of devices. These devices need peculiar instruments to guarantee appropriate management to maintain a high technological level and reach the clinical efficiency goals and correct usage of the available economic resources. In this work has been developed an innovative management analytical tool. The high flexibility of this tool allows supporting the decision makers both in the definition of technologies replacement priority, such as the classic RPV (Replacement Priority Value) instrument and in the choice due to the need of shifting whole buildings or hospital wards. The model is based on a linear mathematical relation, like a weighted sum, which consists of parameters and their associated multiplying factors (weights). These parameters allow to analyse the devices onto different aspect (i.e. technical, functional, economical, etc.); while the weights, which are found by using the Analytic Hierarchy Process multicriteria method, define a hierarchic scale for each factor. The followed design logic allows to use data belonging to a hospital reality (such as inventory data or data computed by other management software) and to combine them with data from questionnaires developed ad hoc for the case study. The output is optimised by using MATLAB scripts (developed particularly for this study) which allow to speed and automatize the calculation process, also giving flexibility at the model in the redefinition of the value of the weights based on the boundary conditions. The tool has been tested and implemented for both the renewal of the entire devices set of the Udine's hospital, and the drawing of a better transfer plan of the technologies belonging to the department of women's and children's health. The obtained results highlight the most critical technologies under two points of view: a technical-performance profile and an inconvenient transfer plan. In conclusion, the suggested model is a valuable management instrument in support of clinical engineering service, but also it can be used to achieve both personal and public goals taking in consideration the money saving (for example investment plans).

02. Medical equipment management in hospitals

A NOVEL COMPUTER-AIDED FACILITY MANAGEMENT SYSTEM

By **Iadanza E., Luschi A.**

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Computer Aided Facility Management (CAFM) systems are decision-support tools based upon Integrated Healthcare Facility Management Models (IHFMM) which provide indexes on those processes that can affect the performance of the healthcare structure. These tools can be very useful both for the hospital top managers and for the technical managers, such as the clinical engineers, for performance and risk analysis, business analytics and process optimization.

This work presents a CAFM system in which the main module is designed to manage and analyze digital plans of hospital buildings, coded on specific layers. The coordinates for each room are extracted from DXF files and stored into a database. SVG maps are then created starting from these data. This allows the software to be unbounded to any external CAD system. Room is therefore the elementary unit of information. The database is connected to other existing databases, such as the clinical engineering equipment inventory and the personnel roster, therefore enriching the core information for each room and becoming a central dashboard. The outputs can be used as a decision-support tool in order to improve hospital's structure and organization and to reduce major workflow risks.

The system is capable of managing a large amount of data, providing users with information about the analyzed rooms, such as room code, destination of use, medical or technical department, risk class, surface, height, volume, number of beds, personnel, assets and medical devices.

On top of the main core module, a dedicated web interface lets the end-user manage the aggregated data, in order to simply analyze different scenarios and make faster decisions.

The web interface is fully HTML5 compliant, with a Javascript client framework which interacts with RESTful Web APIs coded within Microsoft .NET 4.5 Framework and mapped to the tables of the linked main MS SQL database through Entity Framework.

A fully integrated full-text search engine is also available which offers a user-friendly access to the main database. It also offers a dynamic reporting functionality to print PDF reports based upon the search results.

The system is currently fully operating in real world healthcare scenarios. The RESTful architecture of the system allows additional custom modules to be designed and easily be put in communications. This allows creating additional features which provide a more completed analysis in relation to specific needs and workflows.

02. Medical equipment management in hospitals

INITIAL QUALIFICATION SCORE OF A MEDICAL DEVICE IN A HOSPITAL ENVIRONMENT: AN EMPIRICAL APPROACH

By **Houessouvo R.^[1], Medenou D.^[1], Idjiwole F.^[1], Piaggio D.^[2], Pecchia L.^[2], Ahouandjinou M.H.^[1], Monteiro G.^[1], Kinnouezan C.D.^[1], Idrissou M.^[1]**

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Medical devices exploitation in a developing country health system is characterized by frequent malfunctions or very disturbed operations. This is a reality in many hospitals in the South Sahara African Countries. This work proposed a method for estimating a medical device qualification score as soon as it is put into service. For this, an empirical approach based on the operating context analysis of medical devices in Benin hospitals has given a new approach of qualification inspired by the traditional approach of qualification according to WHO. In the methodology, six (6) qualification phases have been identified, namely: (1) Design Qualification (Q-D?C); (2) Receipt Check List Qualification (Q-RCL), (3) Installation Qualification (Q-I); (4) Technical Reception Qualification (Q-RT), (5) Operational Qualification (Q-O) and (6) Performance Qualification (Q-P). For each phase, a non-exhaustive list of steps is associated. An integer value range of 0 to 10 is associated with each step. The sum of the different scores assigned to the steps is weighted out of 100 for the phase. The average weighted score on 100 of the six phases is the desired score. Thus, a quantifiable qualification score between 0% and 100% is estimable for a medical device as soon as it is put into service. If the score tends to 100%, the medical device is in a very satisfactory operating situation and vice versa. Since the list of scores for several devices is available, it will be possible to predict the devices that will be more problematic or not during their operation. As proof, the results obtained on 24 medical devices are divided into three classes of scores (%) namely: [0; 50 [; [50; 75 [; [75; 100]. Seventeen (17), four (4) and three (3) devices respectively have their scores (%) between [0; 50 [; [50; 75 [; [75; 100]. The observation is that the three devices whose scores are between [75; 100] have very few complaints. The methodology reveals an audit of the acquisition chain for optimal and safe use of a medical device. It can be applied to a pool of medical devices to identify the steps that need to be taken to improve the situation of medical devices in Benin.

02. Medical equipment management in hospitals

IMPROVING ELECTROMEDICAL EQUIPMENTS BY SHARING PROTEGEMED'S DATA IN A DISTRIBUTED DATABASE

By Hernandez M.R.[1], Rebonatto M.T.[1], Spalding L.E.S.[2]

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The Protegemed system is a platform that aims increasing electrical safety in surgical procedures and places with intensive care of patients. Originating from a research about micro-shock's risk, the purpose is to measure and analyze the electrical currents, power and differential of electromedical equipment (EME). Differential currents in EME have proved to be dangerous to patients, and Protegemed can aid in research to develop better and safer equipment. The risk is due to parasitic capacitance in electrical installations of surgical rooms associated with failures in EME.

The current architecture of Protegemed is organized with four components: The embedded component, a local web server, the database and the support software. The first is a component that measures electric currents of EME and send to the database. The support software uses the data in the database, executing on a web server, helping the clinical engineer on the decision-making process to maintain electrical safety. With this architecture, the database can be defined as the core of the system, with a possibility to have many embedded devices spread in the hospital.

The biomedical research field is going towards a collaborative work, joining multiple disciplines and institutions. The main issue is the growing increase of complexity and need data. The data, acquired in spread locals need be shared within researchers and with the industry, for validate new techniques for development and to analyse the operation of equipment. Protegemed has expanded and many researchers around the world (England, Italy and Portugal) besides other Brazilian researchers producing knowledge on electrical safety of EME. At the same time, the core of the system has been stuck as a single local database, not allowing an instance of Protegemed to share data with any others. This research was motivated by this situation, and, thus, aims create a distributed database (DDB) for Protegemed data. The DDB helps researchers analyze and compare data from different locations, obtaining information about different EMEs, helping to improve the electrical safety and develop reliability in EME, avoiding putting exposing patients in microshock risks.

The authors have identified possible new research projects: to store information about EME use, in order to develop comparisons aiming to improve the work in clinical engineering.

02. Medical equipment management in hospitals

PROPOSAL OF AN INNOVATIVE ORGANIZATIONAL MODEL IN THE MANAGEMENT OF THE CLINICAL ENGINEERING SERVICE OF A MODERN HOSPITAL

By Salvucci A.

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Targets: Nowadays, the Clinical Engineering Service, as a technology manager, is essential to ensure the proper functioning of a hospital and takes an active part in centralized invitation to tender of assets and services. In an optimization perspective, an analysis was launched on the current organizational model used by the most of the Italian hospitals, in order to be able to underline potential criticalities and to propose an innovative organizational model in the management of the Clinical Engineering Service of a modern hospital, able to evaluate, through the proposal of innovative KPIs, the management of activities that concerning the provision of Clinical Engineering Services. **Analysis:** From the investigation conducted, accomplished after the development of a questionnaire, it was possible to carry out an analysis of the existing situation regarding the organizational and operational methods adopted by the hospital of Udine. Afterwards, many Technical Specifications were compared, developed to outsource maintenance management, highlighting the services that are typically required by hospitals to companies and analyzing at the same time performance indicators or classic KPIs, trying to bring out the role and the activity level required. Successively, were analyzed functions, tasks and criticalities related to the figure of the service supervisor (DEC), technical and administrative/accounting figure, which plays a truly important role in healthcare services. However, during the analysis phase a series of critical issues related to the overall maintenance management emerged. This led to suggest the internalization of the activity of basic safety and essential performance able to ensure a double advantage in terms of effectiveness and efficiency. In order to carry out a solid and efficient analysis, firstly was defined the process of the organizational change that should be configured (Make or Buy analysis); secondly were considered, in SWOT analysis, both internal variables (strengths and weaknesses) and external variables (opportunities and threats).

Results: The positive outcome of the analysis realized, it will allow therefore a better timeliness, quality of service and greater support for the DEC as well as guaranteeing a technical/professional and economic balance. Furthermore, the proposal of new KPIs could be an additional support to measure and manage the activities of each single service.

02. Medical equipment management in hospitals

MANAGING SUCCESSFUL MEDICAL DEVICE WARRANTY PERIOD MAINTENANCE

By **Desta D.**

Jhpiego, Addis Ababa, Ethiopia

Background: Jhpiego-Ethiopia, under the USAID funded HRH Project procured 14 anesthesia machines from Gradian Health System, which were then donated to public hospitals in Ethiopia to deliver anesthesia services as well as for teaching purpose at anesthesia training schools. **Objective:** The objective of this abstract is to share the program learning experience in management of medical devices warranty period maintenance. **Description of interventions:** Through collaboration of Jhpiego, the supplier and the health facilities, a total of 55 biomedical engineers/technicians and anesthesia preceptors were trained. Maintenance visits for each machine was conducted twice a year and 2 batches of spare parts were supplied by the Gradian Health System for maintenance purpose. **Results and lessons learned:** The effective collaboration ensured continuous functionality of all the 14 anesthesia machines. The average running time of the machines was 501 hrs. 501 patients got surgical service. A total of 1,003 anesthesia students received hands on training. Although providing periodic maintenance support incurred extra cost and effort to Jhpiego, we have demonstrated the warranty period support for medical devices should not be the sole responsibility of the supplier. It is possible to achieve better result through collaboration of all stakeholders.

02. Medical equipment management in hospitals

CLINICAL ENGINEER AS A CREATIVE PARTNER OF MEDICAL TEAM

By **Zalewska E.**

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The role of clinical engineers in hospital environment was increasing throughout the years and gained new aspects. At the beginning clinical engineering tasks consisted of supervising service and maintenance, patient safety, providing technical support in the everyday practice to the clinical staff with regard to the medical devices and their use. Position of clinical engineers was growing together with the quick development of medical equipment and its advanced application in medical procedures.

Increasing complexity of medical equipment, broadening of medical applications, and widening of the knowledge base needed for its functions resulted in the need for new area of clinical engineers activity. Understanding the concept on advanced level as well as the technology of medical equipment itself requires knowledge from other fields and a different point of view. Therefore, participation of clinical engineers in medical procedures as a creative partner of medical team is required. This became a very important and unique role for the clinical engineer.

The creative role is to plan the holistic, interdisciplinary diagnostic procedures using various modalities and integrated interpretation of results in difficult cases. This requires understanding of relationships between anatomy, function and bioelectrical activity as well as principle of diagnostic methods necessary in the interpretation of measurements taken by medical devices. Moreover, this role requires engineering knowledge and tools out of the scope of the routine level. So, the task is to integrate the knowledge and experiences in various fields that require high qualifications and interdisciplinary knowledge.

The knowledge and understanding of advanced application of the laws of physics and mathematical knowledge, as well as engineering activities is applied to the interpretation of the results of medical examinations. In particular, the participation of an engineer is required in examinations involving techniques of different modalities, for example, simultaneous imaging synchronized with electrophysiological recordings. Collaboration of clinical engineers with medical teams at such a high level of competences in everyday practice improves health care delivery and is an important factor in creating new ideas and supporting development in medicine.

02. Medical equipment management in hospitals

IRISH NATIONAL ACUTE HOSPITALS COMPUTERISED MAINTENANCE MANAGEMENT SYSTEM (CMMS)

By Adlington J.^[1], Grainger P.^[2], Hackett L.^[1]

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Background. All public hospitals in Ireland are required to adhere to the National Medical Device Equipment Management policy, which states that 'All necessary information required to properly manage the Hospital / Community Service's range of Medical Device Equipment is recorded on a dedicated Medical Device Equipment Management documentation system. This documentation system is to be computerised / digital wherever possible. To achieve this requirement, the health service in Ireland funded a national ECRI-AIMS system that would allow all acute hospitals to migrate their existing databases into one system. Implementation of the National system was primarily achieved by the decisions of the Nomenclature and Governance Sub-committees in conjunction with the Acute Hospitals National Administrator with further guidance from ECRI. The Principal Aim of this project is to allow the Health Service Executive (HSE) of Ireland to identify the end of support dates of medical devices to accurately forecast the budgets required to replace this equipment.

Other Aims set are to:

- On completion of the project, Ireland will have a national asset management database to detail all medical device equipment located in its public
- acute hospitals
- Individual hospitals achieve significant cost savings by eliminating the requirement for a local CMMS as all migrated databases are combined under a national enterprise licence
- By using a universally approved nomenclature system (UMDNS), all manufacturer's, models and equipment types will be standardised through every public hospital in Ireland
- Full asset management available to hospitals that have migrated due to the ECRI-AIMS modules facilitating comprehensive inventory information such as work order history, PM scheduling, custom reporting, remote call logging, contracts management, inspection template and quality control
- Collaboration and networking of Clinical Engineers to achieve common objectives for asset management utilising the various operating modules available.

Whilst the project has not been completed to date, this presentation details how the foundations for the National system have been put in place to ensure the migrations of the remaining hospitals can take place in a planned and organised fashion.

02. Medical equipment management in hospitals

STRENGTHENING UTILITY AND MAINTENANCE OF MEDICAL DEVICES

By Desta D.

Jhpiego, Addis Ababa, Ethiopia

Background: A significant number of medical equipment and devices used in Ethiopian public health facilities are imported. The health sector faces challenges in ensuring that the equipment is adequately maintained and serviced during the warranty period, affecting utility of the equipment and therefore service provision. **Objective:** The objective of the assessment is to share evidence of best practice in management of medical devices. **Method and findings:** The methods employed are; observations, discussions and oral interview with biomedical Engineers, Technicians and anesthesia preceptors. Jhpiego Ethiopia procured 14 anesthesia machines from Gradian Health System, which were then donated to 14 public hospitals across Ethiopia. Our findings indicate that, after the donation, a continuous follow-up, Preventive Maintenance every six month and Corrective Maintenance as demanded has been done with collaboration between jhpiego, the supplier, and the health facilities. Because of this intervention we have observed that, spare part availability is improved, the down time of the anesthesia machine decreases and service provision maximizes at each hospital. **Next step:** The findings will be shared with key stakeholders nationally, to inform and guide future approaches and strategies to ensure medical equipment is appropriately maintained and managed during the warranty period

02. Medical equipment management in hospitals

INTERNATIONAL MEDICAL ORGANIZATIONS AND HTM'S ROLE

By Morris R.G.

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The developing world is in dire need of trained medical professionals and to fill the gap rely heavily on medical organizations that donate their time caring for people in need. Medical equipment in some of these locations are not in the best of condition due to lack of trained HTM personnel or resources to support them. Since patient safety is the number one concern for any medical organization, there should be a well-qualified Biomed there to sort all the issues out, train both the end users and local HTM on the medical equipment fundamentals and provide the C suite with a report highlighting all of the concerns affecting their medical equipment and facilities along with setting a time line for completing the tasks. Still things happen between medical trips and the only way to mitigate the risk is by a thorough and complete line of communication between the hospital staff and the medical organization's leaders including their own HTM personnel.

The question is, what should be the role of HTM with an International medical organization? What tools can be used to mitigate risk and increase patient safety and care while increasing the number of patients to receive medical care.

1. Recognition of CE-HTM as a leader in the traveling medical organization.
2. Initial hospital site survey. What to look for?
3. Pre-Mission communications along with status of medical equipment and facilities.
4. Closeout meeting with C-suite and hospital department heads. HTM plays a major role to ensure the continued success of future medical trips.
5. Training of local HTM department
6. Surveying medical equipment

02. Medical equipment management in hospitals

SUPERVISIONING IT-MEDICAL SYSTEMS BY THE INTERNET

By Rebonatto M.T.^[1], Signor C.R.^[2], Wendling R.F.^[3], Spalding L.E.S.^[3]

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The management of electrical safety of installations and equipment used in surgical rooms is an old concern, which has been detected and discussed more rigorously in the United States since the 1970s. Since then, it has been faced with the adoption of standards and regulations in several countries. IEC 60364 deals with electrical installations in buildings. In part seven, section 710, the focus is specific on medical treatment sites, including surgical centers (CC). It determines the adoption of an isolated power supply system for the CCs, especially where life support equipment is connected, known as the IT system. IT-medical systems can be monitored by Line Monitoring Device (LIM) or Insulation Supervision Device (DSI). The monitoring is essential for the electrical safety of the environments with IT-Medical systems.

A permanent supervision of the functioning of the IT-medical system, aiming to identify and solve possible electrical failures in the installation or in equipment is a priority need of health institutions. This task can be performed by the hospital's supervisor (clinical) engineer or, in some cases, by a company.

In this paper, a platform was developed for the integration and storage of the information produced by DSI in IT-medical systems and the supervision team by the responsible engineers in hospitals or by companies. The objective is to develop a data communication software over the internet that will immediately lead the information on electrical failures in IT-medical systems to a supervisor engineer who will take the necessary steps to keep the patient safe. The platform was created through Web technologies, so that the supervisor engineer can access the information of the platform from its computer. In order to quickly access to information about possible electrical failures, a mobile application was developed; being the supervisory engineer immediately notified after a failure was detected.

The platform was satisfactory in the tests performed. It allows both the hospital's supervisor engineer and the support of the companies that commercialize IT-Medical systems to be notified quickly, contributing to greater electrical safety on the environments where IT-medical systems are used. Besides, repeated failures of medical equipment can lead to improvements in their designs, including IT-medical systems.

02. Medical equipment management in hospitals

REAL TIME LOCATING SYSTEMS – EXPERIMENTATION IN A PEDIATRIC HOSPITAL

By Pietrobon D., Nocchi F., Faggiano F.C., Ritrovato M., Capussotto C., Cannatà V.

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The term Real Time Locating Systems (RTLS) covers a group of technologies intended for identifying objects or people and tracking their position inside a defined area. Collected information is immediately available to users that are in the same area or in a remote location. RTLS are employed in many different industries and in these years are spreading out in healthcare structures, also in Italy.

Typically, RTLS cover a limited area, e.g. a room, a building or a whole hospital, but locating solutions operating outdoor exist too. A "tag", also called "beacon", is assigned to each object or person whose position must be tracked. The tag communicates with a network of receivers, typically by radio frequencies or infrared light. Information collected by receivers is processed to obtain the objects' locations and, in case, other parameters detected by tags (temperature, battery level, proximity ...). End users can finally access data by a software interface. The variety of technologies available corresponds to the many different possible uses of RTLS.

Bambino Gesù Children's Hospital of Rome, Italy, is studying RTLS as a possible solution for improving some internal processes. In particular, the work of health personnel and clinical engineering service can benefit from the location tracking of portable biomedical technologies. In the field of medical physics, RTLS can support the evaluation of radiation dose on parents or caregivers who attend the Nuclear Medicine's young patients treated with radiopharmaceuticals.

In the ICT area, RTLS can be configured for guiding patients throughout the hospital facilities.

Other applications will be considered in future, for example in the pharmaceutical warehouse management.

The hospital's activity on RTLS, currently in progress, consists of an analysis phase and an experimental phase: first, scientific literature and products available on the European market have been studied; then, different solutions are installed and tested according specific objectives for some months.

A set of measurable indicators is defined during the analysis phase and will be used for the evaluation of advantages related to RTLS and for comparison between different solutions.

02. Medical equipment management in hospitals

HOW TO JOIN RFID TECHNOLOGY TO LEAN THINKING IN HOSPITAL LABORATORY

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The aim of this study was to provide an insight to help hospital managers and clinical engineer determine implementation areas where Radio Frequency Identification RFID can have the greatest impact combined with lean thinking theory focused to identify, reduce and eliminate waste as: inventory, over ordering, waiting time, inappropriate processing and rejects & defects.

Materials and Methods: In our work RFID technology was implemented in the biochemical laboratory, in a medium size general hospital at Volos Greece (460 beds) running an annual budget of 800.000€ and performs 1.200.000 examination in average per year. The core idea, in lean thinking, is to maximize value while minimizing waste. Simply, lean means creating more value with fewer resources. Main step of Lean Transformation processes are: Define value, Mapping the value stream, check the value stream flow, Perfection is a continual process.

RESULTS: Today's laboratories face unprecedented changes: increased demand and workload with fewer staff and declining budgets. The RFID technology used for tracking, inventory management, and validation. More over support mapping, value stream and eliminate waste as lean thinking transformation demand. The RFID is a complex process that asks: what is in stock, how much is it, where is it, and when reorder. Validation assures that an action has taken place or that the desired item is on hand. Is the RFID a solution to eliminate waste? After the intervention, biochemical laboratory decreased most indicators. The largest reductions were found in working time for control and spatial positioning of products (52%). Improves inventory management: the average value of the stock was reduced 14%, and storage space decreased by 21%. Finally, the out-of-stock or expired inventory decreased by 11%.

Conclusion: Laboratories are continuously challenged to impact clinical outcomes, increase operational efficiency and improve financial results. Lean-based reorganization of laboratory process flow significantly increased process efficiency. Broader application of systems clinical engineering science, like RFID, might further improve health care quality and capacity while reducing waste and cost. There are critical successes in improving health services for patients through tracking (staff, patients, and properties), inventory management, and validation (medication, documents, treatment, and specimen).

02. Medical equipment management in hospitals

MULTI CRITERIA METHOD TO DETERMINE MEDIC EQUIPMENT OPERATIONAL OBSOLESCENCE IN HEALTH PUBLIC INSTITUTIONS IN BRAZIL

By Rumão Dos Santos L.^[2], Lefort Lamanna F.^[1]

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Management in medic equipment technology park is a challenging and complex question, once it's a time and money demanding task. In Brazil, it's even harder, given the lack of financial resources and the increase of public health services needs. Therefore, the development of a method that can evaluate the level of equipment obsolescence in its life cycle is essential, so that the manager can know how far away from its deactivation time a certain equipment is, to help him take appropriate measures. Besides, it allows cost monitoring, security e operation quality. Even though there are methodologies that help determine the equipment current status, they are hard to apply in countries like Brazil, mainly because they consider indicators that are fit for technology creating countries. Because of it, this study proposes a simple quantitatively method that anticipates data related to the medic operational equipment obsolescence, considering its life time, composed by age criterion and registration validity in Anvisa, the regulatory agency in Brasil; maintenance cost, which includes costs with: operation, labor, stock and software; and availability. For each parameter, a range of values was determined and then categorized in order to make the scale vary from 1 to 5 points. After that, a tool was used, Analytic Hierarchy Process (AHP) to quantitatively determine the criterion prioritization. Lastly, it was a parametric scale was defined to establish the operation obsolescence index that the equipment is into and actions that must be taken for each index. To validate the method, 230 equipment were simulated from 4 ICU (intensive care units) from a public hospital, where the method classified 4% of the equipment in an alert status and have to be deactivated in the same fiscal year, 30% will become obsolete in the next 4 to 5 years, 39% are nowhere near going bad, since they are still in the beginning of their usage life. The recommendations are compatible with the already existent subjective criterion in the institution.

02. Medical equipment management in hospitals

CLINICAL ENGINEERING CONTRACTS ANALYSIS IN EBSEH'S HOSPITAL NETWORK IN BRAZIL

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The correct application of resources is a constant challenge in the everyday life of managers especially because of the contingency context of resources of the health sector in Brazil. Given this scenario, the Empresa Brasileira de Serviços Hospitalares (Ebserh) has been utilizing contracts with Clinical Engineering Companies (CEC) to help them manage their equipment portfolio. Esberh is a public company created to manage the Federal University Hospitals operates in 24 of 27 Brazilian Federative Units (HUF), cause the other 3 units don't have HUF. Its network has 40 hospitals and 100% of them are public hospitals. Before that, the hospitals managed by Ebserh had different solutions to manage their equipment portfolio, all of which had unsatisfactory results. The rate of broken equipments without the proper assistance was high, harming patients' assistance, education activities and research.

In this context, a research was conducted using questionnaires and interviews to verify if the CEC contracts were bringing positive returns in terms of quality and cost reduction. All 5 Brazilian geographic regions participated in this research, given that the biggest majority of the hospitals (75,9%) already had contracts with CEC contracts. Between the hospitals that still weren't enrolled with it, 100% of them agreed that it was necessary measure. In those hospitals, the research showed very precarious situations: no management software and no maintenance coverage of the equipment portfolio inferior to 30% in the biggest portion of the interviewed. Still in this group, 71.4% of the interviewed had a glimpse that a CEC contract could bring cost reductions in the future.

When we talk about quality improvement, all of them indicated considerable gains, except 1 participant. When we talk about cost, the majority (59,1%) indicated that the reduction came from those contracts, but a considerable portion (36,4%) still couldn't make the relationship. Giving the details about this, 4 in 5 interviewed reported higher than 25% cost reduction; the other one said there was an increase in cost reduction, given that until now, his hospital would neglect maintenance. The research with the Esberh's network hospitals showed us that having Clinical Engineering contracts is considered important for all of the participants, given that the higher majority already have that in place. It was confirmed the hypothesis that such contracts would bring sensitive quality gains and cost reduction.

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ANALYSIS OF THE INFORMATION OF INPUTS AND OUTPUTS TO ASSESS A MEDICAL EQUIPMENT MANAGEMENT SOFTWARE

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Abstract: This article pretends an analysis of the indispensable elements for the conformation of an asset manager, being possible to evaluate the efficiency when using a software that allows to streamline management processes related to medical technology, using comparative methods in relation to the traditional management method.

Objective: Analyze the information of inputs and outputs of an asset management software of medical equipment using comparative methods as well as to evaluate the efficiency to highlight indispensable tools and elements for the management process.

Method: This research was carried out under a procedure following a defined structure to specify the objective of this work, beginning with the choice of software which will allow us to identify the input variables as well as to analyze the process of obtaining indicators or results, being possible to evaluate the efficiency and highlight elements and indispensable tools of the same, allowing to make a comparison of the results obtained through the management process of the software and the traditional method.

Results: The advantages of using software in the management process range from the optimization of this process and the saving of time, to the efficiency of the results obtained, allowing to have correct and updated information on the status of the medical tools as well as indicators that make it possible to perform an analysis and evaluation of the tasks corresponding to the management of medical technology. This highlights the benefits that it presents in comparison with the traditional method since the information that is available is safe, updated and it is possible to consult it quickly and efficiently.

Conclusions: The information of the management of assets of medical equipment in a hospital becomes more efficient when it is stored in a software generating a positive impact towards the department in charge because there is security and protection to the information that is introduced by accessing only authorized personnel. In the same way, any document can be update or edit if is necessary. Therefore, traditional method is obsolete because it is more susceptible to losing information, as well as to errors and to people outside the department can access to the information.

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THE CLINICAL ENGINEERING IN HOSPITAL ACCREDITATION

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Objective: Present the clinical engineering activities and the impacts of their results of accreditation in a health institution.

Introduction: In a national context the need of a dedicated professional to medical-equipment's management to reduce deactivated equipment it has proved necessary due the need for repair, parts replacements, acquisition and/or installation. It has been established parameters by the ABNT (Brazilian Association of Technical Standards), ANVISA (National Health Surveillance Agency) and INMETRO (National Institute of Metrology, Quality and Technology), as well as certified private institutions for the exercise of quality control of clinical engineering. Health establishments increased their search for standardization offered by private companies whom would certify them. Those certifies has become competitive factors, mostly in private health institutions. The national organization responsible for the certification is ONA (National Accreditation Organization), a non-governmental and non-profit entity whose methodology is recognized by ISQua (International Society for Quality in Health Care). The certificates offered by ONA is divided in 3 levels. A Health Institution must meet the criteria defined in the respective level to be acknowledge as accredited institution. In Brazilian context is usual for the Health Institution to outsource the clinical engineering with private companies with multi-professional technical body and experience, increasing their chances to be accredited.

Methodology: Application of national and international technical standards, operational procedures and published guide.

Results: An accredited institution reduce significantly expenses with repair, metrology and acquisition of new parts and equipment, while also increase patient safety and equipment availability. The engineers of Orbis Clinical Engineering were able to apply standard operating procedures in favor to ensure the certification achieving accreditation in all 3 levels on different health institutions.

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NATIONAL INVENTORY OF HIGH TECH MEDICAL EQUIPMENT

By Arellanes E.

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For any institution or organization, it is important to know their assets number and keep a constant update on their information, so, an inventory becomes very important tools that contains general information and depending on which assets are included on, it becomes as specific as required. In the health field, there are assets that because of their complexity and high cost must be included in an inventory, such as High Technology Medical Equipment (HTME), however, the task of create an inventory becomes complex when it is considered to integrate information at a national level, so it is a priority to identify the objective and scope pursued and analyze the feasibility of carrying it out. In this case, the challenge of create a High Technology Medical Equipment national inventory, is really complex, however, great benefits are obtained as result; to have a HTME national inventory is a very useful source of information and a resource of vital importance for the National Health System decision makers at macro, meso and micro levels in Mexico. Knowing the resources, we have is an essential point for the planning and incorporation of new medical equipment.

The National Center for Health Technology Excellence (CENETEC, for their name in Spanish; Centro Nacional de Excelencia Tecnológica en Salud) is a Ministry of Health Mexico agency, named in 2009 as WHO collaborating center in health technology. CENETEC according its attributions creates and integrates medical equipment guidelines that can be consulted by medical units in all over the country as a reference for the process of incorporation, operation, maintenance, replacement and disposal of medical equipment. Also gives advice on medical equipment management subjects to different medical units when it is requested. As a national advisor center, CENETEC plays a very important role in the planning process of medical equipment incorporation in the Country.

In June of 2015, CENETEC's clinical engineering department started the National Inventory of High Technology Medical Equipment project, having as main objective to strength the Ministry of Health decision making process trough reliable information. After a year and a half the project was finished and able to be presented as a HTME consult and visualization tool, available for general public consult.

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GUIDE FOR IMPLANTATION OF QUALITY MANAGEMENT SYSTEMS IN HOSPITAL CLINICAL ENGINEERING SECTORS

By Leal F.

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The objective of this work was to create a managerial practice tool that could assist Clinical Engineering professionals in performing their activities in hospital units, through the implementation of a Quality Management System applied to Health Technology Management. In order to achieve this objective, a guide for the implementation of the Quality Management System (QMS) was developed based on the ISO 9001: 2015 standard and on compliance with the provisions of the ABNT NBR 15943: 2011 standard, which addresses the guidelines for a health equipment management program. This Guide aims to assist hospital health professionals in the use of internationally accepted and recognized practices for quality management, as well as the application of good health equipment management practices, with the purpose of improving the quality of processes and engineering services in hospitals. A literature review was carried out to collect specific knowledge related to quality management and health equipment management. Then, for the development of the methodology, all the requirements of the two mentioned standards were studied and analyzed and a template tool was used to develop the proposed Guide, resulting in the elaboration and use of 52 documents, separated in 19 appendices and 33 attachments. All the documents prepared were correlated, through a single document, the Quality Manual (Model). The Quality Manual developed, in addition to bringing a step by step to the implementation of the quality management system, also brings to the reader explanations about the requirements of ISO 9001: 2015 and practical examples of activities related to the requirements of the ABNT standard NBR 15943: 2011.

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PROACTIVE MAINTENANCE OF MEDICAL DEVICES AND EQUIPMENT ON CRUISE SHIPS

By Amori E.

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Proactive maintenance is a rather new preventive maintenance strategy in the world of medical and diagnostic equipment. Modern medical devices have become very complex and sophisticated and more often than ever before are expected to operate in the advanced point of care facilities under stringent environments. Any healthcare organization must ensure that their medical and diagnostic devices are effective, safe, accurate, reliable and operating at the required level of performance. The importance of requiring recurrent inspection, calibration and optimization models to medical equipment in the cruise ships is a crucial and not negotiable condition for safety of all passengers and crew members. Medical services corporates that operate in the medical centers on board of cruise ships must include all their medical and diagnostic equipment in their "calibration" program following manufacturers' recommendations and procedures to prevent failures and predict faults. This paper presents a proactive maintenance solution program for highly sophisticated diagnostic equipment which utilize a built-in self-diagnostic engines to accurately assess the system's software and hardware statuses, even identifying potential problems not otherwise predictable. The purpose is to provide to the cruise management company fleet a remote 24/7 service for the connected medical devices to assess problems near real-time for prompt action and to reduce the downtime that critically impacts safety and effectiveness of the on board medical services.

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MAINTAINENCE OF BIOMEDICAL EQUIPMENT RESOURCE CENTRE (BERC) IN PUNJAB, PAKISTAN

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A Biomedical Equipment Resource Centre (BERC), first of its kind was conceptualized and implemented in Punjab, Pakistan for complete and efficient management of biomedical equipment in the province. BERC manages the maintenance system through a networked computerized maintenance management system (CMMS) and Customer Centre to ensure an uptime of 95% of all medical equipment in District Head Quarter Hospitals (DHQs) and Tehsil Head Quarters (THQs). The main idea behind establishment of BERC was to set up an organization which ensures the equipment life cycle management by

- Planning future procurements.
- Evaluating current contracts.
- Maintaining equipment.
- Identifying and Building capacity of the HR through additional resources and trainings (service and operational).
- Planning Maintenance budgets
- Reporting various Key Performance Indicators (KPIs) for the maintenance system.

BERC acts as a liaison between the procurement department, health facilities and the maintenance mechanism. The three main components of BERC are:

- RFID tagging and Line Listing (Inventory Management, through ECRI's software)
- Computerized maintenance management System and Call Centre
- Three District Level Workshops and nine associated mobile workshops

The study will describe the progress of the project that has been partially implemented and was piloted in November 2017. Since then 95 % of the equipment has been inventoried and tagged. An in-house call centre has been established with a hotline. All infrastructure equipment is in place and HR recruited. Training Centre has been established with all IPM equipment and DEMO equipment. There have been 3700 complaints have been completed (including installation requests) since the launch. Mobile workshops are fully equipped and are handling all complaints since the three main workshops are under renovations. Follow up and monitoring has been started but might take a few months before being fully implemented. The overall impact of the all the initiative has been tremendous. This has resulted for Punjab, one of the most populous provinces in Pakistan to rise from an overall functionality of 64% in 2012 to 93% in April 2018.

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A LONG ACTING MECHANISM TO IMPROVE MEDICAL FIXED-ASSETS MANAGEMENT

By **Wang H., Huang J., Wu X., Xie C., Yang L.**

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The rapid economic development in China has increased the hospitals' capability of purchasing medical fixed-assets. It leads the increase of regulatory requirements on fixed-assets. However, the traditional management systems have been organized without taking the users and financial resources into account, leading large waste and a poor coincidence rate between the physical evidence and accounts. In this study, we established a platform for suppliers inputting the parameters of new-purchased assets and for managers checking the fixed-assets more convenient and accurate. According to clearly assignment of responsibility, we overcame the communication barriers in the medical equipment management chain. As a

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INTEGRATION OF CE/HTM AND IT IN HEALTHCARE SYSTEMS

By **Schoener B.**

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Medical device technology is developing and advancing at an extraordinary pace. The field has seen the movement from simple stand-alone mechanical devices, to complex digital devices and combinatorial devices that are integrated with other medical devices and systems, utilizing external data storage and analytic engines not resident on the device itself, and linking to electronic health records (EHR), financial and other business systems. This evolution has resulted in healthcare delivery organizations (HDO) rethinking the roles of Clinical Engineering and Healthcare Technology Management (CE/HTM) and Information Technology (IT) departments. The purpose of this briefing is to share findings from interviews with twelve (12) HDOs that addressed the interface between HTM and IT Departments. The briefing focuses on these organizations' drivers for change, strategies employed, structural and reporting interventions, process changes, and methods to address cultural differences. This briefing is targeted at CE/HTM leaders and practitioners.

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BEST PRACTICE: MR SYSTEM – URGENCY TO IMPROVE MR RELIABILITY BECAMES AN OPPORTUNITY FOR UPGRADE MR SYSTEM BY A LONG TERM SERVICE CONTRACT

By **Taiariol M.^[1], Rizzetto M.^[1], Crivellaro M.^[2]**

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Magnetom Avanto Is installed since 2010 in Pordenone Hospital. In March 2018 after 2 spontaneous quench Customer and Siemens Healthcare agreed in a project to improve MR reliability, upgrade MR System and sign a Long-term service contract. The hospital carried out the tender procedure, identifying contractual conditions, including the choice to transfer clinical activities to mobile MR during the period of the downtime.

To gain MR Reliability Siemens performed a cool down process, a procedure usually done in a Magnet factory. Siemens could perform the process in two different ways, a traditional cool down procedure which last about 1 month and a LP cooler procedure which last 2 weeks. In Pordenone Siemens planned to deliver a LP cooler procedure.

After LP cooler procedure Siemens performed an Avanto Fit upgrade, a MR technical upgrade that provide "Tim@ 4G+Dot@" technology.

The whole procedure (LO cooler procedure and Avanto Fit upgrade) took place from 19th November to 15 December.

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CAST A NET: PROTECT YOUR MEDICAL DEVICES FROM ATTACK WITH COMPREHENSIVE ACQUISITION AND CYBERSECURITY STRATEGIES

By Lane M.

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ENVIRONMENT - The healthcare environment is seeing significant growth in medical devices and in connected medical devices. Medical device manufacturers are tapping into the potential of advanced computing and analytics to improve the value and information available for patient care. With this in mind, the healthcare environment is ripe for attack by malevolent actors. Within healthcare delivery organizations (HDOs), sit millions of medical devices. Many medical devices today contain components that are vulnerable. These components include: 1)device software, 2)firmware, 3)connection ports, 4)removable media, 5)operating systems, 6)remote support, and connected applications. Recent studies have demonstrated vulnerabilities in pacemakers, imaging systems and more.

HDOs and Medical Device Manufacturers (MDMs) are actively taking measures to improve the security posture of medical devices. Medical Device Manufacturers are working to harden their devices and improve the security posture of the device itself. Healthcare Delivery Organizations are deploying strategies to segregate devices on the network and deploying monitoring strategies. To ensure the medical device security posture of an organization is at peak performance, the HDO must ensure comprehensive strategy is deployed throughout the lifecycle.

STANDARDS - There are numerous standards to manage the overall risks of medical devices. A commonly used NIST framework includes key elements of; identification, protection, detection, response and recovery. Developing tactics to address each aspect of the framework is essential to protecting the medical device, the environment and ultimately the patient.

LIFE CYCLE

Planning - The lifecycle of a medical device begins with Planning for purchase. A well defined Medical Device Security Procurement Process includes the establishment of 1) Governance Structure for procurement review, 2) Vendor Assessments, 3) Device Assessments and 4) Contracting. The completeness of the procurement plan and tools strive to reduce the overall risk of a medical device security incident.

Management - Once a device is in the healthcare delivery environment, strategies must be deployed to monitor the security posture of the device. Properly managing the device once installed requires: 1) Managing the Inventory and monitoring, 2) Establishing a Risk Profile of the device, 3) Patching and responding to vulnerability disclosures and 4) Disposal.

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PRACTICAL SUPPORT FOR THE MANAGEMENT OF ELECTROMEDICAL EQUIPMENT IN A LEASING CONTRACT

By Mariotti M.^[1], Cionini F.^[2], Grossi C.^[2], Ginghamli A.^[2], Sani L.^[2]

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In the last couple of years, to meet lower financial resources, Health Authorities and Hospitals have chosen to acquire their own assets by favouring leasing contracts as opposed to purchase agreements. The disparity in management of the two contract types by the Clinical Engineering Services (SIC), caused by the limited control of the actions by the lessor company, has rendered the formalization of the entire process via specific documents necessary. In this regard, the present study led to the drafting of a managerial procedure that is characterised by its vast perspective, making it applicable on the whole region of Tuscany and anywhere leasing contracts want to be administered. This document was organised in 7 operational modes, which were all identified on the basis of the main phases of contract management. They are each described by using flow charts and corresponding notes, which outline the operativity and consequentiality of the various phases. In order to overcome the difficulties encountered related to the retrieval of the documents and due to the undefined management approach and control of the service, support modules, whose compilation was assigned to technicians of SIC, have been attached. The need to detail the operating instructions has made it crucial for the addition of an addendum to the procedure: the guidelines manual. This document was arranged in 9 parts, identified on the basis of the main findings of the procedure: each of these contain instructions and highlight questions SIC technicians could incur in, proposing solutions and action strategies, making the manual a real practical and operational support. Once the documents were composed, they were verified and tested with a simulation of the management of a real leasing contract. Aside from examining accuracy and handiness, this test led to a revision on the work that was carried out, hence perfecting the support forms in the procedure and including more detailed notes in the manual. Throughout the entirety of their implementation, it is expected that all the steps will be monitored so to identify any further refinements and to ensure continuous improvement of the whole process in terms of economy and quality. The possibility of utilising devices that are able to simultaneously furnish a general view of the procedure and more a specific one on single instructions, facilitates learning and proves to be significant support for those managing leases and those educating others.

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DATA HYGIENE: CLEAN YOUR DATA FOR OPTIMAL DECISIONS

By Lane M.

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DATA INTEGRITY: Decisions today are based on the collective input of data into our information systems. Whether the decisions center around population health or the management practices of a healthcare technology management program and the inventory they manage, ensuring the data being used for decision making is “clean” is critical to driving successful outcomes.

Databases over time may become “dirty” because records are incomplete, incorrect, improperly formatted, duplicated or irrelevant. The integrity of the database is derived from five key attributes:

- - Accuracy - the data documented is detailed and true
- - Complete - all necessary data elements are present
- - Consistent - data is consistent with established standards
- - Relevant - data adds value and supports the organizational objectives
- - Timely - the data is available in real-time and is kept current

Maintaining procedures that seek to drive data integrity and monitor overall compliance lead to Quality Data.

DATA MANAGEMENT PRACTICES: Quality data is derived from formal management processes. Similar to evaluating the quality of a device coming off the assembly line for errors, systems need to be in place to monitor the quality of the data entered. A formal knowledge management plan can lead to high quality data. The plan will include a formal Governance Structure that drives the Standardization Rules and Quality Control procedures.

Standardization Rules - 1) Established Standard Operation Procedures for new records, 2) Data Cleansing Activities for established records

Quality Control - 1) Analysis Reporting (Automated and Manual) and 2) Staff Training

DATA CLEANSING : Data Cleansing is the process of analyzing, correcting, and standardizing corrupt or inaccurate data records within a dataset. Data cleansing requires specialized software, subject matter expertise, and a strategic implementation plan to manage a mass, ever changing dataset. A data cleansing activity will be driven by the SOPs for the data set. An SOP encompasses all data components, including naming convention, abbreviations, groups and formatting requirements. The Data Cleansing act consists of a pre-defined and scoped set of tasks to include: Database to be focused on defined, Data standards & source defined, Spelling mistakes corrected, Correct case applied, Data standardized, and Quality control reviewed.

The end result of a data cleansing effort is high quality data the leads to high quality decisions.

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FORECASTING FAILURES WITH SPARSE DATA: DECISION SUPPORT FOR X-RAY TUBE REPLACEMENT DEALS

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In many situations in health technology management, it would be advantageous to predict when devices will fail. Such forecasts could inform the optimisation of management arrangements and would have a significant impact on the sustainability of health services. Previous attempts to use data and analytical models to forecast device failure, have been met by limiting technical challenges, including: the sparseness of failure data with which to produce a forecast, and the need to account for the variation of type and usage, in the equipment population. These challenges are particularly acute when considering X-ray tube failures.

X-ray tubes are the replaceable components of X-ray and CT scanners, that generate photoelectric emissions. As well as being essential for the function of mission critical scanners, tubes vary in cost, up to in excess of 100,000 EUR. Being analogous to light bulbs, tube failures are sparse and usage-dependent. These failures are also generally considered irreparable and require costly replacement.

In GSTT (Guy's & St Thomas' NHS Foundation Trust), a company proposed a deal, wherein they would underwrite tube replacement costs, up to twice the value of a down-payment. This down-payment would be selected by GSTT annually. The objective of this work was to forecast the cost outlay due to x-ray tube failures, using the available data. In order to guide this decision using sparse available data, a novel Bayesian, hierarchically-structured survival analysis was developed, tested and applied. By reconciling and combining data and models within a hierarchical taxonomy of scanner types and contexts, this method extends the reliability analysis of medical devices using survival methods. This Bayesian approach, wherein the relative probabilities of potential failure characteristics are evaluated, also crucially enables uncertainty to be quantified.

Over four years, forecasted cost probability distributions were used to derive the down-payment selection. The resulting down-payments were remarkably effective as predictors—more so than one might expect, given the probabilistic nature of this work. These results indicate the promise of this method, and suggest that there may be potential to apply this approach to other device groups and other survival-analysis methods altogether.

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SINGLE INSTRUMENT TRACKING AND MAINTENANCE

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This project is born base on the conviction that patient safety is a crucial matter for Hospital Universitari Vall d'hebron (HUVH). We had several problems concerning surgical instruments that resulted in a poor quality of the park, due to the variability of the sets, their aging and the lack of expert maintenance. The sterilization unit struggled to supply the surgical block with the required sets and traceability of the process was paper based. We had no inventory of instruments, while cost was not reduced.

To study the problem, we audited the sterilization process and the instruments park and did a preliminary inventory (initial instrument listed were 20.000 and by the end of the project the real inventor was over 60.000 pieces). We reviewed the use of most relevant sets and studied the maintenance process. We thus concluded that we needed to:

- -Implement a tool to help us improve the instrument processing process and link it to the maintenance process in order to replace pieces quicker.
- -Integrate the sterilization process in the patients Electronic health record (EHR) to trace it in case of an incident
- -Renew our surgical instruments park and guarantee its quality
- -Standardize the whole process and the surgical sets

Our strategy was to grant quality, safety and cost control for our surgical instruments and thus launched a public tender with a global approach with a single expert supplier that will provide all services with the following requirements:

- -All cost in the tender
- -No increase of Hospital recurrent maintenance budget
- -Expertise assessment and maintenance
- -Implementation and responsibility of the whole process

The supplier will provide: Surgical instruments Renewal+ Maintenance (flat rate contract), Surgical instruments marking with laser (QR-Code+legible alphabetical coding) and Traceability Software for Single Instruments not only for sets.

These two years project resulted in high availability of surgical sets in the OR and a quality rise. The standardization of sets increased their usability and efficiency. The sterilization unit works with higher expertise. Patient safety is ensured by digitally linking the sterilization process data into the EHR. Real time information of the inventory, maintenance and use of each instrument piece allows evaluating cost and planning new investments. It was crucial to the success project to track single instrument instead of sets, because it allows having exact information and ensures quality and safety.

02. Medical equipment management in hospitals

CLINICAL ENGINEERING ACTIVITIES IN BRAZIL

By **Silveira A.^[1], Knob E.^[2]**

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Health care establishments play an important role in the development of health policies at the national level. With many technologies available to aid in diagnosis, therapy and life support, hospitals in turn become sophisticated centers of technology (BRONZINO, J. D, 2000).

The performance of the Clinical Engineering services has become a strategic topic in private and public health institutions regarding the management of biomedical equipment.

This work demonstrates the mapping with a national scope, identifying the size of the Health Care Establishment, the existence or not of the Clinical Engineering activity, evidencing the level of involvement in decision making, the use of current management techniques and the comprehension of the processes of maintenance and calibration. Health care establishments play an important role in the development of health policies at the national level.

02. Medical equipment management in hospitals

THE ARRIVAL, INSTALLATION AND ACCEPTANCE OF MEDICAL EQUIPMENT

By Xu Y.

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Objective: To explore the reasonable process of arrival, installation and acceptance of medical equipment, and to establish a complete and standardized acceptance system. For the follow-up electronic archives and information hospital construction to provide a basic guarantee.

Methods: according to the practice of medical equipment management in hangzhou hospital of traditional Chinese medicine in recent years, the work of medical equipment acceptance was divided into three steps: arrival preparation, installation and debugging, and equipment acceptance. In addition, in the final acceptance, more attention should be paid to the communication with clinical medical staff and timely training.

Results: during the construction of Hangzhou Dingqiao Hospital, a branch of Hangzhou Hospital of Traditional Chinese Medicine, we have been exploring, correcting and implementing standardized operation. Improve the efficiency and quality of medical equipment acceptance through institutionalization and process construction.

Conclusion: the institutionalization and process management of medical equipment are helpful to give full play to the function of medical equipment and ensure the economic and social benefits of hospitals.

02. Medical equipment management in hospitals

MEDICAL EQUIPMENT MANAGEMENT IN HOSPITAL

By Musiwa E.

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Medical Equipment management in Hospitals forms part of the chain of activities that goes on to provide quality health service delivery to patients Medical Equipment management is entrusted with the responsibility of making sure that the many pieces of medical equipment in Hospitals are managed well to be in a safe functional state to be used by both the patients and the operators. Medical equipment management should also focus on improving equipped maintenance systems (inventory) and planned preventive in conformity with equipment life circle, in addition workshops for medical equipment users and maintenance personnel should be organised as often as possible. That will strengthen in-house capacity in medical equipment usage and maintenance so as to enhance Health service delivery. Sufficient working space in Hospital workshops should be created and satellite workshops where other services of the hospital are located, this will enhance medical equipment planned preventive maintenance programs by sharing best practice between hospital staff.

The repairs and maintenance component of health service requires continued upgrading of technical personnel, users and development of the new recruits There are today many maintenance procedures in practice Manly the users, planned preventive and the corrective maintenance are the commonly used ones. In order to be able to implement their programs training of the above must be put in place. The training should be done soon after the equipment is procured for the users and in some cases for the maintenance personnel should even begin the training at factory level or on installation of the equipment at facility level. Procurement of equipment should be a collective responsibility that is the procurement office, the user, account, and the maintenance personnel. This should go on until the equipment is installed and is functional in the facility.

Well managed medical equipment is a bonus to the patient the health facility and obviously a booster to the maintenance personnel. Proper storage of medical equipment is also one of the contributing factors to a huge span of medical equipment therefore 5s practice is recommended to achieve perfect management of medical equipment

Conclusion: The management and maintenance of Healthcare Technology (medical Equipment) is facing a lot of challenges in Zambia as such it needs to be brought to the fore of management issues. Once its priority is recognized the resources that are put in its acquisition can be guaranteed to be put to good use. It is for this reason that equipment committees be constituted at all levels. This amplifies further the notion that maintenance and management of Health Care Technology (medical Devices) is a collective responsibility and that is any of the stake holders in the life cycle of equipment does not play their role the management and maintenance of this valuable asset will be compromised.

02. Medical equipment management in hospitals

A COMPREHENSIVE IN-SERVICE BIOMEDICAL ENGINEERING TRAINING PROGRAM TARGETING LABORATORY EQUIPMENT CRITICAL TO THE HIV CLINICAL CASCADE IN HIGH HIV BURDEN COUNTIES IN KENYA

By Anyango P.A.

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Background: Kenya's network of more than 2,500 public health laboratories perform only the most basic tests, while more advanced testing is performed in national central laboratories. As the country strives to increase the number of laboratories reaching accreditation, it is challenged by a severe lack of resources, including Biomedics capable of management and maintaining vital laboratory equipment. This has been identified among the facility based Biomedics. They lacked confidence to work on laboratory equipment, which created a poor working relationship with laboratory technologists who believe they leave the equipment worse than they found it. Due to this, a large percentage of laboratory equipment in the country was on service contract that was expensive. Those not in service contract either isn't functioning or runs the risk of not properly running laboratory tests resulting in inaccurate diagnosis.

Objective: The overall goal of the partnership is to strengthen the capacity of the biomedical engineering staff on preventive maintenance service and repair on laboratory equipment to support HIV/AIDS diagnostics.

Methods: The in-service biomedical engineering training program targeting biomedics at the national level in the National Public Health Laboratory Services (NPHLS) started in 2015 with four counties with the highest HIV burden in the country. Taking a stepwise approach, AIHA and partners from the University of Texas Medical Branch, developed a training program starting with non-automated equipment critical to the HIV clinical cascade and is transitioning to highly automated equipment.

Results: 60 Biomedics have been trained on Eleven non-automated Lab equipment and now have confidence on the service, maintenance, repair, verifications and calibration of non-automated laboratory equipment. No service contracts and more labs have accredited.

Conclusions: Through a holistic and comprehensive approach, specialized training can improve the performance of Biomedics in low resource countries.

02. Medical equipment management in hospitals

A HEALTH MANAGEMENT SYSTEM FOR HOSPITAL MEDICAL EQUIPMENT – A CASE STUDY IN A GREEK HOSPITAL

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For the past few years, in Thoracic Diseases General Hospital of Athens- "Sotiria", a Medical Equipment Management System, WEB-PRAXIS has been used from the Department of Biomedical Engineering. This system has been developed by the Institute of Biomedical Technology, in order to secure the safe and efficient organization of hospitals biomedical equipment. It is a very important tool that contributes in the role of the clinical engineers of the hospital.

The role of a clinical engineer has many responsibilities such as the constant check of the entire biomedical equipment inside the hospital, the collaboration with hospital's personnel and the biomedical companies that provide and support the medical devices and, also, train and supervise the technicians. Web-Praxis provides the clinical engineers of our hospital the ability to manage the above responsibilities with effectiveness, giving them the chance to follow the accurate procedures. First of all, the clinical engineer in our hospital has to inventory and archive all the biomedical equipment and its characteristics, such as model, type, serial number, date of installation, purchase price, manufacturer, GMDN, group, supplier. Secondly, the clinical engineer is to report the technical errors and damages of the equipment by recording the type of the damage and notify the company in order to schedule the repair and also the final result. Another operation of the clinical engineer is the financial and technical registration of the maintenance contracts. Information such as warranty, dates and actions of previous maintenance procedures, cost of the contracts and others are being inventorying in the system. Lastly, periodic inspections with standard protocols and procedures is a basic action in order to keep the quality assurance and safety of the patients.

The goals of the use of Web-Praxis is the patients' security, the upgrading of the equipment, the management of the protocols, the personnel's training, the data analysis and statistics and the management of adverse events. The final users of Web-Praxis are the clinical/biomedical engineers, the administrators, the doctors and nurses, the logistics managers and the accountants of the hospital.

The results of the use of Web-Praxis in our hospital are cost effective studies, monitoring equipment lifetime, patients; safety, index production, total quality management, real time monitoring and update and most importantly Surveillance.

03. ICT and medical informatics

RECOGNITION OF CARDIAC TISSUES USING K-MEANS METHODS

By Alqahtani T.

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Nuclear cardiology uses to diagnose the cardiac disorders such as ischemic and inflammation disorders. In cardiac scintigraphy, unravelling closely adjacent tissues in the image is challenging issue. Since the existence of fleck noise that disturbs the contrast and make its analysis more difficult. Thus, digital image processing uses to increase the detection rate of myocardium easily using its colour-based algorithms. In this study, colour-based k-means was used. The scintigraphs was converted into colour space presentation. Then each pixel in the image was segmented using colour analysis algorithms. The segmented scintigraph was displayed in distinct fresh image. The proposed technique defines the myocardial tissues and borders precisely. Both exactness rate and recall reckoning were calculated. The results were $97.3 + 8.46$ ($p > 0.01$). The proposed technique offered recognition of the heart tissue with high exactness amount.

03. ICT and medical informatics

AGILE DEVELOPMENT AND MEDICAL DEVICE

By Picci G., Boarini C.

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The project goal is to develop a completely new product for clinical diagnostic laboratories. We have joined an Agile lifecycle model working with stakeholders to continuously add features allowing them to give us early feedback as the project develops. We will define some new requirements and write and test the code that fulfils them. During the course of the iteration, teams first plan the iteration, breaking the stories into tasks, and then commit to completing some number of stories. The team then implements the stories, driving each towards a definition of done. The definition of done establishes policy for what constitutes story completion, which assures that the story is properly coded, reviewed, tested and accepted into the product baseline. As the team works on delivering solutions that meet the sprint goals, Agile by nature promotes testing early. Unit implementation, verification, and testing should be done in each sprint. It is very important in a high assurance environment that the definition of done include all quality, safety, security and regulatory requirements that need to be satisfied for completeness. Furthermore, the verification and validation for definition of done is traced through to the acceptance criteria for each user story and then originating the product requirement. Once the Scrum team finishes sprint planning and agrees on the content of the next sprint, the development team, guided by the ScrumMaster's coaching, performs all of the task-level work necessary to get the features done where "done" means there is a high degree of confidence that all of the work necessary for producing good-quality features has been completed. The hardening sprint is an extension of the sprint process, but the main focus revolves around verification and validation. This is the final step prior to the software release. Integration and regression testing is another a task that should be done in the hardening sprint. The hardening iteration has an empty backlog, implying no new user stories. The hardening sprint is a high value, dedicated time for focusing on some of these remaining activities. This can include the elimination of accumulated technical debt as well as full regression testing, traceability updates and finalizing system documentation.

03. ICT and medical informatics

TECHNICAL REQUIREMENTS FOR SECURE DM HOST CONNECTION ON MEDICAL IT NETWORK

By Spagno C., Beltrame M., Salute D.

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Data and systems security are improving in importance both as a result of current regulations (i.e. GDPR) and of the increase numbers in cyber-attacks to healthcare information systems too.

The most of medical devices (DM) need a network connection to work properly: current trends in medicine e data science require integrated data for personalized and precision medicine applications based on artificial intelligence. It is clear that only by exploiting corporate resources and network medical devices are able to provide high-level functional performance and able to guarantee these functionalities.

In this IT resource sharing scenario medical devices secure networking is essential and it can be guaranteed only if the minimum necessary technical characteristics are defined precisely since the definition contract.

To achieve this goal, we developed a technical document suitable to be used in any purchase as it is a synthesis of the possible safe scenarios in a medical network (according to EN 80001). This technical doc regulates responsibilities among the different actors and defines the areas and the contributions of each one during the DM life: installation, acceptance test and maintenance.

In detail, according to the corporate security model, it defines the minimum requirements to use the services provided by the corporate infrastructure: i.e. network authentication, dynamic VLAN assignment, segregation technique (firewall), user authentication and authorization based on corporate directory services, antivirus and security patching.

The corporate security model and the defined requirements derive from literature best practices and standards; among those some are defined according to SANS Institute, Critical Security Controls, in Italy partly mandatory.

03. ICT and medical informatics

DESIGN OF A WEB-BASED MEDICAL EQUIPMENT MONITORING AND MANAGEMENT SYSTEM FOR BIOMEDICAL ENGINEERING SERVICES IN SRI LANKA

By Thaladhithiya Vithanage A.R., S A J K., R M Perera S.E., I Senevirathna R.M.U., R Bandara S.M.D.

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Medical equipment management is an important and urgent requirement to provide reliable and economical service to the health sector in Sri Lanka. In addition, convert the current manual system which leads to incline the efficiency and reliability of the service to the systematic, automated medical equipment monitoring system helps to improve efficiency of the process of Biomedical Engineering Services. The system is web-based, and it integrates a biomedical engineering units and hospitals. **Objective:** Design a framework for implementation medical equipment monitoring and management system used for Biomedical engineering department. Method – we initially enrolled 50 staff (Biomedical Engineers, Biomedical technical staff and ICT Officers) during 10 May 2018 to May 30, 2019. Result – 80% of medical equipment data collected from Line Ministry Hospital and 70% of collected data stored in web-based system. Computerized service and maintenance monitoring system Prepaid standard specification for basic medical equipment and published for user reference. The following example shows few results in the error analysis of medical equipment by the maintenance sub-system. There are lacks of proper communication system between Biomedical Engineering Services and line ministry hospital, outdated old machines, and machine location identification. These problems arise because absence of proper complaint system. The developed system can be used to improve work quality, to reduce the maintenance cost, and to promote the reliability of medical device used in patients and end users. **Conclusion:** Through related Web-based Medical Equipment Monitoring and Management System, it efficiently improved monitoring of the service contract of medical devices immediately and continuously. Through software we are able to monitor medical equipment easily and manage complaint in a proper manner, so they quickly done solution for a particular breakdown.

03. ICT and medical informatics

WHATSAPP: A SURVEY ON THE PROSPECTS OF USE IN DIGITAL RADIOLOGY

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One of the roles that clinical engineering in the development of health technologies and devices is certainly to ensure, after appropriate assessment, an osmosis from the world of industry and consumption to that of health. New frontiers are now offered by smartphone applications for exchanging multimedia files (images, video, audio), such as in the case of so-called instant messengers. These applications (APP) are useful for sending text messages, multimedia files (images, video, audio), geo-location to other users. Every day millions and millions of people use instant messenger programs such as WhatsApp to communicate with each other. These applications have simplified and revolutionized the way we communicate and live, thanks to the ease and low costs (in most cases just a simple Internet connection). Not many years ago to communicate it was necessary to be in front of a computer and have Skype, or it was possible to send text messages or make calls. Precisely the possibility of sending large multimedia files makes these messengers interesting in terms of health prospects, especially in sending static and / or dynamic images in medical diagnostics, such as in radiology. The possibility offered by the virtual keyboard to navigate in a finger-based and cooperative way in more subjects participating in the groups formed has great potential. WhatsApp was chosen as it was particularly appreciated by the community of European users and a study was set up to evaluate the acceptance of the technology subjected to the osmosis process in two steps. The first step concerned the transmission of static images (Istisan Report 17/10, ISS, Rome), the second the transmission of dynamic images. Specifically, the challenge reported here is focused on dynamic transmission. Through an appropriate procedure with a guarantee of privacy and security, DICOM acquisitions were converted to AVI format to upload to a cloud and sent using WhatsApp WEB. The tests carried out with a 70 % 3G network with devices equipped with a different operating system and with a target cost of around 150 e. A high acceptance of the methodology was recorded among the 15 study participants (radiological technicians, doctors and engineers) in 25 trials. All of the participants were convinced that the more promising sectors were the fields where the decision is particularly affected on the dynamics/kinematics of the medical images, indicating other fields to explore such as also echography.

03. ICT and medical informatics

AN IDENTIKIT OF A MEDICAL APP FOR THE CONTINUITY OF CARE IN BREAST CANCER

By Giansanti D.^[1], Capannini M.^[2], Giovagnoli M.R.^[2]

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Introduction: The “mobile health” comprehends all those medical practices supported by mobile devices (smartphones, PDAs, tablets, personal digital assistants’ PDAs) and other wireless devices. Much of M-Health uses APP applications designed for health purpose such as: (A) Promotion of health and health-welfare (B) Consultation of clinical information (C). Signal monitoring (D) Help in the management of chronic diseases. During the design the first aspect to consider is to discriminate if the App is a medical device (1). The second aspect to consider is the acceptance of the App. This is an important aspect that fits into the eternal debate between those who consider these Apps a limited-use gadget and those who consider the Apps a great opportunity. The reason behind the failures is often due to the lack of a methodical collection of wishes by the citizens and in general of the actors potentially involved in the implementation of the App. Today the design of an App has become very simple and immediate, the main and qualifying element moves towards attention to the requirements with involvement of the “actors” present in the surveillance and care process, using a so-called Community-Engaged Approach (CEA) (1). This project focuses to the continuity of care in breast cancer.

Objective: The MAIN OBJECTIVE is to carry out a wide-ranging feasibility study on the implementation of an APP for the Breast Oncology, with the involvement of the “actors” present in the surveillance and care process. For the purpose of achieving this main objective was prepared a specific tool based on questionnaires that allows the collection of fundamental feed-back by subjects involved with CEA approach. The destination users are the citizen, the health care operators and the stake-holders involved in the health care processes.

Results: The first product is the survey tool. This tool was developed using an electronic methodology based on OneDrive (Microsoft) using the approach indicated in (3). Three specific surveys have been designed for the three different actors: (a) the public (i.e. those ones not directly involved in the process); (b) women involved in the process (for screening and/ or monitoring after a diagnosis); (c) the health care operators involved in the process. The second result is a preliminary outcome with a high acceptance of the subjects involved in the process.

1. Giansanti D. Telemed J E Health. 2017 Sep;23(9):773-776

03. ICT and medical informatics

IMPROVING PATIENT FLOW LOGISTICS IN A CARDIAC SURGERY ENVIRONMENT: A SINGLE CENTRE PIVOTAL TRIAL

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Background: To make hospitals more patient-centered it is necessary to intervene on patient flow logistics. A significant increase in serving capacity may be obtained by improving the ability to move patients through the treatment system, a measure known as "throughput". Use of technology to optimise throughput in the surgical environment is still uncommon.

Aim: the study aimed to develop and validate a computerised algorithm to optimise throughput in a cardiac surgery tertiary care centre.

Methods: Three dedicated scores were developed on current published data: the Admission Priority Score (ADP), the Operation Room Priority Score (ORPS) and the Discharge Priority Score (DPS). The performance of each of these scoring systems and that of the computerised algorithm in optimising patient flow logistics were then prospectively evaluated and confronted with the performance of conventional clinical governance. The ADP is used during an outpatient visit to established the patient's position on waiting list; the ORPS at the time of admission to the ward to clarify the position of the patient in the list to operation; the indicators for both are 4: pathology, clinical condition, waiting time, age; 14 patients were recruited to develop this score. The DPS is used at the time of the patient's exit from the intensive care unit, to place the patient's position on the discharge list. The indicators are 3: clinical condition, news (national early warning score), waiting time.

Results: the three scores safely and effectively optimised patient throughput. The automated algorithm allowed a critical reappraisal of conventional, human driven, hospital resource utilization.

Conclusions: Development of an automated patient flow algorithm provides valuable prospective planning (i.e., decision making) information and demonstrates pattern for interventions to increase inpatient throughput in cardiac surgery setting. The automated algorithm allowed a critical reappraisal of conventional, human driven, hospital resource utilization.

03. ICT and medical informatics

DATA INTEGRATION - A PM PERSPECTIVE FROM A BIOMED BACKGROUND

By Alam A.

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Typically, in data integration with EMRs occurs with the project team and the EMR analysts working with the clinicians to understand what variables types should flow across into their patient chart. The project team/EMR analysts do the working, testing, nomenclature development and other project based roles as part of the PM. They'll even procure a third-party integrator if need be. The second portion to this is that fact that while data integration is a high impact functionality, it is a very small portion of an overall EMR integration. As such, data integration almost occurs "behind the scenes" without much thought put into it. The EMR vendor follows a very standard method of integration as they've done in previous implementations. Once the integration is complete, it is the biomed staff that get calls about issues with data integration. In this presentation, I hope to shed some light on my role with an EMR integration. I'm a clinical engineer by background so I was able to advocate for the biomedical department during the implementation. I would like to show how advantages a clinical engineer's role is in such an implementation to ensure that the hospital's needs are met short term and long term.

03. ICT and medical informatics

QUALITY INTEGRATED HEALTH NETWORK

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Primary Healthcare Providers (PHP) in the US have to navigate a complex system of regulations that have caused many of the practices to close their doors or to be absorbed by major hospital corporations.

The Centers for Medicare & Medicaid Services (CMS) via the Medicare Access and CHIP Reauthorization Act (MACRA) establishes a Merit-based Incentive Payment System (MIPS), supported on Health Information Technology (HIT). The Office of the National Coordinator for HIT (ONC) as part of the 21st Century Cures Act proposed rules that explicitly mandate the adoption and use of the Fast Healthcare Interoperability Resources (FHIR).

According to ONC and CMS, a successful health system collects, shares, and uses information to focus healthcare on outcomes-based care. Clinical Quality Measures (CQM) help providers to measure and track the quality of healthcare services. CMS and ONC also created options for PHP to associate towards higher healthcare outcomes: Accountable Care Organizations (ACO), focus on care improvement for an entire patient population, across the continuum of care. Clinically Integrated Networks (CIN), provide care improvement for physician practices across specialty types. Patient-Centered Medical Homes (PCMH) improve patient outcomes for primary care services. Options are complex to implement and there is no single provider offering all the technology required to fulfil all rules and regulations.

Alluriam Healthcare Systems, Inc. (AHSI) is a network of companies, who share best practices and best technologies to provide a state-of-the-art solution for ACO's, CIN, PCMH, Government Agencies, and their patient population (Members). AHSI also offers a team of executive consultants that assist healthcare organizations in planning their transition to patient-centric, Value Based Care.

Alluriam allows all members to become part of a Qualified Health Information Network (QHIN). At the core of the QHIN resides a FHIR compatible Cognitive Intelligence enabled Healthcare Exchange (CI-HSX). The information is centralized and stored in an encrypted cloud database, traffic is tracked, complying with the higher standards of HIPPA/HITRUST. This solution provides the ability to monitor CQMs required by Value Based Care. QHIN also integrates IoT devices and social networks to serve as a means of addressing PCMH. The solution can be expanded to include the ISO13606 standard and provide worldwide coverage.

03. ICT and medical informatics

A DIGITAL PLATFORM FOR THE WOMEN AND CHILDREN HEALTHCARE: DESIGN AND IMPLEMENTATION OF A SOLUTION TO SUPPORT THE INNOVATIVE MANAGEMENT OF CLINICAL PROCESSES

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INTRODUCTION: In an increasingly "smart health" scenario in healthcare, according to the continuous improvement of the quality, safety and appropriateness of health interventions, it is essential to use technological information and communication systems that allow the exchange of clinical-diagnostic information between the structures of the healthcare network, the collection of critical information for management control, the path monitoring and assessment of the outcomes as well as the conduct of research activities. In all this, digital natives who use IT tools and self-manage health information/education, using internet search and sharing information on social media, are increasingly using apps with "health" content, without any guarantee of quality and privacy in relation to the contents presented.

TARGETS: The objective of the project that the IRCCS "Burlo Garofolo" and the Research Area of Trieste are carrying out, is to activate in 2019 a pilot action in the field of social and health processes, with an approach aimed at managerial innovation, dedicated to medical functions in the maternal-children field, promoting the creation of an interactive and personalized information platform on which to converge a series of services, in particular a digital agenda for the future mother that allows managing appointments, visits and exams, weight control, etc ... and a chronicity management system to support the care and monitoring of the diabetic patient. The ecosystem to be implemented has the objective of strengthening the offer of services in support of collaboration between professionals (teleconsultation), the interaction between professionals and citizens; to strengthen the citizen's empowerment towards the health offer; to improve knowledge exchanges among professionals; to propose and validate a new management model in the social-health field.

INSTRUMENTS: The tools are: an online platform with modular architecture (DM 93/42/CE certified in class II A) for assistance with information and dialogue with users (knowledge base, chatbot, ...); an app that allows for planning activities and appointments, secure communication with Burlo professionals and with MMG/PLS, the inclusion of clinical and laboratory measures; a QnA chatbot to support all the processes described.

03. ICT and medical informatics

GDPR, CYBERSECURITY AND MEDICAL DEVICES (MD): HOW THE DATA PROTECTION IMPACT ASSESSMENT (DPIA) AFFECTS THE CALCULATION OF A RISK EVALUATION INDEX FOR THE RISK MANAGEMENT OF MD CONNECTED TO A HOSPITAL MEDICAL-IT NETWORK

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INTRODUCTION: The connection of the MDs to a medical-IT network represents an advantage for the patients health care, but implies an accurate risk assessment since the information exchanged are suitable to reveal the health status of the patients. The GDPR introduces the privacy impact assessment (PIA) of treatments into a new privacy and security management model, with the aim of evaluating the risks associated with clinical and health data. The purpose of this study is to give a numerical value to the PIA and integrate it with a Risk Evaluation Index (REI) calculated on the single MD, considering the safe and effective use of the devices, the privacy and security of data and systems.

MATERIALS AND METHODS: The study was carried out by the Clinical Engineering and Information System offices of two different Friuli Venezia-Giulia hospitals. For the DPIA a questionnaire has been developed and re-elaborated according to the Italian Data Protection Authority PIA software. The questionnaire was applied to around forty MDs for which the degree of protection was obtained for access, modification and loss of data. The degree of protection was used to calculate the likelihood and severity of risk necessary for calculating the risk matrix. These values were then reported as factors and risk categories within the REI, providing input to the statistical models that allowed to obtain the weights for calculating the REI for each MD.

RESULTS: Carrying out the measurements and calculating the indices it emerged that most of the MDs analyzed according to the parameters of the PIA have medium/low for the loss and average risks for access and modification of the data, respectively. Statistical models have allowed to obtain values for REI with high specificity and sensitivity. The results highlight the expected collinearity between the categories of privacy and IT security risk and, using only privacy, a representative equation was obtained at a lower computational cost and with equal results.

CONCLUSIONS: The questionnaire, in addition to being designed and adapted for the healthcare environment, allows for an objective assessment of the risk of the single MD highlighting the strengths and the critical points. By integrating the result into the REI it is possible to implement a predictive analysis on the hospital equipment fleet and trace the data security on the single MD according to the GDPR. Matricial analytical models will provide further developments of the REI.

03. ICT and medical informatics

CREATIVE TELEMEDICINE APPS ENHANCE GLOBAL HEALTH CHALLENGES

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Creative use of information, communication (ICT) and health technology have enhanced health challenges in many countries around the world. The challenge for biomedical engineers, physicians and medical informatics is to develop telemedicine apps to enhance the global health. Populations living in low setting countries did not have access to specialist care and quality diagnostic services and thus depended on the scarce resources of their health system. Inside such countries don't exist equity between urban and rural populations. In this context the telemedicine apps should be directed towards developing better equity in the provision of health services in low setting countries. The utility of telemedicine apps to enhance global health challenges in Paraguay was investigated. **Methods:** This descriptive study was carried out by the Telemedicine Unit of the Ministry of Public Health and Social Welfare (MSPBS) in collaboration with the Department of Biomedical Engineering and Imaging of the Health Science Research Institute (IICS-UNA) and the University of the Basque Country (UPV / EHU). To evaluate the utility of telemedicine apps in different diagnosis areas, the results obtained by the tailored telemedicine apps implemented in 67 public countryside community hospitals were analyzed. **Results:** A total of 472,038 remote diagnoses were performed between January 2014 and March 2019 in 67 community hospitals. Of the total, 63.130% (297,999) corresponded to electrocardiography (EKG) studies, 35.030% (165,323) to tomography, 1.836% (8,697) to electroencephalography (EEG) and 0.004% (19) to sonography. There were no significant differences between the remote and the "face to face" diagnosis. With the remote diagnosis a reduction of the cost was obtained, that supposes an important benefit for each citizen of the 67 communities. **Conclusions:** The results show that creative context adapted telemedicine apps can enhance significantly the global health challenge, increasing access and equity, and reducing costs. However, before carrying out the implementation in other countries, a contextualization with the country epidemiological profile must be performed.

03. ICT and medical informatics

THE ITALIAN ELECTROTECHNICAL COMMITTEE GUIDES FOR HEALTH SOFTWARE MANAGEMENT IN MEDICAL ENVIRONMENT

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The increasing spread of software components, as well as the equally high rates of technology innovation and technology obsolescence in the healthcare context, engage Clinical Engineers in a continuous trade-off between update and performance demand on one side, and safe management of the healthcare structure technology portfolio, in compliance with current regulations, on the other side. The latter is an especially complex, pressing issue, which involves and deals with, among the others, a plethora of technology solutions and configurations of ICT and medical systems connected with/through IT-medical networks, patient's safety, confidentiality and ethic management of data, risk management. At an Italian level, the Italian Electrotechnical Committee (CEI, Italian member of the IEC - International Electrotechnical Commission and of CENELEC - Comité européen de normalisation electrotechnique) has been hosting a working group since 2012, aiming at delivering explanatory guides relevant and mandatory to interpret laws and standards, and to support safe management of software products in healthcare. The group, made of experts from Italian National Institute of Health (ISS), representatives of industry, and representatives of the healthcare organizations, published the first Guide in February 2015 (CEI 62-237), which incorporated an innovative approach based on the proper contextualization of software products, either medical devices or not, to the specific healthcare scenario, and addressed the risk management of IT systems. A second Guide was delivered in 2017 (CEI 62-252), aimed to represent a guide, in support of the Healthcare Responsible Organizations, for the proper management of medical IT networks; the guide was based on the provisions of CEI EN 80001-1: 2016-02 and with reference to the related Technical Reports already published in the IEC website. Following the entry into force of the new EU Regulations (2017/745 (MD); 2017/746 (IVD); 2016/679 (GDPR)), Guide CEI 62-237 underwent a review which is currently entering into the public enquiry phase. Basically, existing topics had been properly updated in the new version of the Guide, and emerging issues strongly related with software and ICT systems used in healthcare context had been addressed, among which Cybersecurity, GDPR based on the concepts of «privacy by design» and on the figure of the "Data Protection Manager" for the coordinated management of corporate security and confidentiality policies.

03. ICT and medical informatics

MODELING AN INTEGRATED NETWORK FOR REMOTE PATIENT MONITORING, BASED ON THE INTERNET OF THINGS FOR A MORE PREVENTIVE AND PREDICTIVE HEALTH SYSTEM IN WEST AFRICA

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Background: Because of the health systems globalization, it is important to examine the organization of health systems in Africa, in terms of patient care, to highlight the failures and propose possible solutions. **Objective:** Modeling an Integrated Network for Monitoring Patient Data in West African Health Systems based on the Internet of Things (IoT). **Methodology:** To achieve this, three steps were followed. 1) Identification of the different characteristics of IoT-based health surveillance systems, WBAN systems and physiological parameters monitorable on a patient. 2) The modeling of West African health system architecture in the form of a cloud of Technocentres. 3) Cross analysis between different IoT technologies, characteristics and functional requirements identified. All this is based on wireless medical sensor networks in Wireless Body Area Network (WBAN) systems. **Result:** This work modeled health systems in Africa as a patient data monitoring network. **Conclusion:** The implementation of this monitoring network model will be a tool for large-scale decision-making for a health system in Africa. It will enable the West Africa health system to have an information database and to insure a preventive and predictive health system.

Keywords: architecture, health care, hospital, patient, internet of things, monitoring technocentre, WBAN, sanitary system

03. ICT and medical informatics

DIGITIZING MALARIA CASE MANAGEMENT PROTOCOL IN GHANA: A PILOT STUDY

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Background: It has been a common practice in Ghana for patients to seek first aid medical attention from community pharmacies or chemical shops. Management of malaria cases is no exceptional, as patients who experience symptoms of malaria visit pharmacy shops to seek medical attention. The Ghana Health Service guidelines for malaria case management ensure that all persons presented with malaria symptoms at any health facility are tested through microscopy or malaria Rapid Diagnostic Test (RDT). Malaria case management interventions such as point of care testing using RDT kits ensures accurate diagnosis and effective treatment and can be well monitored through real-time data capturing solution. This study evaluated the use of a mobile phone platform, known as the Fionet Platform to remotely monitor RDT testing and understand issues faced by healthcare workers in using the malaria diagnosis test kits.

Methods: To ensure adherence to malaria case management protocol of 'Test, Treat and Track (3Ts)', the Fionet mobile App was deployed. Under this pilot study, 28 pharmacy shops and 13 Over the Counter Medicine Shops were selected from Greater Accra Region (GR) and Central Region (CR), respectively. The pharmacists and Medical Counter Assistants from these facilities were trained to use the mobile App for malaria testing. The shops were also supplied with RDTs through the National Malaria Control Programme. Inventory of RDTs supplied to these shops were tracked to ascertain whether some tests were conducted without using the mobile App. Interview were done to investigate the reluctance to use the App during testing.

Results: A total of 5312 RDT tests were recorded through the Fionet platform. 74.7% was malaria negative and 24.2% was malaria positive. Shops in CR recorded more malaria positive cases than shops in GR. 91.91% of malaria positive cases were treated with ACTs and 14.85% of malaria negative cases were also treated with ACTs. 9.1% of malaria negative patients treated insisted they want ACT treatment and 91.8% were given ACT treatment because the patients were showing malaria symptoms according to the caregivers. For the Fionet bypass processed RDTs, the caregivers indicated that the RDT incubation period is too long when they use the App.

Conclusion: The mobile App helps give accurate malaria treatment. Caregivers do not adhere to test protocol and treatment when test is done manually. The wrong treatment would not have been recorded without the App.

03. ICT and medical informatics

SIMWALK: AN APPROACH FOR SIMILARITY SEARCH IN MEDICAL IMAGE DATABASES

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Similarity search is a relevant topic that is explored by machine learning and information retrieval, it comprises mechanisms that deal with the issue of efficiently search a database to find the most similar images to a query image. Similarity can be expressed through distances between objects in a metric space. Two traditional similarity-based queries are range query (Rq) and k-nearest neighbour query (k-NNq). A Rq consists of finding all images similar to a reference one which is within a given distance radius. A k-NNq consists of finding the k most similar images to a given reference one. Similarity queries compose a content-based image retrieval (CBIR) system that aims at retrieving images based on their intrinsic features, which are extracted by image-processing techniques. Although there already exist several researches, we still have in these systems a problem called semantic gap that is the disparity between the result returned by the system and the result expected by a user. This occurs because CBIR systems remain restricted to direct assessment of distance between images in a database to a specific query image, not considering the possibility of taking as reference all images that are being retrieved by the search, rather than only the starting query one. Another interesting topic addressed in methods for clustering, image analysis and classification is the Tourist Walk (TW), which can be described as a tourist that wishes to visit n cities distributed in a map of d-dimension. The tourist can perform its trajectory through these cities, but its steps is limited by a deterministic rule, namely: at each time step, go to the nearest city not visited in the previous μ steps. Nevertheless, TW has not been explored as a method for performing similarity retrieval, as an alternative to Rq and k-NNq. So, the hypothesis of this study is that TW leads to more semantic results in similarity retrieval. Therefore, we propose a new method based on TW to perform image retrieval. Thus, we developed the SimWalk, a method capable of retrieving images considering their similarities and we've applied it to a medical image database and evaluated its applicability regarding the results accuracy. SimWalk has showed better results in retrieving images from the same class, so we can say that it is a more effective alternative to reduce the semantic gap in similarity search.

03. ICT and medical informatics

IMPLEMENTATION OF AN EHEALTH APPLICATION IN ONCOLOGY: A REAL-WORLD FEASIBILITY STUDY

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Introduction: Outcomes and success of new technology can be evaluated from the perspective of implementation process, service and client [1]. Acceptability is an important aspect when implementing health care solutions [2]. Currently, there are only a few studies assessing a real-world implementation of a digital solution for patient reported outcome (PRO) monitoring in a clinical oncology setting. Additionally, text-based interaction between patients and health care professionals (HCP) remains under-reported in oncology. As numerous digital health care solutions are introduced and taken into clinical use, there is a need for evaluation providing evidence-based information. An eHealth application (app) Kaiku Health (Kaiku Health Oy, Finland) used in PRO monitoring and communication between patients and HCPs is being implemented into treatment process of multiple myeloma patients in Oulu University Hospital. The aim of this study is to evaluate the feasibility of the app among patients and HCPs.

Material and Methods: Feasibility is measured during the real-world implementation and subsequent 9-12 months of follow-up. Feasibility outcomes include acceptability, usability, technical feasibility, impact on the treatment related processes, and the extent of uptake. In addition, HCPs' attitude toward implementation process is assessed. The data is collected via questionnaires [3-4], log data (app: e.g. quantity of log-ins, contacts and filled PRO questionnaires; hospital information systems: e.g. hospital visits), and HCP interviews preceding the implementation.

Results: Preliminary results on the baseline interviews with HCPs (n=5) and baseline questionnaire assessing acceptability of the app and attitude toward the implementation process showed that the general idea about the app was positive. Patients (n=22) thought that the app will positively influence their treatment processes. However, in the HCP interviews, benefits of the app were mainly speculative and the fear of increasing workload was observed.

Discussion: This study will provide new information on the real-world implementation of an eHealth app for PRO monitoring and communication between patients and HCPs in chronic cancer care.

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03. ICT and medical informatics

ENGINEERING APPROACH TO THE "GENERAL DATA PROTECTION REGULATION" AND HIS IMPLEMENTATION FOR GENERAL PRACTITIONERS

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At May 2018 the new European GENERAL DATA PROTECTION REGULATION entered definitively in force in all European Countries. This new Regulation updates the previous 1996's legislation on the Protection of personal data processing as approved by the Universal Declaration of Human Rights. In this context, health data are treated with specific attention as they are defined as "particular data" and entities of strength management in order to guarantee their confidentiality, integrity and availability, in respect of the dignity of the person.

As part of a complete health care process within a public healthcare hospital, the patient's first step is with his trusted "general practitioner", as well known as "family doctor". In Italy, this figure is not employed in a hospital, he is a freelancer who works in agreement with the National Health Service. He is the manager of a Health Dossier of its patients which is the subject of very intense treatment of data, both to colleagues who work on the network, and to hospitals, both to state social security institutions, and to national tax agencies. The present work aims to propose a data risk processing management based on risk management of engineering models: the FMEA and HAZOP techniques proposed by EN 14971 are two proactive risk analysis and management techniques that are applied to the analysis impact.

The consequent proposal, according to the Deming cycle of continuous improvement, will be the obvious conclusion of the proposed work, as an alternative to the most commonly used model of the French CNIL.

03. ICT and medical informatics

A SYSTEM FOR INVESTIGATING ASSOCIATIONS BETWEEN DAY-TO-DAY VARIATIONS IN SLEEP AND HEALTH/WELLBEING STATUS

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Chronic low quality sleep and acute sleep deprivation are associated with several health issues (e.g. cardiovascular disease, obesity, type 2 diabetes, all-cause mortality, risk of falling, impaired reduced daytime performance and impaired balance). However, the effects of day-to-day variations in sleep on health and wellbeing are less known.

Current methods for sleep assessment are unsuitable for daily, objective tracking of sleep quantity and quality. Polysomnography is limited to a few night recordings given its need for specialised facilities and staff. On the other hand, sleep diaries offer the means for habitual assessment but are subjective by nature. Wearable sensors represent a promising alternative, as they enable the continuous monitoring of physiological and behavioural variables, which can be used to infer health status and health-related behaviours linked to clinical outcomes and adverse events.

The aim of this project was to prototype a medical-grade system for tracking day-to-day variations in sleep quantity and quality in real settings (e.g. home and hospital wards). Our prototype uses a patch-type device to record electrocardiography (ECG) and chest actigraphy (3D accelerations). Sleep quantity and quality are characterised by activity measures computed from 3D accelerations and heart rate variability measures computed from the ECG recordings.

As a case study, the system was piloted investigating the link between day-to-day variations in sleep and balance, which is relevant for the prediction of falls in later life. Study participants underwent in-home sleep and lab-based balance assessment for two consecutive days. Participants with a day-to-day deterioration in sleep quantity and quality (i.e. decreased duration and increased fragmentation, increased nocturnal activity and decreased heart rate variability) also exhibited significant changes in balance (i.e. larger body sway area, amplitude and standard deviation). Conversely, subjects with no significant alterations in sleep quantity and quality showed no significant changes in body sway. These results prove that wearable devices can be used for monitoring day-to-day variations in sleep quantity and quality. Moreover, these results also suggest that the balance control system is sensitive to day-to-day variations in sleep quantity and quality. These findings may be relevant for fall prevention in fall-prone populations (e.g. older adults and inpatients).

03. ICT and medical informatics

DATA REPOSITORY FOR DECISION-MAKING IN A HEALTH INSTITUTION

By **Ortega A.**

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In the present work is described the process for the realization of a graphic interface that fulfils the function of a repository and that, by using queries, shows the required information coming from several data sources, in order to achieve an integration of the information and prevent it from being dispersed, thus facilitating the process of data analysis. To achieve the objectives, we first resorted to an investigation in which information was collected on methods for data analysis, after having clear concepts, we searched for data sources (such as open source databases) that were part of a training of the methodology proposed in this work. By having the data, they are exported to the MS SQL Server environment for storage and organization. Then, through the Matlab Database Explorer application, connect the Matlab environment with the SQL Server and establish a communication with the data, in order to interact with them from Matlab. The next step was to design the graphical user interface in Matlab's GUIDE environment to create a search engine for the database, using the previously established connection. In parallel to this process, the SQL Server Data Tools tool of Visual Studio was used, in which the data analysis was done by means of the methods investigated in the first instance, with which we identified patterns that could help in the decision making based in the data used. With this methodology already done, we went to local health entities, which will provide information from their databases to apply this methodology. As a final result of the work, a graphical interface capable of searching three different databases and a data mining analysis was proposed, with which alternatives are proposed to improve the service provided.

03. ICT and medical informatics

ORÁO: OPHTHALMOLOGIC MEDICAL RECORD FOR CHROMATIC PUPILLOMETRY

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Chromatic Pupillometry is a novel approach to assess retinal disorders. It consists in the stimulation of the eyes with different wavelengths and light intensities. The pupil response to light stimulations represents a non-invasive way to evaluate the status of the photoreceptors of the subject. So, this method turns out to be particularly suitable to be applied in paediatric population.

The Italian Ministry of Education funded a project with the aim of assessing the chromatic pupillometry as a method to diagnose Retinitis Pigmentosa (RP) in children. The project has been designed as a multi-centric, case-control pilot study. The study sample consists of 40 subjects with an age range from 8 to 16 years. 20 subjects are affected by RP (Cases), while the remaining 20 are healthy (Controls). The project involves three University centres: Naples, Milan and Florence. The first two have been made responsible for the recruitment of the patients and the performance of the ophthalmologic and pupillometric investigations. On the other hand, the electronic medical record to gather data collected by physicians has been developed in Florence.

The medical record has been named ORÁO. It has been developed in close collaboration with the scholars involved in the project. The result is a customized IT solution which meets the needs expressed by the physicians and matches with the workflow of the pupillometric protocol they established. ORÁO has been designed as a cloud-based application with a 3-tier, RESTful architecture. The latter allows the integration of third party application. It is reachable via web by the physicians involved in the project.

According to standards, the interfaces of ORÁO have been designed with high attention to their Usability (ISO 9241-11:2018, IEC 62366-1:2015). Usability is strictly related to safety: a poorly designed interface can induce the user to commit errors, compromising the safe use of the platform. The usability of ORÁO has been assessed with the Heuristic Evaluation: the usability issues have been identified and the ones associated to the highest severity index immediately addressed. Some elements and redundancies have been introduced to reduce the risk of error: navigation menus, patient personal data menu, explicative message of error and feedback.

03. ICT and medical informatics

THE WAITING LIST PROBLEM IN HEALTHCARE SERVICE: MONITORING AND CORRECT MANAGEMENT - GOING TO THE DIGITAL CONVERSION

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Background: The waiting list is a critical point for the Italian Health Service. The long waiting time effects the level of patients satisfaction and service quality. The goal of this study is to show how to reduce the negative impacts of waiting on customer satisfaction and perceived quality by a cross connection between management software and booking system.

Methods: A routine waiting list reporting should be used to guarantee the quality of waiting list management and to pinpoint potential problems in access. The monitoring of waiting time (refer to Piano Nazionale di Governo delle Liste d'Attesa 2019-2021) represents the right way, as well known, to check and analyze the slots booking management not used in outpatient clinics. It's easy to catch what could be the wrong effects on outpatient process through a point monitoring of management software data. Patient's priority classes and the patient no-shows incorrectly create the reservations management, which effected of sure to increase waiting times. Unused space could be reallocated to a different priority class and this is possible by the management software connected to the booking system.

Results: Getting a better management of the health service, using a timely check and schedule actions on lists, based on the verification of the patient availability to receive the service allowed, make possible the iteration process till to fill the unused slots with new reservations. In addition, the software already in use could be improved to study the events monitoring and at the same time the organization itself. The information management, data monitoring, an appropriate resources allocation and a timely processes execution are, all of them, necessary due to define the patient journey process and its digitalization.

03. ICT and medical informatics

A SAAS OPEN PLATFORM FOR DIABETES WELLBEING

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For individuals with diabetes, self-management is crucial to maintaining quality of life and preventing long-term complications. At the same time, health care providers and researchers need to access population-wide meaningful diabetes-data and focus on approaches that can reduce the growth of a global problem. Current diabetes care solutions available on the market to individuals, health organizations and pharma companies, are patchy and isolated. And above all they are not open. Hundreds of mobile applications for diabetes self-management are commercially available to-date. While some of these may improve outcomes in the short-term, they lack of a proper and reliable integration platform with flexible integration protocols to offer concomitant support from health care providers and enable the collection of a critical mass of data to make solutions really useful.

We are currently implementing a Smart Integration Solution, as an open SaaS integration platform, to meet the needs of both diabetic patients and diabetes care stakeholders with up-to-date technology. A mix of Cloud and Edge services, augmented with IoT sensors, wearables and a mobile app with open integration protocols, operate as a patients' assistant, ensuring accurate, reliable diabetes data collection and decision-making support. We support evaluating diabetes-related data, such as blood glucose readings and their analysis, carbohydrate intake, insulin units, balance with the appropriate level of physical activity and assessing personal sentiment. Such activities pose significant personal and social impact as patients seek and receive support from multiple resources, including family and health care providers, thus affecting in patient's social context. Our tool reassures and empowers patients in the self-management of their condition with openness, availability and accessibility. A patient-focused solution that stimulates the adherence to tailored treatment that self-sustains the generation of improved quality of health measures. It provides seamless and tailored data-views to diabetes health care stakeholders, who need access to population-wide meaningful diabetes-data. We offer the opportunity to stimulate and support the adoption of effective measures for the monitoring, prevention and control of diabetes and its complications, particularly in low and middle-income countries. This can also provide recommendations to governments, individuals, the civil society and the private sector.

03. ICT and medical informatics

SECURING HEALTHCARE INFRASTRUCTURE BY PROTECTING MEDICAL DEVICES FOR GDPR COMPLIANCY AND PRIVACY DATA PROTECTION

By Iorio M.

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The solution presented addresses very critical aspects in the modern Healthcare environment, introduced by the pervasive use of Medical devices. If this has dramatically improved the whole patient care aspects, on the other hand it poses new challenges for the Healthcare Organizations: difficulty to patch against vulnerabilities; outdated OS; weak or hard-coded passwords; lack of encryption; use of legacy PCs; device mobility and nomadicity, and so on. Aspects like extended cybersecurity threat perimeter, patient data privacy, compliance with EU regulation such as GDPR and IT infrastructure management and control are key.

In the networking area, the Medical device is considered an IOT device: it has embedded in it a wired and/or wireless connection that lets it communicate with the outside world, even though it is not purposely built for the IT world.

Extreme Networks's IOT Defender provides three main features. First, it authenticates medical devices connected to the network, avoiding malicious replacement with unauthorized or tampered with devices. Second, once in the network, it controls device behaviour ensuring it does not move away from a licit traffic pattern creating a security policy, even dynamically generated, that locks down how the device is allowed to communicate. Third, it can create a secure IPSEC encrypted tunnel in order to keep confidentiality, authenticity and integrity of the highly sensitive data it handles between the medical devices and the Server Farm.

Deploying cybersecurity software between the IoT endpoint and the network, IOT Defender improves security level of devices that don't have, or cannot have for limited resources, enough compute power to run it locally. The deployment is easy and mostly automated, it scales very well for big environments, and the solution remains easy to manage and maintain. Also, it is platform independent, with almost zero impact. In addition, the visibility of the protected medical devices provides a very useful Inventory tool. All these aspects are key even for GDPR, where it requires "Data protection by design and by default". As a result, Business continuity is allowed at every stage. No service to the patients and the public needed to be stopped, suspended or made unavailable. IOT Defender addresses many of the security weakness of the medical devices, ensures data protection and patient privacy, protect Hospital whole environment and reputation.

03. ICT and medical informatics

PEH - PERFORMANCE EVALUATION IN HEALTH

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In the project PEH the purpose of this design analysis is to establish a functional and informational support constituting the cycle of performance management, detection and evaluation of operational activities at individual-level organizational structure and, overall, the level of leadership and governance. The solution proposed in the project PEH is of a totally new methodological point of view since it may be a first experience of assessment and self-evaluation based on the CAF (Common Assessment Framework) model, which is based on objective and verifiable and is supported by a information system and a virtual environment can provide objective.

Assumption is that this design goal is achievable through the implementation of ICT infrastructure, dedicated to the management of collaborative work environments and advanced to implement tools for measuring the contribution of each civil servant's decisions and activities targeted by the government project, allowing the assessment then the contribution provided professional individuals, and in particular the management, in the process of implementing plans and programs. The structure of collaborative software provides information systems for inter-thematic or thematic PA a vision, not topical or limited, but holistic approach.

The aim of the project involves measuring and evaluating the contribution of individual employees, and first of the management, the activities of the Administration initiative addressed. A further objective is to build a system of Key Performance Indicator (KPI) related also to the motivational profile. In particular, the project aims to: 1. creation and management of virtual communities responsible for implementation and monitoring of strategic plans and objectives defined at the regional or local authorities; 2. implementation of computer and telecommunication platform for the management of those communities; 3. management of implementation of the plans offered by using the tools of a virtual environment created; 4. implementing tools for tracking, measuring and evaluating the activities and contributions that each operator, at various levels of responsibility, role and function, makes the implementation of those plans; 5. implementation and sharing of assessments carried out within the public involved.

03. ICT and medical informatics

DECISION SUPPORT IN POST-TRIAGE PRIORITY OF NON-CRITICAL ELDERLY PATIENTS

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Triage is a sorting process which quickly determines the order by which patients arriving at the Emergency Department (ED) will be treated. It rapidly identifies patients requiring immediate care due to urgent, life-threatening conditions, as well as assessing the severity of the problem so as to ensure that care is appropriate and timely. In order to assist medical personnel involved in the ED triage process, a general methodology has been developed based on the Emergency Severity Index (ESI). The ESI triage procedure categorizes patients into five groups, from level 1 (most urgent) to level 5 (least urgent). Patients arriving at the ED that do not have a severe/and or life-threatening condition are required to wait to receive medical care. These patients are triaged at levels 3-5 and do not normally receive immediate care, even though those triaged as level 3 are treated with higher priority over those with levels 4 and 5, etc. Also, post-triage, patients that are triaged at the same level wait to be seen by a doctor in the ED based on a first come first served basis. For the elderly population, where the complexity of problems is increased and frailty is often an issue, a long wait may cause deterioration of their condition resulting in adverse events on one hand, while on the other, due to atypical illness presentation, they may be under-triaged, i.e. underestimating the level of urgency of care needed. Therefore, the problem is two-fold; on one hand to be able to provide decision support in order to minimize, as much as possible, under-triaging and on the other hand, it is important that patients are also prioritized after the triage classification within their classification category and not be tended to only on a first-come first-served basis.

To deal with the post-triage dynamically changing patient conditions, this work extends a two-stage Medical Decision Support System (MDSS) to perform two complementary decisions: i) automatically provide assistance in the triage classification and ii) to suggest and update the priority with which patients are seen by the ED doctor at post-triage for patients within an initial triage level, in particular for elderly patients. The MDSS is based on the soft computing modelling technique of Fuzzy Cognitive Maps, which is able to handle such complex and dynamic situations and aid in decision making. Patient cases will be included to show the importance of the model.

04. Health Operations/Project Management

INDUSTRY AND HEALTH 4.0 - THE FACILITY MANAGER AS FAUTOR OF INTEGRATED MANAGEMENT TO REDUCE BOUNDARIES BETWEEN CORE ACTIVITIES AND SUPPORT ACTIVITIES OF HEALTH ORGANIZATIONS

By **Mesoella G.**

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The digital transformation in the health field is having a strong impact on several fronts: robotization, privacy, introduction of new sources of risk, etc. All these aspects have a common need: to provide for an integrated management of the totality of the activities that revolve around the healthcare. In fact, often, as in many other companies, there is a tendency to have separate managements of what are the core activities and those that are all the other support activities within the facility management (FM). The FM as a support service for core activities, according to a Key Performance Indicator (KPI) model, is able to guarantee the customer the achievement of objectives on which the activity is measured. In this the facility manager tends to have a holistic management, also in view of an integrated SQA system (Safety, Quality, Environment). Once the support services have been identified (from the cafeteria to the plant and equipment maintenance services) and the supplier selection strategies ("make or buy"), an important focus takes place on risk analysis and assessment. From here, the presence of different actors begins to be felt. These actors must interface with each other to better manage the interferences and go to minimize the totality of the risks: the facility manager, with the activities he will manage, will go to introduce interferential risks, which will add to the risks inherent in health care (clinical risk and workplace risk for healthcare professionals). The all-round view of the risks and the "security" sphere of the healthcare world is completed with the IT risk strictly connected to cyber security, Big Data and the management of data digitization. In this approach, the FM can be of great support to the reality of a hospital company both in the design from scratch, and in the case of pre-existing structures (for example in the case of transfer of hospital activities in different departments / structures) with the application of the PDCA model for continuous process control. In support of what has been said, in the connection between industry 4.0 and health 4.0 it is evident that the facility manager plays a pivotal role. The challenge to the FM will be to have the management of health reality as much integrated as possible, touching all the aspects highlighted above, adapting to the continuous development of technology and the era of industry 4.0 and Big Data.

04. Health Operations/Project Management

A METHOD FOR EVALUATION OF MEDICAL TECHNOLOGY FOR RELOCATION WITHIN THE HOSPITAL

By **Martinez Licona F.M.^[1], Cornejo Cruz I.S.^[2]**

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The management of medical technology is a strategic activity for the optimal use of medical devices. As costs increase and access to financial funds reduce, it is essential to carry on actions that aim to optimize the current resources. In the other hand, medical care requests have exceeded the offer and constitute a public health problem. This issues directly affect the demand for most clinical services provided in healthcare institutions. Their current facilities are insufficient to meet the demand of an increasingly growing population. So, they have to expand in order to meet people's expectations. In public health, the allocation of resources for the acquisition of medical devices is limited. Although it is a matter of incorporating the technical, financial, and economic aspects to the evaluation, the decision to assign these resources is mainly oriented to satisfy the demand on the current service. Long-term aspects such as relocation or its removal are not considered. We proposed a methodology that uses the analysis of clinical, technical and economic factors applied to the relocation of medical devices within the hospital. It is intended to help the decision-making process to be carried out based on evidence. We assessed the current status of the medical device by applying the following technical, clinical and economic criteria: physical and safety conditions, functionality, effectiveness, efficiency, and reliability within the clinical service and maintenances, disposables and unit costs. Since this assessment is focused on the relocation of the medical device, we assigned the following weights to the general factors considered: 40% technical, 35% clinical, and 25% economical. We disaggregated each factor into specific aspects, as mentioned above, and we proposed the evaluation through the consideration of percentages of accomplishment. As a result, we released three formats to be fulfilled by the clinical engineer responsible for performing the relocation assessment. The format information was mapped into three regions of consideration previously defined: low-risk, middle-risk, and high-risk conditions. The medical device to be evaluated is located within one of these regions in a radial graph so the decision maker can visually appreciate the current status of the device. The results on a limited number of medical devices show that this information, although it is primarily intended for relocation, is also useful for further decisions as removal.

04. Health Operations/Project Management

OPERATING ROOM MANAGEMENT: THE RE-ENGINEERING OF PROCESSES ON A QUALITY PATH

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The following Project lays the foundations for a path to follow that verifies the efficiency of an operating unit for traditional, laparoscopic and robotic surgery of the A.O.U. Federico II of Naples, throughout the identification of any critical issues and possible solutions to reduce waiting lists and optimize the resources present in the healthcare company. The path is based on ISO 9001:2015, which promotes the adoption of a process approach that aims to increase customer satisfaction through the effective application of the system. The implementation of the project involved a period of monitoring of the activities, processes and paths that characterize the operating theatre. The activity was carried out manually using a resource who monitored the times and the room processes. For the monitoring to be valid, it is necessary that there is data collected over a period of at least 6 months. Allocating a human resource only to this task is onerous and ineffective, especially if you want to optimize all the operating blocks present in the University Hospital Federico II. Starting from this need, a management flow was defined within which an IT system for data collection and processing is implemented. In this case, the main data monitored are the times that mark the passage of the patient in the operating room, from the entrance to the operating room to the exit.

Prior to the implementation of the project, each operating room had a paper card on which four times were manually recorded: patient entry and exit, start and end of intervention. Considering that, a software for automated monitoring was designed with other four times in addition to existing ones: beginning and end of anesthesia, patient turnover and room cleaning. The management flow includes four main phases: Periodic internal audits, data collection and their analysis through a scoring system, finally implementation of improvement activities. The analysis of the times is carried out through one of the scoring systems present in the literature and whose validity has been verified, in particular through the indexes of efficiency, delay and the excess staffing cost. From the analysis of these indexes, it was possible to adopt solutions relating to the drafting of the operating room lists, to the organization of the staff and the warehouse. All this to make the activities of the Operating Block effective.

04. Health Operations/Project Management

THE VALUE OF CE-HTP-HTM IN IMPROVING HEALTH NETWORKS IN PERU

By **Rivas R., Clark T.**

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Health reform created (2013) stated: protection of public health and patients. One objective was to build and sustain capacity for prevention, detection and rapid response; another objective was to provide on-time quality services. "2018-Health Ombudsman Report" informed the hospital's context has: 67.7% with insufficient efficiency regarding the demand; 45% don't have enough medical equipment; 57% don't provide 24 hours echocardiographic service. MoH's 2018 focused on planning and management health investments and maintenance. Interactions of WHO Collaborating Center at the Univ. of Vermont USA with MoH started in October 2018 and continued in 2019, aimed to 2 levels: 1) authorities responsible for the management and planning and 2) executive and managerial staff focusing on: Planning, Implementation and HTA. Results: a) Participants agreed the appropriate use of technology is crucial to rationalize the time and cost, allowing to meet a greater demand, increasing the coverage of services; b) CE-HTP-HTM pertinence to improve Health Integrated Networks-HIN objectives was stated by MoH staff and c) Areas of opportunities to improve services with training. HIN, group of organizations that provide primary health care services was created by MoH in 2018; "2019 HIN Management Guidelines" include:

- Management of technology.
- Relevance of interoperability gap of information systems.
- Technology Decision Making based on HTA.

MoH Guidelines is required to improve primary health care; it is also required methods, procedures and standards based on CE-HTP-HTM to support the achievement and sustainability of objectives. The paper contributes in this regard.

04. Health Operations/Project Management

ALBANIA AND THE REGION COLLABORATION

By **Picari L.**

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This work presents the attempts to establish collaboration between Albania and neighbouring countries in the Mediterranean and West Balkan countries. It presents the progress done in this region to share expertise, best practices and promote common approaches in health technology management, market surveillance, assessment etc., in line with current European Union legislation. Initiatives to implement projects specially with Kosovo, Italy, Greece and North Macedonia aim to increase the efficiency of health technology management systems and strengthen capacity building. This process aims to further strengthen the cooperation of state institutions and professional country associations.

04. Health Operations/Project Management

ENTREPRENEURIAL MODEL FOR CE STARTUPS BASED ON LEAN STARTUP AND SAINT STARTUP TOOL APPLICATION

By **Fernandez Aviles L.E.**

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Setting an entrepreneurship pathway for clinical engineering or health technology management startups is a big challenge, as many universities don't include entrepreneurship topics in their bachelor programs. While startups struggle for their new ideas/projects to succeed, there are proven methodologies that will help their initiatives preserve (continue pursuing success using a validated business strategy) or pivot (shift in their strategy to validate a new approach) their business. This article focuses on the application of Lean Startup (LS) methodology and Saint Startup (SS) tool in a startup built by Mexican HTM specialists; TINC.

Objective: Validate if the application of LS will improve the results of a Clinical Engineering startup (with a validated product) by measuring improvement in key business areas proposed by the SS tool in combination with the team's participation in Start-Up Chile's acceleration program (AP).

Method: We used the SS tool to evaluate the startup's current progress in order to determine if the team was targeting the necessary areas to reach their goals. With areas of opportunity detected, the team was able to address them participating in a 7-month AP. After the AP, SS tool was used again to measure results and compare them to the initial state.

Result: The tool provided information about progress in 10 areas considered to be essential for any startup (5 more than the startup was currently focusing on). By adjusting the team's roles to target these areas, completing SS tool tasks, as well as participating in Start-Up Chile's AP to enhance team capabilities, the startup made huge progress accomplishing an increase of over 300% in revenue and customers. Thanks to the team's efforts and results, the startup was awarded as one of the top 10 startups to participate in LATAM's most important acceleration program, received a total of US\$80,000 in equity-free funds by the Chilean Government, and received an extension of 7 months of the acceleration program.

Conclusion: Using a validated methodology as a framework for entrepreneurship (like Lean Startup), measuring progress on key strategic areas with validated tools (like Saint Startup), and receiving support on identified opportunity areas by validated acceleration programs and mentors (like Start-Up Chile), a Clinical Engineering startup with a dedicated team and validated service/product can enhance their results and scale to become a feasible business.

04. Health Operations/Project Management

PRINCIPLES AND PRACTICE OF MEDICAL EQUIPMENT PLANNING IN HOSPITALS OF TRADITIONAL CHINESE MEDICINE

By Lou X.M., Wan G.F.

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Taking the Dingqiao Campus of Hangzhou Hospital of Traditional Chinese Medicine (TCM) as an example, this paper focuses on its overall medical equipment plan. Through case studies, it provides a reference for the equipment planning of large TCM hospitals. This new public hospital started its construction in Dec 2014. It was designed and built as a tertiary level hospital, the highest classification for health-care facilities in China. It enhances the level of medical care, teaching, research, health-care management, service quality from its main campus as well as emphasizes contemporary comprehensive rescue capacities and the advantages of traditional Chinese medicine. It is committed to providing high quality diversified health-care services in order to meet and exceed growing demands from more people.

In addition to the necessary capital equipment, routine diagnostic and therapeutic equipment, we need to use the equipment based on TCM theory to provide patients with comprehensive traditional medical services.

We have adopted the following principles:

1. Plan for once, phased procurement.
2. Integration and coordination with infrastructure planning and construction.
3. Different from western medicine hospitals, TCM hospitals need to deploy multiple types of TCM health intervention equipment such as acupuncture, moxibustion, magnetic therapy as well as meridian detectors, etc.
4. In order to give full play to the advantages of traditional Chinese medicine, it is necessary to plan for traditional Chinese medicine preparation equipment. Different characters such as herbal pills, powder, cream and decoction of traditional Chinese medicine require different processing equipment.

04. Health Operations/Project Management

A HIGH TECHNOLOGY LABORATORY DESIGN AND IMPLEMENTATION: THE OPBG EXPERIENCE

By De Vivo L.^[1], Pireddu M.^[1], Nacca A.^[2], Nunzi P.^[3], Fioramonti E.^[4], Di Paola C.^[4]

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Objectives: OPBG had the need to re-engineer the Analysis Laboratory activities since 2006. However, logistic and organizational issues held the HTA evaluations back until 2017, when Research Laboratories were moved from Gianicolo and spaces were cleared. Reorganization focused on the automation of the Analysis Laboratory processes and aimed at: activities' integration, technological updating, sample traceability, reduction of errors and risks for both operators and patients, resource optimization and production yield improvement.

Methods: A multidisciplinary group of professionals worked on the project, each one involved for his own competences. The first step was the assessment of the requirements and led to definition of spaces, analytical lines, sections, technological equipment, sample logistics and workflows. A comparison with other hospitals was also considered for the evaluation. At the same time, the analysis of the project constraints, including structural and plant constraints, was carried out, together with a prediction of the resources required for implementation in terms of times and costs. Results were sent to three leading companies and each presented a personalized design hypothesis. Detailed studies were carried out with the winning company for the executive project's definition.

Results: The project marked the transition to a modular automated laboratory consisting of a stand-alone preanalytical, a core lab with integrated preanalytical, two analytical lines and a storage system. This adjustment led to the reorganization of the whole laboratory's workflow, supported by the introduction of the pneumatic mail and a centralized special wastewater disposal system.

Conclusions: The realization and relocation of the laboratory were carried out according to the timing specified by the Top Management, even though the overlap of activities and flows represented a very critical issue. The continuity of the laboratory service was guaranteed throughout the entire process. The project follow-up is scheduled at 6 and 9 months from the start of the activities, in order to evaluate the coherence of the implementation in relation to the hospital needs.

04. Health Operations/Project Management

MANAGERIAL METHODS FOR MEDICAL DEVICES AND DEVELOPMENT FOR INNOVATION IN THE CLINICAL ORGANIZATION

By **Stroili M.^[1], Sancin D.^[2], Scartabelli V.^[3]**

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The reduction of beds and technological development have increased the Medical Devices (MD) in hospitals to monitor critical patients and improve speed and accuracy of diagnosis and the therapies for the quality of life. The complexity and quantity of the MDs made it necessary to create four work tools, supported by software and managed by the Clinical Engineering Services. The MD Inventory shows the administrative, economic and operating data of all the machines and assigns a different number to each MD. A specific Database reports all the failures of each MD. The Registers contain the electrical checks, scheduled maintenance and faults. The Renewal Plans decide the eliminations and new acquisitions of MD with a priority index. Health Technology Assessment Services (HTAs) have been set up in large healthcare organizations with doctors who work with engineers. The HTA service analyzes the large databases for risk analysis of the functioning of the MD with techniques such as the FMEA and enhances the Equipment User Manuals. The Manuals contain data regarding the correct operation of the MDs and possible failures. An innovative Procedure proposed by the HTA (GNB Proceedings - The standardization of radiation oncology treatment and the chronological checklist in the discharge of a structured patient report, follow up and electronic sanitary file-FSE.2018 Milan, Patron publisher) introduces the standardization of work organization in high-tech centers, such as radiotherapy. However, this standardization procedure is applicable to any clinical structure with inpatient or outpatient. With a checklist each care Department defines its steps during the pathway of diagnosis, treatment and follow-up for each patient. The checklist establishes the chronological order of the interventions and the consequent numbering of the actions and increases the control and clearness of the clinical actions carried out. A computerized checklist must be present in all the workstations of doctors, technicians and nurses to facilitate the registration of all the steps that operators must take to ensure safe care to patients. At the end of the visit or admittance, patients receive a "Discharge report" with the checklist that describes what has been done and still needs to be done to treat it well.

04. Health Operations/Project Management

HTPMP-HEALTH TECH PROJECT MNG PLATFORM. SIMPLIFY PROJECT MNG IMPLEMENTATION IN HEALTH TECH CONTEXT

By **Iachetti G.^[1], Poggialini G.^[2]**

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Project Management is still a low developed and deployed knowledge in Clinical Engineering. From Project to Program and Portfolio Management it has a wide range of potentiality. One of the most challenging problem in Project Management for Clinical Engineers is to connect professionals from different specializations, keeping monitored and controlled the "triple constrain" (scope, cost and schedule). Each Clinical Engineer, who started a Project with some "formal" method, has experienced how it's tough to keep informed each stakeholder and in the same time control the change request that normally can arise. The HTPMP is a Platform based on Microsoft Sharepoint and Microsoft Project Office 365 - Premium Pro. This kind of platform is commercially available like others. It's customization has been the core of the work presented. In the platform is possible to create different user profile, from "sponsor users" with access to reporting and updated visual information by web page to Project Manager of external supplier, giving them an autonomous sub-project in which it's possible to re-scheduling or just update the completion percentage.

By the Sharepoint documental repository is possible to share with each profiled users all the documents without any fear of "not-updated" ones. The updating functionality is in the data flow and validation process itself. The older version remains in log. Another important feature of the platform is that can easily support one of the most time consuming and challenging process of complex project in healthcare: assessment of change request and perform integrated change control. Each change request is classified in minor or major and is linked with an owner, responsible for its solution.

The platform has been used for a new radiotherapy dept project with 17 users. The project finished on time, within cost constrain and with 22 issues and 192 drawing and other project docs (reporting, for the most part). The project sponsor authorized 3 change requests with activities "adsorbed" in total floating of the project.

04. Health Operations/Project Management

THE UNIQUE ROLE OF A CLINICAL ENGINEER IN HOSPITAL AND HEALTHCARE MANAGEMENT

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Healthcare is internationally regarded as one of the most complex sectors in the world today. Models of care are changing, technology is rapidly advancing and the requirements on the system are changing at an alarming rate. Healthcare has often been referred to as the 'two headed monster', with medical and non-medical professionals working alongside to deliver patient care in an ever evolving and changing environment. Both professions are highly qualified in their respective fields, with clinicians very knowledgeable in the biomedical and treatment aspects of patient care and others educated in managing the various functions of an organisation that delivers patient care. The healthcare system has to manage, and attempt to balance where possible, the interacting challenges of increased life expectancy, technological progress, mismatch between supply and demand of the workforce, increases in healthcare regulation, while dealing with shrinking budgets for the increasing population.

Given the challenges noted, it is clear that the profession of Clinical Engineering has the upper hand on many other professions when it comes to working in healthcare management. At the core, they are highly qualified and trained engineers – analytical, detail-oriented and systematic problem solvers. Many of the world's top CEO's have an engineering background, with engineering being the most common undergraduate degree among Fortune 500 CEO's. Engineers are renowned for being practical, skilled in the area of IT and of strong mathematical aptitude – all of which are useful in a developing world of technological advancements. Clinical Engineers are engineers trained to understand the clinical aspects of healthcare and its terminology, and have the role of applying and implementing medical technology to optimise healthcare delivery, through the application of specialist engineering, physics and scientific principles.

This paper looks at the challenges encountered within the healthcare system, and how Clinical Engineers are ideally placed to deal with those challenges and help to progress a safe, effective and high quality of healthcare for our patients. The author of this paper is an Acute Healthcare Hospital Manager and a Clinical Engineer, and many engineering colleagues within

04. Health Operations/Project Management

MULTIDISCIPLINARY HYBRID OR

By Conti C.

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The Baggiovara hybrid room is a project aimed at combining the functionality of a latest generation multi-purpose operating theater with the best of digital angiography available on the market today, in one room. His strong multidisciplinary (extended to Vascular Surgery, General, Neurosurgery, Urology, Endoscopy and Cardiology) and its vocation oriented both to the election and to the urgency make the project unique in his kind. Layout technical choices focused on maximum symmetry they are optimized to guarantee the best functionality in the different settings operational, as well as the versatility of X Ray diagnostic with Volumetric Isocenter. Great attention to sterility with the achievement of ISO 5 quality classification according to the UNI EN ISO 14644 standard. The room is fully integrated with the hospital information system and is complete with multimedia system in 4K able to optimize the vision recognizing grayscale or color images.

04. Health Operations/Project Management

CLOCK MANAGEMENT OF MEDICAL EQUIPMENT

By **Zhu J., Lou X.M.**

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Clock Management is an important part of first Aid process. The acceptance system of China chest pain Center has the requirements of clock unified scheme and management clearly calling for the establishment of a unified clock scheme, management system and objective records, to ensure the accuracy of the diagnosis and treatment process. Emergency equipment, such as defibrillator, ECG, ventilator and so on, will be directly related to the integrity of clock management. Due to the lack of equipment clock management system, many equipment has not achieved the accurate uniformity of clock. This project realizes clock management through the technical method of clinical engineer, so as to ensure that the first aid process is more perfect and rigorous.

The equipment management department has formulated the equipment clock management system, which requires clinical staff and equipment maintenance personnel to strengthen the management of the equipment clock.

The methods of equipment clock management are as follows:

1. The equipment connected to LAN can be synchronized with NTP time server to realize automatic management;
2. The single machine version of equipment or the equipment which cannot be set up synchronously is managed manually, and the clinical engineer is responsible for training clinical staff to calibrate the clock.
3. The instrument time proofreading project is added to the daily use record book of medical equipment.
4. Clinical engineers should inspect the accuracy of the equipment clock on a regular basis.

Through the implementation of medical equipment clock management system, the accuracy and unity of equipment clock are obviously improved, which also makes the first aid process more rigorous and accurate.

04. Health Operations/Project Management

DIGITAL TRANSFORMATION OF THE BIOMEDICAL ENGINEERING MISSION INTO A HEALTH CARE INSTITUTION

By **Dion H., Weigel R.**

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French hospital engineering is suffering the full impact of the evolution of the health sector and is confronted on the one hand with an explosion of innovations, requirements and constraints, and on the other hand, it is invited to drastically reduce its personnel costs and investments. The answer to these contradictory injunctions is only possible through technical and managerial evolution, which must be based very largely on the development of digital technologies in all components of hospital engineering. The control of biomedical information assets (storage, access and dissemination) is becoming an essential issue for the proper functioning of an organization. It is no longer enough to limit the use of CMMS (Computer Assisted Maintenance Management) software.

Information related to biomedical heritage management is now produced and received in digital form. However, it is still common practice to print this information for filing, archiving and physical distribution. In this demanding context and with high objectives, biomedical services must be accompanied by new digital tools that go beyond CMMS functionalities, to enable efficient, digital and mobile information management.

The project consists of an organizational evolution of a biomedical service in a digital and digital world. This intangible space where information is hosted, stored, distributed and accessible via dematerialized media is at the heart of the transformation of the service to improve its efficiency.

Software for digitising the technical and organisational procedures and processes of the maintenance function exists and will undoubtedly establish them as business software in the same way as CMMS software did 20 years ago. However, they are not or little known to the biomedical community. The industrial world is more advanced on this type of software solution. These softwares are recent and their development is linked to the democratization of mobile devices (tablets and smartphones) and to an increasingly digital management of data. The Association Française des Ingénieurs Biomédicaux (AFIB) has supported the Centre Hospitalier Louis Pasteur de Dole as part of its institutional project on this issue of the digital and digital transformation of biomedical services into biomedical engineering health establishments. As a result, two software packages were deployed: one for maintenance procedure management and the other for organizational process management.

04. Health Operations/Project Management

MATRIX, A NEW ERA IN FACILITATING 10.000 MOBILE MEDICAL DEVICES IN A DUTCH ACADEMIC HOSPITAL

By **Been S.^[1], Nieuwenhuis E.^[2], Prins A.^[3]**

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The University Medical Center Utrecht (UMC Utrecht) uses its medical devices inefficiently. Especially medical devices that are used by a wide range of departments throughout the hospital. The UMC Utrecht is not unique. Several hospitals in the Netherlands, in Europe and even globally face the same issues¹. Caregivers spend a significant amount of time searching for lost medical devices. On the other hand, hospitals seem to have an overcapacity of equipment, which is visible in the large amounts of devices in storage. In UMC Utrecht every clinical division has its own set of medical devices, which meets the care demand at full capacity. This partition makes utilization of devices more inefficient and complicates managing regulatory compliance of these devices. To tackle this inefficiency and safety issues, another organization model regarding medical devices is required. The focus should shift from object to process management, supported by technology, like location based services and task & object management. We aim to offer a hospital wide service to unburden caregivers. The service contains 4 elements: Cleaning, Maintenance, Transport and Storage on hospital-wide used mobile medical devices. This service concept is designed to improve the availability of the medical devices, to achieve an even more responsible application and to improve the caregiver competence on usage of medical devices. MAtriX is a hospital wide project which requires a collaboration between all departments and all hierarchical levels, from caregiver to the board and from cleaner to IT architect. Besides technology and process management the key to success is co-creation (with caregivers and industry) and stakeholder management in design and implementation. Recently we learned in our Experience Center: Caregivers are excited about the designed service concept. A flexible, scalable, open software system is recommended. There is not a single localization solution (RFID/BLE/WIFI) that fits all needs. This summer we will pilot the designed service concepts on 2 departments, including the required IT-solution to evaluate and optimize the service. These insights will be used for a business case for hospital wide implementation.

1. Ruslan Horblyuk et al. - Out of control little-used clinical assets are draining healthcare budgets. 2012 Healthcare Financial Management

04. Health Operations/Project Management

SURVEY OF ECONOMIC FEASIBILITY INDICATORS FOR MEDICAL EQUIPMENT INCORPORATION

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The incorporation of new technologies in health has been shown to be more challenging each year. Health Care Establishments need to be prepared for new infrastructure requirements, methods, concepts, inputs and methodologies. Concerns about patient safety have changed the concept of how and what materials used in clinical procedures can be reprocess. Several single-use accessories and supplies options have emerged and a thorough market assessment prior to the incorporation of new health technologies has a significant impact on the cost-benefit of technology. This paper presents what can be analyzed in the incorporation process of health technology, as an example was evaluated the automatic external defibrillators. Only the cost primary for incorporation is not sufficient to obtain the cost-benefit without assessment the real cost during the technology life cycle, maintenance, the supplies and disposal. In the cost's evaluation of the automatic external defibrillators it could be verified that the price of the supplies is high compared to the cost of the equipment. The direct costs with the equipment are only of the electrodes representing on average 10% of the total cost of the equipment. The option to rent the equipment instead of buying it, also can be an alternative. With this analysis the savings generated throughout the technology life cycle may be enough to replace it when it is in a state of obsolescence. Low complexity technologies may conceal a high cost, called Iceberg cost. The indicators presented are from the Brazilian market where procurement and contracting in public sectors are regulated by procurement and contracts to guarantee free competition and meet the specific requirements of each institution, aiming the best cost benefit.

04. Health Operations/Project Management

THE HOSPITAL UNIVERSITARIO VIRGEN DEL ROCÍO IN SEVILLE, SPAIN HAS GOT THE ISO 13485:2018 DURING THIS YEAR

By Sanmartín Sierra J.D.

SEEIC, Sevilla, Spain

The Clinic Engineering Service of the Virgen del Rocío University Hospital of Seville has obtained the certification of the UNE EN ISO 13485: 2016, in Quality Management Systems for Health Products. This Certification is the specific management of Health Products and aims at the correct administration of quality products and services at the applicable regulatory level. Currently, there are few Electromedical Services, nationally, certified in this Sanitary Products standard. Circular 3/2012, on technical assistance from the Spanish Agency for Medicines and Health Products, and the guide UNE 209001, on the management of Health Products, mark what a quality management system should have.

The Electromedical Service of the Virgen del Rocío University Hospital in Seville has wanted to be certified not only in ISO 9001 but its reference standard was the specific one of the Sanitary Products, ISO 13485. The main difference is that ISO 9001 is a general reference in quality management systems and ISO 13485, as specified by the Sanitary Products, accredits compliance with legal requirements and current regulations on Sanitary Products and in vitro diagnostics. The Electromedicine Service is part of the Engineering and Maintenance Sub-Directorate that reports to the Economic Department, and manages the medical devices, both the electro-medical equipment and the in vitro diagnostic equipment, both governed by different European recommendations. Within the management of these devices, corrective, preventive, conductive and legal technical maintenance is carried out, always in accordance with the recommendations of the manufacturer, of the equipment. In addition, the service advises, from the technical point of view, the preparation and information of the Technical Prescriptions for the acquisition of new equipment.

During 2018, the Electromedicine Service managed more than 15,000 technical interventions on 11,000 main medical devices, in addition to another 24,000 between main and peripheral devices. Also, 88 health alerts. All this has involved more than 50 daily interventions and more than 1,000 a month. The new ISO 13485 certificate will expire in 2022, when it must be recertified, and, until then, it will be audited, on an annual basis, by an external audit company, which guarantees, in this way, that quality standards are maintained, which add value to the daily management of health technologies at the Virgen del Rocío University Hospital, Seville.

04. Health Operations/Project Management

THE VIEW OF A GENERAL PRACTITIONER ON IMMEDIATE ACCESS FOR PATIENTS TO THEIR LABORATORY TEST RESULTS

By Fitton R.

West Pennine Local Medical Committee Manchester England

This project audited the use of online access to laboratory results by 160 patients and analysed the capacity benefits to patients and doctors. The project examined the practice and literature concerning a recommendation for responsible and immediate sharing of results with patients for improved safety, efficiency and outcomes and a research. One of the critical components of high-quality patient care is efficient and accurate clinical laboratory testing as many clinical decisions depend on laboratory test results [2]. It is, therefore, imperative that test results are appropriately and timely communicated not only to medical practitioners but also to patients.

Patients should receive care whenever they need it and, in many forms, not just face to face visits. This rule implies that the health care system should be responsive at all times (24 h a day, every day) and that access to care should be provided over the Internet, by telephone, and by other means in addition to face-to-face visits. The project examined a real sample of patients who had accessed their online laboratory results. An average of 187 clinical appointments (of which 87 were with doctors and 45 with nurses) and 290 telephone calls were saved. If 30% of patients used RA at least twice a year, these figures suggest that a 10 000-patient practice would save 4747 appointments and 8020 telephone calls per year.

Assuming a consultation rate of 5.3%, annually, that equates to a release of about 11% of appointments per year, with significant resource savings for patients and the environment.

Online access to real-time laboratory results has the potential to improve patient safety and to increase GP capacity and time to provide care. Patients and doctors will benefit as many clinical decisions depend on laboratory test results. It is, therefore, imperative that test results are appropriately and timely communicated not only to medical practitioners but also to patients. Accessing results by telephone can be difficult after daytime hours and at weekends. The process of laboratory test results communication in primary care can be improved by integrating test result management tools into patients' electronic health records (EHR) and improving patient engagement in the process.

04. Health Operations/Project Management

TESTING THE HEALTH LITERACY OF TWENTY BANGLADESHI PATIENTS BEFORE AND 6 MONTHS AFTER THEY HAD ACCESS TO THEIR ELECTRONIC MEDICAL RECORD

By Fitton R.

West Pennine Local Medical Committee Manchester England

We give print outs of their record and letters as well as access to the record to the ELOS patients. Doctor Fitton (GMC and MDU indemnified) was employed for a no income contract to compare the answers of the questionnaires to the patients' notes. We assessed if there are changes in understanding after the record access.

"Learning how to manage your own treatments and diseases. Patients who understand their health and diseases have better results from their treatments. It is necessary to know what is wrong with you to help yourself. We are giving patients as much information about themselves and their diseases and treatments as we can. We would like to see how much difference makes to your understanding so that we can help other patients better. Please could answer these questions for us before you see your records and after you have seen and owe a copy of your record. We will see if having seen and having copies of your records does improve your understanding of your diseases and treatments."

Every patient increased their knowledge score after having their records for 6 months. Health literacy for patients is the same as for doctors. It improves with practice and experience and requires knowledge, skills and application. Our study showed an improvement in health knowledge and further studies may conform this and lead on to studies showing how patients can utilise their records to improve their health and health care outcomes.

05. Clinical risk management, safety, emergency preparedness

IMPLEMENTATION OF IMPROVEMENTS IN THE REVERSE OSMOSIS WATER TREATMENT SYSTEM FOR HAEMODIALYSIS AND MATERIAL CENTRAL AND STERILIZATION

By Souza E., Rezer R., Marciano M.

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When not treated properly, the water with inappropriate conditions, can cause clinical symptoms in human beings. In the market there are some types of processes of water filtering and separation. The reverse osmosis, process the fluid against the concentration gradient in the reverse form than the osmosis. In this process, occurs the removal of bigger organic molecules, ions and microorganisms. the project proposed realising a 'retrofit' (improvement, adequacy, automation enlargement and safety items) in 2 Systems of Reverse Osmosis with the goal of guaranteeing more systems control, by installing new devices, automation of components/elements, as well as the data integration in one interface (IHM-Interface Man Machine/Supervisor) and the possibility of remote access.

05. Clinical risk management, safety, emergency preparedness

PRESENTATION OF METHODS OF HOSPITAL EQUIPMENT DECONTAMINATION IN UNITED ELECTRONIC DOCUMENTS: SUPPORT TO THE CONTROL OF HOSPITAL INFECTION

By Souza E., Marciano M.

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The hospital infections are commonly the more occurred complications in hospitalized patients. It is estimated that in Brazil from 5% to 15% of patients admitted to the hospital contract some infection coming from a hospital process and increase on average, 5 to 10 days to the hospitalization. Considering that there is a big variety of hospital equipment in a hospital, and a frequent incorporation of technology causing it to occur a variety of types and ways to care about the decontamination of its pieces and parts, it is made necessary to update these methods and make them available in an electronic/digital manner to disseminate information as well as to facilitate the access to routine consultation. The main purpose of this project is to make available in electronic/digital document, to the professionals of the Hospital Infection Control Services, to those responsible for the process of decontamination (CME) and users, the proper instructions from the manufacturers, concerning the decontamination methods of hospital equipment and their parts. As specific goal we look for Developing and Standardize the evaluation flow of decontamination methods of equipment and its parts and pieces in the acquisition process, so that all the impact be evaluated in advance, such as: decontamination method, flow alteration necessity, processes, controls, related costs to new incorporation, budget planning, etc. It was observed the following orientations from the manufacturer: 7 types of cleaning methods, 15 methods of disinfection and 11 indications of sterilization cycle, to each brand and equipment model in operation in the hospital. It is expected that the availability of decontamination methods (in one electronic document), revalidation of the infection control commission, can contribute to update the information (reorientation and updating the professionals responsible for decontamination activity), as the incorporation of new technology are being made in the hospital.

05. Clinical risk management, safety, emergency preparedness

MEASUREMENT AND EVALUATION OF ACOUSTIC NOISE EXPOSURE DURING CLINICAL MRI EXAM FOR PATIENT AND STAFF

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Purpose: To assess the equivalent sound level MRI patient and operator expose to during MRI exam with multiple sequences.

Methods: The equivalent continuous A-weighted sound pressure level (L_{eq}) during the MR examination of 179 patients on one MRI scanner and ambient noise of operating room were measured at the exit of the magnet bores and the position of operator with a sound level meter that is insensitive to magnetic field, respectively.

Results: It cost patients about 7.95 ± 2.38 minutes to completed MRI exam on average, and the noise level they exposed to were likely to be 101.4dBA (95% confidence interval: 100.6, 102.1, t-test). The maximum sound level various from 97.4~127.7dBA. The ambient noise level obtained at the operator position in operating room was 69.5dBA over 30 minutes.

Conclusion: The equivalent noise level during patient examination exceeded the IEC limit of 99dBA and an amount of countries' permissible levels of 97.3dBA over 8 minutes of exposure (85dBA for averaged over 8 hours per day). The maximum sound level during MRI exam has reached 127.7dBA, which exceeded the permissible limit of 115dBA, set by OSHA. Though the daily exposure to ambient noise for staff at operating room was less than 85dBA, it was higher than 55dBA, the permissible level established by FDA of China. Therefore, the use of ear protection devices is essential for all patients and operators.

05. Clinical risk management, safety, emergency preparedness t

OPTIMIZATION OF PATIENT SAFETY, WORK- AND CURE ENVIRONMENT IN NEW SINGLE-BED CARE UNITS IN RIJNSTATE

By Kruis N.

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Moving from ward care to single-bed care has been a trend over the last years. A significant amount of patients prefer single-bed care over wards. Single-bed care improves the rehabilitation of the patient and is more comfortable for the family. However, in single-bed care environments the distance between the nurse and patient is longer and they are often divided by a closed door. To notice whether the medical equipment monitoring the patient vitals sends out an (urgent) alarm, nurses need an alarm management system. A potential risk with such a system is an overload of alarms. This leads to alarm fatigue which can lead to safety risks for the patients. Our aim is to optimize patient safety, work environment and rehabilitation of the patient while preventing alarm fatigue in the implementation of an alarm management system at the new single-bed care units of Rijnstate Hospital, starting with the department of Intensive Care.

Technical and functional requirements were defined with various departments to determine the best system for alarm management in Rijnstate Hospital. The choice for IQ Messenger was made because of the possibility to connect with many medical devices of various vendors and their development plans for IQ Messenger in the future. Table top sessions and audits with the nurses, clinical specialists and other staff developed the workflow of working at a single-bed care unit with the alarm management system. Discussions and various tests defined alarm settings in the alarm system, such as filtering, volume, sound, etc. After initial rollout, the go-live evaluations and experiences were used to periodically optimize the alarm settings in the alarm management system and workflow around the patient.

Today the Intensive Care uses the new build single-bed care unit with the alarm management system. Compared to the old ward care unit, patients, staff and visiting families experience the new Intensive Care to be more quiet and calmer. The alarm management system is reliable, patients feel safe and staff feels it is dependable and allows them to react appropriately to incoming alarms. The work environment has improved by receiving only alarms that need action and the more quiet surrounding. This allows more focus on the patient which can improve their rehabilitation.

05. Clinical risk management, safety, emergency preparedness

RISK ANALYSIS OF ELECTROMEDICAL EQUIPMENT DURING USE IN THE HOSPITAL ENVIRONMENT

By Souza W., Marciano M.

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The objective of this paper is to collect and analyze the potential risks related to medical equipment. Map the failure modes, in other words, the way of the fault The form of the fault where the equipment, accessories, systems and processes leaves to perform its function or disobey the manufacturer's specifications. From this survey, planning barriers and actions to minimize the risks. The FMEA ("Failure Modes Effects Analysis") was used as a method to assist in the classification of the potential risks of medical and hospital. It is a method used to prevent failures and analyze the risks of a process, through the identification of causes and effects to identify the actions that will be used to inhibit the failures.

The FMEA was transcribed in a spreadsheet and adapted. The Risk Index was obtained from the result of: "Probability (notes from 1 up to 10, remote up to the inevitable), multiplied by Severity Degree (notes from 1 to 5, from no consequence up to stop more than 4 hours) multiplied by Degree of Detection (note from 1 until 5, from easy to impossible)".

The survey, analysis and filing of data were filled by a focal group, which operates in the Clinical Engineering. The group is composed by experienced professionals and experts in the management and maintenance of medical and hospital equipment (from 5 to 20 years of activity in the area).

05. Clinical risk management, safety, emergency preparedness

A COMPREHENSIVE SYSTEM FOR THE PREVENTION OF LEGIONELLOSIS IN A HOSPITAL

By Gimigliano M.^[1], Talarico F.^[2], Minchella P.^[3], Alcaro T.^[3], Panduri G.^[3]

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This article aims to demonstrate that a comprehensive prevention system is able to diminish risks of Legionella Pneumophila spreading and infection. Risk mapping was the first intervention, then control of critical points and, in particular, a plant of water treatment have been developed. Monitoring of possible bacterial contamination has been performed through laboratory analysis, as it is prescribed by ISS (Istituto Superiore di Sanità) guidelines. Site of entrance of cold water in the hospital was the first critical point to control by a disinfection treatment. Furthermore, maintenance has been improved providing for specific instructions to the maintenance companies.

MATERIALS/METHODS: Pugliese-Ciaccio is a general hospital with 450 beds. Firstly, a protocol for prevention of legionellosis was adopted by the hospital. Water plant and distribution were analyzed in detail. Water has periodically been sampled in a series of specific control points along the distribution system. A UV lamp with a UVC probe and a chemical disinfection including H₂O₂, Ag⁺ ions and an anti-corrosion product (based on phosphorus silicate) have been provided at the entrance of the water supply. Besides, a further UV lamp was installed in the point of return of warm water before entering the boilers. Finally, possible presence of Legionella had been monitored for two years.

RESULTS: The concentration of Legionella in the samples of water was always found below the threshold considered at risk. After some months of use of disinfection treatment, the concentration of Legionella was found significantly decreased along the entire water distribution system. After two years Legionella is ever under dangerous limits.

CONCLUSION: A combined approach using physical and chemical disinfection has achieved the result of reducing the likelihood of legionella infection both by decreasing the pre-existing microbial contamination and by impeding new contamination.

05. Clinical risk management, safety, emergency preparedness

REDUCING CLINICAL RISK WITH A CORRECT MANAGEMENT OF MASTER PATIENT INDEX

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Integrity of data in Electronic Health Records plays a fundamental role in health care quality. Patient identification and its clinical history management using a Master Patient Index is a key aspect when dealing with EHRs, but it also brings relevant consequences when patient identification processes are faulty. In our Institution, we recognized critical aspects in managing MPI related to incorrect identification matching and patient record duplication. Such kind of errors causes fragmentation of health history of one patient among multiple records, and can lead to a dramatic decrease of quality of care and exposure to subsequent clinical risks.

To deal with these problems, we revised our way of managing Master Patient Index and developed a system of record analysis based on automated duplicate detection and human based correction. We defined two patient records as duplicate if six fundamental fields (name, surname, date and place of birth, sex, Italian fiscal code) were identical. Starting from this assumption, we revised the process of patient admission in order to improve quality of patient registration and prevent the creation of new duplicates.

The software used to eliminate duplications was built using Python scripts and SQL queries. From a set of 1,100,000 total records, we identified 79% as unique records and 7% of records with duplicates. We merged duplicate record (10%) into a master record, found using an algorithm for calculating the weight of each record related to the same patient based on completeness and accuracy of non-fundamental fields like contacts or street address. In the same phase, we identified 4% of faulty records (one fundamental field is empty). The third phase, human-based correction, is driven by a set of conformance and similarity algorithms applied to fundamental fields. A team of operators, provided with the list of records obtained from similarity algorithms, was instructed to deep check and eventually correct the duplications.

In conclusion, integrating best practices in managing patient record and applying simple software-based systems to correct duplications is a way to achieve good results in completeness of EHRs, although the use of advanced systems will not completely eliminate human errors.

05. Clinical risk management, safety, emergency preparedness

MEDICAL ALARM SYSTEMS: WHERE DOES IT GO?

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Introduction: In the last years, a shift is observed towards single patient rooms. Single room care reduces the amount of noise, which is considered to improve patient recovery. Also, it increases the patient's privacy and improves infection prevention. However, this situation introduces challenges for the alarm management as the caregiver is not always in the proximity of an alarm generating machine. Therefore, mobile devices are used to notify the caregiver that a patient requires help. An alarm can be triggered by the patient (nurse call system) or a medical device can automatically trigger an alarm (medical alarm system). E.g. an alarm from a physiological monitor can alert in case of a deterioration of the patient. An increased dependency on nurse calls or medical alarms raises the standards for the security of those systems.

Methods: The current status of the alarm systems in The Netherlands was investigated through literature research and site visits. Furthermore, the effect of the new medical device regulations (MDR) on the alarm systems in The Netherlands was assessed.

Results: Several hospitals are in the process of combining the nurse call system and medical alarm systems. The combined alarm chain exists of separate integrated systems: several medical alarm sources, a message broker and network components. Despite a similar basic structure in all hospitals, alarm chains must be customized according to the individual circumstances in each hospital. This enlarges the difficulty for manufacturers to guarantee a safe alarm chain. Furthermore, the few players on the Dutch market may not be ready yet for the changes brought by the MDR.

Discussion: If one element in the alarm chain malfunctions, a notification should be given to the caregivers. The issue which arises is guarding the alarm chain and ensuring patient safety. The lack of clarity on who takes responsibility for the safety of the entire alarm chain causes tension between hospitals and manufacturers of alarm sources and the message broker(s). Suppliers of all systems must collaborate with each other to ensure a safe alarm chain. Hospitals struggle with managing these suppliers. Also, in the light of the new Medical Device Regulation, which classification is required for each part of the

05. Clinical risk management, safety, emergency preparedness

USE OF ELECTRONIC BOWIE DICK FOR STEAM AUTOCLAVE TESTING

By Marciano M., Schneider L., Silva R., Martins L.

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Before starting the processing of material in saturated steam autoclaves, a steam penetration test according to ISO 17665, part 1, known as a bowie dick, is indicated. The traditional test is performed by challenge package, standard that allows to check the penetration of steam inside the package in 3.5 min.

An electronic vapor penetration test is currently being evaluated to demonstrate equivalence to the traditional method. In this way, this work had as objective, through the use of the electronic dick bowie device: a) Analyze the parameters of temperature, pressure, time, noncondensable gases, b) Comparison and mapping of curves and other parameters of the electronic BD cycle, with the system used in the autoclave performance qualification. As a method, the electronic bowie dick test device was inserted inside the inner chambers of 3 different brand autoclaves. As a result, it was possible to identify the behavior of the sterilization parameters of these autoclaves, the deviations from the expected profiles, as well as the possible causes of deviations and the opportunities for corrections and adjustments. Conclusion: This electronic Bowie Dick test device is believed to be able to compose a protocol of regular performance testing of the steam sterilization process at the Hospital Material and Sterilization Centers.

05. Clinical risk management, safety, emergency preparedness

CLINICAL RISK IN IV INFUSION THERAPY: IMPROVING THE SAFE USE OF INFUSION PUMPS

By Nocchi F., De Santis S., Masucci G., De Santis M., Timpani S., Tiozzo E., Capusotto C.

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Introduction: Infusion therapy is one of the most common clinical practices in healthcare and is associated with serious risks to patients, due to both technology and organizational issues. Infusion pumps are involved in a large number of adverse events. During the last decade, several safety improvement initiatives in infusion therapy were undertaken to promote awareness of the clinical risk and address specific safety themes.

Technology: Risks are mainly due to ergonomics, with investigations of adverse events highlighting the role of suboptimal user interfaces in user programming errors. Alarms are among the most frequently reported causes of device problems and produce alarm fatigue, leading to desensitization and distraction of clinical staff, thus posing patients at risk. The emerging need to connect smart pumps to IT networks to effectively adopt and maintain drugs libraries, requires the assessment of the IT security of infusion systems.

Organization: Risk arises mainly from inadequate user training, reported as a major cause of incidents. Educational programs should include all new staff. A massive training should be provided when a new pump model is adopted, while audits and user training should be recurrent. A key step for risk reduction at the facility level is to promote uniformity of pumps and their accessories. Improper installation, storage, and maintenance of pumps are other relevant issues. A high number of IV pumps in a hospital, combined with their portability, poses organizational issues in case of recalls, planned technology renewal, or when updates of drug libraries are needed. Dose Error Reduction Systems (DERS) can prevent several adverse events related to pump programming, but the organizational effort required to adopt these systems and a low compliance from staff can limit their benefits. Furthermore, many risks can only be prevented by implementing interoperability of infusion systems with the Electronic Medical Record.

Conclusions: To mitigate risks associated with IV infusion therapy, both technology and organization are relevant. Industry should continue to focus on ergonomics, including both devices and software systems for hospital-wide management of infusions. Increasing awareness in hospital management and effective education of users are crucial to reduce risk at the facility level. Following successful experiences, initiatives at national and international level are desirable.

05. Clinical risk management, safety, emergency preparedness

STUDY ON THE RISK ASSESSMENT AND CONTROL METHOD OF MEDICAL DEVICE USE

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Exploring the methods of risk assessment of medical equipment safety incidents and operations, and how to use the corresponding evaluation criteria/methods to conduct risk assessment of medical devices use risks and adverse events in actual management work, and demonstrate the actual operation steps through an example. These measures can help equipment managers to identify potential risks, control risks, ensure safety, and improve risk management.

Key Words: risk assessment, risk control, medical equipment management s.

05. Clinical risk management, safety, emergency preparedness t

THE DESIGN OF A DEVICE FOR THE ASSESSMENT OF THE APPS FOR THE TEXT NECK PREVENTION

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The text neck is a syndrome caused [1] by an excessive tension on the cervical spine due to incorrect motor/postural tasks exercised during the use of the smartphone [1-2]. Several Apps use the smartphone as “a tutor who protects from the text neck”, stinging us in holding the device in front of the face and advising us, for example, to perform physical exercises after a programmed time. Some examples of these types of applications available on Google Play: Text Neck indicator; Head-Up-Protect your neck!; Text Neck. The general idea of this project was to design a tool for the assessment of the neck angular improvement while using smartphones Apps with biofeedback embedded acting as a tutor to prevent the text neck. The tool was based on IMUs with accelerometers and a properly designed protocol based on the activity with the smartphone. The device used to validate the App was based on an Inertial Measurement Unit with accelerometers [1-2]. It consists on two components. The first component is arranged in a helmet in order to monitor in nautical angles the head-pitch and head-roll. The second component has been designed to be affixed in the back to monitor the back angles and to finally provide information useful to detect the relative neck-back angle. The protocol consists on a subject monitoring while using 1 hour of smartphone while sitting on an ergonomic chair assuring a vertical back position in two conditions:

C1) Without the App for text neck activated.

C2) With the App for the text neck activated.

Each trial associated to each condition should be repeated 5 times in different days. The timing of the system was aligned with the time of the smartphone; the screen lock was settled to 0s to don't allow pauses. The only instruction was to use the smartphone in texting activity (the more critical according [1]) as chatting in the social-networks. The use of the ergonomic chair avoided the use of the second component of the device. An application in a case study on HeadUp-Protect your neck! indicated that the reduced angular inclination on ten 18 years old subjects in C2 was equal to 30,3 % in mean value (STD \pm 7%) for the roll angle, 38 % in mean value (STD \pm 11 %) for the pitch angle. The outcome was encouraging, and we are now planning the enlargement of the study.

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05. Clinical risk management, safety, emergency preparedness

THE CONCENTRATION OF LARGE SIZE DUST PARTICLES IN THE INHALED GAS OF ANAESTHESIA MACHINE WAS INCREASED BY SODIUM LIME ABSORBENT

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Objective: The concentration of dust particles in the respiratory tube of anesthesia machine was studied to verify that a sodium-lime carbon dioxide absorber was one of the factors that caused the concentration of dust particles of large size in the inhaled gas of anesthesia machine.

Method: Lime absorber used in experimental group will be a certain type of sodium anesthesia machine, to a certain type of calcium lime absorber used in the control group, anesthesia machine through the 2.83 L/MIN flow laser dust particle counting instrument connection anesthesia machine line sampling mouth breathing, breathing anesthesia machine line connects to the inspiratory and expiratory mouth of anesthesia machine and the other end connects simulations lung, anesthesia machine was detected in breathing circuit gas in 0.5 μ m and 5 microns dust particles content, through the SPSS statistical software to analyze data.

Result: Two kinds of carbon dioxide absorbing agent, the experimental group sampling 65, anesthesia machine in gas 0.5 microns particles mean and standard deviation of 20344 + 19136, the control samples from 55, anesthesia machine in gas 0.5 microns particles mean and standard deviation of 2057 + 1853, $P < 0.05$, the difference was statistically significant, the control group sampling data of 55 anesthesia machine into a gas 5 microns particles have 7 times detection, the experimental group 65 data sampling, 5 microns particles have 22 times detection, $X^2 = 7.25$, $P < 0.01$, the difference was statistically significant.

Conclusion: A certain type of sodium lime was used as the absorbent of anaesthesia machine, and the concentration and detection rate of 0.5 micron particles in the inhaled gas of anaesthesia machine were higher than that of calcium lime as the absorbent.

05. Clinical risk management, safety, emergency preparedness

USABILITY OF THE HUMAN-MACHINE INTERFACE OF BLOOD BANKS AND PLASMA FREEZERS

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Human errors in the use of medical devices are a common source of hazardous situations and harms to the patient. For this reason, the user interface is the focus of usability studies.

Usability is defined by the ISO as “The extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency, and satisfaction in a specified context of use”. Usability studies are an integral part of the evaluation and risk analysis of medical devices and therefore allow to provide a complete risk management related to the intended end user and to propose appropriate risk minimization measures.

In the usability study proposed, the classical risk assessment methods, compliant with the international standard ISO 14971, were integrated with usability evaluation methods, in compliance with the international standard ISO 62366. These latter methods were applied to the specific case of blood banks and plasma freezers, as it is known from clinical literature that the safe use of such medical devices is highly dependent on a fool-proof and intuitive human-machine interface.

In this complete risk assessment, a dozen of intended end users were involved in usability tests, in which they simulated different phases and tasks of use of the medical devices under assessment and actively participated in the identification and implementation of risk minimization measures, being part of what is called “participatory design”. The involvement of end users was fundamental for the development and updating of a more adequate human-machine interface.

This study has shown that a structured, engineering approach divided into several steps of the usability evaluation of medical devices allows adequately and effectively assessing and minimizing the risks related to human error.

05. Clinical risk management, safety, emergency preparedness

SMARTPHONE SURVEY FOR MEDICAL DEVICES: WHAT DO HEALTH CARE OPERATORS THINK ABOUT COMPUTER SECURITY?

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The critical issues related to the extraordinary diffusion of innovative technologies (eg. Artificial Pancreas) connected in the health care network (over 300,000 Medical Device classes) inevitably intertwine with the safety and efficacy characteristics of the services provided and the protection of the data processed (GDPR), creating a context of high attention where performing quantitative analyzes depends on the information entered in the SIS, while the analysis of the sensitivity of the operators may be relevant to their behavior.

Recently the focus was on the attacks, for example of ransomware type, in the health systems and the potential vulnerabilities come to light for some types of critical medical devices (mostly active implantable) that can be connected in net. Raising awareness among national health system actors can be crucial for a better understanding of the behaviors to be adopted. For this reason, we propose a Survey carried out via Smartphone that allows us to measure ourselves with our degree of knowledge and motivation. Goals of the project and final users that will benefit

Targets: Develop a tool (based on Forms) for electronic and automatic data collection via the common messenger systems for smartphones. Investigate the state of perception of «Security» in the National Health Service by inviting those who work in this field to participate in the study.

Recipients: Institutional and / or National Health System holders

Results: The first result is the product “survey”. The second result is a preliminary outcome of the methodology. From the survey, with the submission to 33 health professionals of different professions (conducted also to verify the robustness of the methodology) it emerged that both the submission and the compilation of the online survey showed no criticality. A first analysis shows (a) a safety self-perception of 2.75, above the average value of 2.5 and (b) a desire to invest in training in this area. The tool that has proven to be robust can be used for wider investigations to provide relevant information to the stakeholders of the national health service.

05. Clinical risk management, safety, emergency preparedness

TOWARDS ERROR RESISTANT MEDICAL DEVICES

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The increasing number and complexity of medical devices in hospitals implies for physicians and nurses a heavy burden that can deteriorate therapy quality and safety. The situation can be described as follows: more less skilled users (including the patients themselves) are using medical equipment with more complex interfaces. The interface design is treated as if it is a “common sense” issue. But the issue is not as simple as that, since the decreasing of use error and use associated risks requires the application of a usability engineering procedure in the design of the interface and in the whole life cycle of the medical equipment. The usability of medical devices and the testing of this usability is a very modern discipline. The most of medical device developers did not hear about usability testing of medical devices before the late nineties of the 20th century. IEC62366 and IEC 60601-1-6 give a tool for medical equipment manufacturers to integrate a usability engineering process in order to guarantee safe use and operation of medical equipment. This paper tries to point out briefly: 1) the concept of usability of medical equipment and the importance of the compliance of the medical equipment with the usability standards for safer operation of medical equipment, 2) the human mind capabilities and limitations and the importance of considering it by designing of the interfaces of medical devices, and 3) the most important medical device use error root causes and how to make the medical devices less prone to use errors or “error-resistant”.

05. Clinical risk management, safety, emergency preparedness

THE ECRI “TOP 10 TECHNOLOGY HAZARDS” THROUGH THE YEARS. NEW ITEMS AND OLDIES IN THE RANKING

By Nocco U., Del Torchio S., Marazzato G.

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ECRI publishes a list of the top 10 “may-be-problems” in technology. Top 10s from 2007 to 2018 were reviewed to identify the most recurrent events among the listed and changing in ranking or description through the years. Five major issues were identified.

Alarms It is clear that alarm-related adverse events may be the result of a variety of factors: inappropriate management either of the patient or of the device, inappropriate alarm configuration practices or inadequate training.

Endoscope Disinfection Hazards are at first presented as “cross contamination between patients” and they are modified from 2013 into “Failure to adequately reprocess contaminated instruments”. Inadequate cleaning of flexible endoscopes is a common problem: it’s present from 2010 and from then on gradually decreased in ranking, from 1st to 8th place in 2013. From 2013 on a new progress is experienced, ending with 1st place in the 2016 Top 10 list. The 2017 and 2018 Top 10 confirms its attention to device reprocessing which is not only to be limited to endoscopes but to all reusable instruments.

Infusion pumps A hospital may have hundreds of pumps. Infusion related hazards show that through the years the outlined hazard moved forward in ranking starting from 7th place in 2011 up to 2nd in 2013 and 2014. After a pause, the 2017 Top 10 ranks infusion pump related hazards as 1st, and in the following years workaround bar-coded identification systems plus confusion between items vital to infusion are considered.

Radiation dose the review shows that CT radiation dose is common to all the Top 10 analyzed. In 2015 this problem shows an evolution and develops in ‘dose creep’.

Information technology has been lately urging the technical community. IT hazards were introduced in the top 10 in 2010 and never left the ranking. An evolution of the problem can be outlined. From 2011 the item can be “exploding”, being divided into different items that fill up the grid. New hazards and items can be listed such as patient/data mismatches, neglecting change management for networked devices and systems or poor alignment between the configuration of health IT system and a facility’s workflow, cybersecurity and hacking the hospital network,

Conclusions The common aspect that can be found is training. The common cause is a lack of training and awareness in operators. This is why ECRI recommends a better and more continuative training of personnel. This is the area where facilities must concentrate.

05. Clinical risk management, safety, emergency preparedness

MEASUREMENT OF THE ELECTRICAL RISK IN CRITICAL AREAS FROM HOSPITALS OF YUCATAN STATE AND MEXICO CITY

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Within the hospital environment, safety aspects should be a priority to provide quality services focused on the patient. In general, infrastructure, medical devices, and clinical procedures require a reliable and safe electrical installation to function. Guaranteeing these requirements is part of an electrical safety program, which begins with a diagnosis of the situation the hospital keeps in this regard.

Keeping the hospital infrastructure in good condition is essential to provide health services to the population. This project aims to know the existing measures on electrical safety of patients who are in the areas of Intensive Therapy and Emergency of hospitals in the Yucatan State and Mexico City through the application of a survey to the people in charge of the maintenance areas for medical equipment and electrical installations. The study focused on three aspects: considerations on the care of the grounding, practical issues on electrical safety and general concepts.

The aim is to identify the level of electrical risk of these clinical areas according to a proposed classification based on the weighting of the points to be evaluated established from the authors' heuristic. The recommended risk levels were tested with three different systems of machine learning using simulated data for the questions related to grounding. A neural network based on a two-layer perceptron was used, obtaining a correct classification percentage of 98.05%. When a Bayes Naive system was applied, the rate of the correct class assignment was 80.5%; analyzing the cases where erroneous class assignments are presented, it was found that they are oriented towards the high-risk level. When a decision tree was used based on the CART algorithm, it was found that the dominant attributes, which determine the search were the frequency of measurement and the resistance to ground in the area; the percentage of correct answers was 99.5%. With these results, it is considered that both the questions that were formulated and the allocation of the weights reflect a large extent the actual situation of the clinical area in terms of its level of electrical risk. The project is in the information collection stage, so it is expected to contrast the results obtained with the information to be collected.

05. Clinical risk management, safety, emergency preparedness

USING UV ROOM DISINFECTORS IN A HOSPITAL SETTING

By Gaev J.

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Hospitals rely on ultraviolet light for room disinfection without assurance that the devices are working properly. ECRI Institute has developed unique methods to test UV room disinfection devices in the laboratory and in the hospital setting. Hospital Acquired Infections (HAI) have greatly increased in severity. Clostridium Difficile (C. Diff) has a very high mortality rates (up to 10% of patients over 65 years of age). Hospitals take extra care to disinfect rooms that were occupied by those patients. Ultraviolet-C (UVC) light is a popular method to supplement traditional methods of disinfection. The device is placed in the room and operated according to the manufacturer's instructions. Hospitals purchase and use these devices to reduce HAIs. These devices are not classified as medical devices in the United States by the FDA, and there are no standard methods that have been adopted by the industry to measure their output. Each manufacturer makes claims about the effectiveness of their device and it is not possible for the purchaser of the device to verify these claims.

ECRI Institute has been concerned that the actual performance of the devices may not meet the expectations set by the device manufacturers. The most common expectation is that 99.99% of the C. Diff spores will be killed (also referred to as a "log 4 kill"). We solved the problem of verifying device output by developing and validating a method to accurately measure the output of UVC devices and associate that output with the reduction of C. Diff spores. We exposed C. Diff spores to various amounts of UV light and measured the reduction in spores. In addition to our laboratory testing, we developed a program to measure the effectiveness of the devices in patient rooms. Our field work confirmed that the devices did not meet the user's expectations in all areas in the patient rooms. Incorrect device placement was associated with decreased effectiveness. We will present case studies based on our field experience in hospitals, summarize the issues that limit device effectiveness and make recommendations as to how the performance of UV room disinfection units can be improved in a hospital setting.

05. Clinical risk management, safety, emergency preparedness

BEDSIDE COMMUNICATION AND MANAGEMENT OF VITAL PARAMETERS AND ALARMS IN CARE-INTENSIVE ENVIRONMENTS: SIMULATION MODEL DEVELOPMENT FOR THE CLINICAL EFFECTIVENESS ANALYSIS OF AN INNOVATIVE TECHNOLOGY

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The deliberation n.7301 of 31/12/2001 provides for the inclusion of a call system with acoustic and luminous signalling within the minimum equipment of the recovery ward. However, traditional call systems are inefficient since they are based on the following incorrect assumptions: patients and staff are unmoving, information sources are static, and assistance is unidirectional. Taking care of a patient involves different figures who should be dynamic and should be able to exchange information.

Furthermore, the high number of clinical calls and alarms might be an issue, because on one hand they are essential to fulfil patients' needs, but on the other hand they could cause stress and additional workload on medical staff. Indeed, they sometimes ignore some calls or waste a lot of time on non-urgent requests. In addition, the identification of an alarm and the prompt intervention seems to be more difficult during travelling.

An ideal alarm system should have 100% sensitivity and specificity. Nevertheless, the alarms are designed to be extremely sensitive, at the expense of specificity. The alarm fatigue, that is the work overload due to an excessive alarms number exposition, is a critical problem in terms of safety in the current clinical practice because it involves desensitization and alarm loss, causing sometimes even the patient's death. Therefore, appropriate approaches to notifications should be evaluated, including the effectiveness of mobile wireless technologies: linking patients, staff, data, services and medical devices simplifies communications and workflows.

Several issues related to the communication among staff members, between patient and caregiver and to the alarms and vital parameters distribution in care-intensive environments have been analysed, focusing on the clinical effectiveness analysis of an innovative technology to support the UOC MCAU-PS of the CTO Hospital activities. Afterwards, we have created a simulation model with Simul8, so that a digital twin reproduces direct and indirect activities in two cases: with and without (What If and As Is Model) the aid of the technology. The model provides a set of Key Performance Indicators (number of performing activities, average alarm resolution time, waiting time) on which the compensatory aggregation method is applied to elaborate a single final score in both cases. This score is 52,5 in the As Is Model and 80 in the What If Model. So, the clinical effectiveness has been demonstrated.

05. Clinical risk management, safety, emergency preparedness

A THEMATIC REVIEW OF MEDICAL DEVICE RISK MANAGEMENT

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The Medicines and Healthcare Products Regulatory Agency and Emergency Care Research Institute guidance is consistent in the view that planned preventative maintenance maximises equipment availability, safety and longevity of service. Trained and competent staff should undertake planned maintenance, in line with the manufacturers' instructions or with their express approval for any variations from those instructions.

The previous Clinical Engineering service applied a protocol which determined that programmes of planned maintenance were not required on medical devices classified as non-life threatening and consequently this deviated from the manufacturers' recommendations. This categorisation appeared to offer little or no governance with an absence of sound risk management. Given the deficiency of an apparent evidence base or an audit trail to uphold such determinations, this posed a significant risk for the University Health Board.

Risk management is concerned with the recognition, interpretation, control, and prevention of failures when medical devices are used to offer treatment and monitoring for patients. In this paper, we present a multi-criteria decision-making model to prioritise medical devices according to their criticality. Devices with higher criticality scores are now assigned a higher priority in a maintenance management program. The results take into consideration the advances in device reliability, internal surveillance and thus support reduced preventive maintenance obligations.

05. Clinical risk management, safety, emergency preparedness

RELIABILITY STUDY OF PET-CT BASED ON FMECA

By Ying C.

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Failure modes, effects and criticality analysis (FMECA) is a procedure used to identify potential failure modes, determine causes and effects of failure modes and mitigate or remove its effects on system functional performance. For the last several decades, FMECA has been widely used in military, automotive and other industry. But there is no specialized FMECA method for the medical equipment management. As a high-end medical equipment, PET-CT has a high degree of system integration and complex structure. And one hospital usually only has one PET-CT, it is difficult to deploy. Meanwhile, for patients, due to the need for medication before boarding, the equipment downtime will bring higher costs. Therefore, for the medical equipment management department, it is necessary to ensure PET-CT's long-term stable and reliable operation. Our research invited 6 senior technical support engineers or nuclear medicine technical managers of PET-CT manufacturing enterprises and 4 senior clinical engineers to have a brain storm. Combined with the management attribute of PET-CT, the study optimized the evaluation parameters of FMECA and formulated the evaluation criteria. In addition to conventional parameters, including frequency, severity and detection level, this study adds a "restorability" parameter. The structure of PET-CT system is decomposed into 7 subsystems, 22 key components, and 44 possible faults are enumerated. The fault mode, impact and hazard analysis are carried out for each fault. According to expert scoring statistics, risk priority number (RPN) and the risk measurement factors of optimized evaluation parameters were calculated to determine the key components affecting the reliability of PET-CT. The calculation results showed each fault's risk coefficient and the faults with high risk coefficients mostly occur in the CT detection part. The top 4 RPN faults were the same as top 4 RPN* "restorability". The main problem brought by "repairability" index was whether "failure of PET detector" or "intermittent exposure failure of CT tube" deserves more attention of risk management. This study proposed a specialized FMECA procedure for PET-CT and provided operation template for FMECA be applied in medical equipment risk management. The result can help to improve the reliability of PET-CT and is benefit to the clinical engineers to carry out risk prevention and control.

05. Clinical risk management, safety, emergency preparedness

VISUALIZATION TOOL OF THE MEDICATION PROCESS TO HELP INCREASE MEDICATION SAFETY

By Ten Wolde A.

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The Princess Máxima Center is a research hospital focused on the treatment of children with cancer. Our goal is to cure each child with cancer with the best possible quality of life. Medication plays an important role in the treatment plans (for example pain medication and chemotherapy). A safe medication process is crucial for patient safety. However, it is prone to calculation and administration errors and it is highly complex (multiple departments and many medical technologies and software applications are involved). Therefore, it is important to understand how this process works to be able to reduce risks. With this information, technological innovations can be selected to support this process.

Project description: The goal of this project was to make a comprehensive visualization of the current medication process that does not only include the different steps in the process, but also the dependency on medical equipment. This visualization can then be used as a tool during meetings with healthcare professionals to look beyond the scope of their department.

Preliminary results: Our first step was to divide the medication process into four main steps: prescribing, preparing, providing and administering medication. To include the dependency on medical technologies we plotted these four steps against the interoperability model. This model, created by the Dutch organization Nictiz, consists of five layers which can be used by a hospital to set up their organization and infrastructure. Subsequently, we elaborated on this model by adding a technology layer to show where medical equipment plays an important role. Finally, we also included which healthcare professionals and locations are involved.

Future outlook: The model proposed can be used as a tool in a multidisciplinary group of healthcare professionals to discuss the current risks present in our medication process. The main advantage of this tool is that it takes the entire medication process into account and does not solemnly focus on one step, but it stimulates the healthcare professionals to look at the big picture.

The next step in our project is to use the visualization of the medication process during project meetings with representatives from all departments involved to assess risks and possible technological innovations. Finally, we want to use this information to set up a multi-year plan to further increase medication safety in the Princess Máxima Center.

05. Clinical risk management, safety, emergency preparedness

WHEN THE THREAT IS FROM THE INSIDE: A MANAGEMENT PLAN FOR INTERNAL EMERGENCIES

By **Lucesoli A., Andreanelli A., Galeazzi S., Regine N.**

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Hospital disaster planning usually focuses on management of external events causing a sudden and massive influx of casualties. Minor attention has been paid to the case of internal emergencies. However, events like fires, floods, earthquakes may require a partial or total evacuation of the nosocomial structure. For instance, during the recent Central Italy earthquake, a few sanitary structures had to be evacuated. Management of internal emergencies may result particularly complex, especially when critical units are involved: the urgent transfer of patients from intensive care units or during a surgical intervention may be disastrous if not accurately planned. Italy, in particular Marche where Ancona Clinical Hospital is located, is a well-known for its high level of seismic and hydro-geological risk. Internal emergency planning is thus crucial to prepare the sanitary structures to face critical events. In developing the hospital Internal Emergency Plan (IEP), we involved a multidisciplinary team encompassing clinicians, nurses, hospital direction, engineers, to deal with the complex and multifaceted problem of emergency management. Besides technical issues considered in every IEP, particular attention has been paid to all the sanitary aspects related to the safe evacuation of bedridden and critical patients. To this end, we elaborated for each medical unit a specific "sanitary evacuation procedure". Estimating the number and clinical condition of patients, the procedures indicate the emergency tasks to be carried out, relevant equipment and medical devices (oxygen tanks, portable medical devices, emergency trolleys, etc.), the medical operations to be performed to preserve patient life. Several techniques taken by "catastrophe medicine" (e.g. mattress slide) are adopted to move bedridden patients to safe areas even in case of unusable lifts and buildings inaccessible to rescue vehicles. Emergency evacuation tests are performed annually by simulating the presence of patients affected by specific illnesses. Response time and application of the appropriate measures for each patient are both verified to evaluate the procedure effectiveness. Recently, our IEP has been successfully applied to face a fire in the Infectious Disease Unit: the whole unit was evacuated and fire was extinguished before firefighters arrival without consequences for patients or health staff.

05. Clinical risk management, safety, emergency preparedness

HOSPITAL MEDICAL DEVICE VIGILANCE SYSTEM SOFTWARE DESIGNED TO REDUCE RISK AND INCREASE SAFETY

By **Shrolik O., Grainger P., Kearney B., Mc Grath C., Dillon B.**

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In 2009 the HSE published the Medical Devices/Equipment Management Policy Incorporating the Medical Devices Management Standard. The Alert Management is one of the aspects of this policy. In 2014 Dublin Midlands Hospitals Group implemented the online software that used for the distribution and management of Medical Device Advisory Documentation such as Medical Device Safety Alerts issued by the National Health Products Regulatory Authority (HPRA), Manufacturers Field Safety Notices and Hospitals Internal Incidents involving Medical Devices (MD). Defined performance objectives of this system:

- To maintain the Medical Device Vigilance Committee and support its governance of Medical Device Advisory Documentation.
- To establish a collaborative environment workflow when assessing the impact of Alert and Manufacturers Field Safety Notes on each Hospital in the Group.
- To have full assess the Advisory Documentation and agree appropriate local actions e.g. completion of recommended actions, further dissemination of information, training of staff, change of product, withdrawal of product.
- To ensure that the recommended actions are followed up and processed in a timely manner and that the relevant MD Alert is closed/signed off.
- To determine if incidents that arise in the Hospital are reportable to the regulatory agencies (HPRA, Radiation Protection Institute of Ireland etc.) and to control completion of the relevant documentation submission.
- To generate and publish the periodic Medical Device Vigilance reports.
- The general benefits and strategic outcomes of the System:
- Compliance with HSE requirements and HPRA recommendations;
- Traceability system for all Medical Devices used by Naas General Hospital staff;
- Analysis of the MDVC work and feedback: to Clinical Engineering Equipment Management System (Purchasing and Maintenance of MD); to Hospital Senior Management Operational Group (Strategic Planning).

This paper presents a brief overview of collaborative environment system in terms of Medical Device Vigilance Group in Naas General Hospital. Collaborative environment allow geographically distributed groups to work together to achieve results.

05. Clinical risk management, safety, emergency preparedness

APPLICATION OF PARETO'S PRINCIPLE IN MONITOR ALARM MANAGEMENT

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Objective: Manage the alarm of the ICU's monitor.

Methods: First, the alarm data of the ICU ward is collected by accessing the central monitoring system database. Then we analyze the alarm data information and use the Pareto's principle to screen a few high-frequency alarms. Finally, analyze the mechanism of high frequency alarm occurrence and its causes and take intervention measures.

Results: According to Pareto's principle, the average daily alarm for unit beds fell by 36%, achieving good results.

05. Clinical risk management, safety, emergency preparedness

THE CHALLENGE OF MRI INTERVENTIONS RELATED TO MRI-ENABLED FUNCTIONAL IMPLANT-PACEMAKER

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Introduction: The number of MRI imaging cases has been increasing year by year, as cardiac implantable devices compatible with conditional MRI (Magnetic Resonance Imaging) have become popular since 2012. But, various problems with MRI imaging have been reported for patients with conditional MRI-enabled cardiac implantable devices. OUH (Osaka University Hospital) has experienced 127 cases from 2013 to 2018, but it is safe and flexible by constructing its own system it corresponds.

Device characteristics: Heart implantable devices are known as one of the non-drug therapies for bradycardia arrhythmias. Although, due to the magnetic field and RF (radio frequency) generated at the time of MRI examination can be various adverse effects. Therefore, conditional MRI-enabled cardiac implantable devices have a number of improvements to devices body and leads for minimizing the effects of magnetic fields and RF pulses as compared to conventional cardiac implantable devices. Under certain conditions, the adverse effects of MRI can be avoided. In addition, mode change corresponding to each disease such as DDD to DDO or VOO is also required.

Case: At some centers, there is an increasing number of reports that MRI exams have been planned and would be almost implemented for patients with non-MRI enabled devices. There are many cases report where examinations are performed under inappropriate conditions also for conditional MRI compatible devices. In addition, some hospitals unique regulations such as supporting only patients who have had transplants at its own hospital can be a hardship on patients.

Countermeasure: OUH has built its own protocol to solve many problems including those cases. When MRI imaging of patients with conditional MRI-enabled cardiac implantable devices is required, information is shared from the doctor to nurses, radiologists, and clinical engineers using a mailing list that includes all members. Thereafter, the patient is addressed using a hospital reservation flowchart, a flowchart for referral from another hospital, and a flowchart on the day of examination. Moreover, just before the MRI imaging, a checklist is used which is specific to each company's device and created independently.

Conclusion: Even in a large number of MRI imaging certified facilities, there is a difference in the response to MRI imaging between facilities. In order to respond to a variety of different conditions, it is desirable to share a protocol that can be handled safely like OUH in the future.

05. Clinical risk management, safety, emergency preparedness

BEYOND BIG DATA: LEVERAGING CMMS DATA TO IMPROVE PATIENT OUTCOMES AND ACCESS FOR INTERNATIONAL HEALTH

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This project takes a comprehensive view of medical device use errors and mitigation strategies through an international health perspective. Three years of use error data from a large hospital system including more than 140 hospitals with a wide range of complexity as well as standard data definitions within its computerized maintenance management system (CMMS) was utilized in this study to determine top overarching trends in use errors. A descriptive analysis was completed on the secondary data to determine the top three trends for use errors and proffer solutions to improve safety of care for all users. This data was also evaluated to determine the impact or potential impact on access to care based upon the average time to repair the equipment. The study evaluated hard costs related to use errors based upon salary and repair costs. International health forces including models for development, science, technology and innovation, resources and human rights will be considered in the development of the overall understanding of medical device use errors and their impact on international health and access. Using this international health conceptual model as a framework or lens to view the issues, suggested mitigation strategies as well as an enhanced post-market regulatory surveillance system would provide specific insight to the key stakeholders within the healthcare industry, regulatory bodies and the WHO/PAHO office.

05. Clinical risk management, safety, emergency preparedness

MANAGING CYBER SECURITY RISK – A LOCAL RESPONSE TO THE WANNACRY RANSOMWARE THREAT

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Background: Medical devices like information technology or control systems can be vulnerable to malicious attacks. However, where a medical device is involved, care provided to patients may be directly affected which could delay treatment resulting in serious injury or death. From a Clinical Engineering perspective, Healthcare Technology Management is changing due to rapid changes in clinical innovations. At the Royal United Hospital a number of devices are connected to the network. Wearable medical devices are also remotely monitored from nurse's stations. In some cases, medical software or medical device are integrated with mainstream IT and operating as a medical device. These systems are sometimes interfaced with other networked devices, Electronic Health Record or Clinical Information Systems. Although these developments contribute to improving healthcare, it also exposes medical devices to cyber security risks and highlights the need to protect patients and the organisation. With advances in technology and digitisation of healthcare and as the trust adopts the paper-lite systems, so also come associated challenges. Hence the need to proactively manage these risks in order to balance protecting patient safety and continuous development and improvement of healthcare technology.

Objectives: A reflection - two years following the WANNACRY Ransomware attack and the road to developing a preparedness response to ensure patient safety and to protect the organisation.

Methods:

1. Bridging the gap between IT and Clinical Engineering to support incident management teams
2. Incorporate cyber security assessment into medical device procurement projects
3. Scoring against 10 cyber security standards
4. Changes in medical device asset inventory
5. Hazard Vulnerability Assessment
6. Development of medical device emergency plan

Conclusions

1. Establish good feedback and reporting
2. Contribute to improving governance
3. Promote best practises across the trust

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06. Development of innovative devices

MILK HEATER FOR NEWBORN

By Rezer R.^[1], Marciano M.^[2]

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We present the work of implantation of the low-cost open-source platform, the prototype is destined the performs heating of the syringe in enteral therapy equipment for newborns. It was used a set of components whose main function is to measure the temperature at which the milk is being infused. It will send signals to the process that will control the resistances. The system was based on quality and safety guidelines for RDC 7. The goal is to automate the preservation of the environment, improve hospital admission capacity, increase nutrient conservation, improve comfort during enteral therapy for newborns and as a consequence their recovery.

06. Development of innovative devices

AMPADU DELIVERY CHAIRS

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The child delivery policy of Ghana prescribes that all mothers should deliver in health facilities where skilled deliveries can be assured. However, about 44% of deliveries are done at home by Traditional Birth Attendants (TBAs). The main reason is that women have the option of choosing a preferred birthing position when they deliver in their homes, unlike at the health facility where they are made to lie on their back with their leg in stirrup position.

To the laboring mother, the stirrup position provides discomfort and excessive stress since she is made to push her baby, all by herself, without the helpful force of gravity that characterizes delivery by either kneeling, sitting or squatting. Evidence have shown that sitting and squatting positions make delivery easier and faster and also prevent many complications to the mother and the baby as compared to the stirrup position. This is the main reason why Kumbungu community and others in the Northern parts of Ghana practice these alternative birthing methods.

The intervention, therefore, helps to reduce the home deliveries and increase skilled delivery at the facility level whilst bridging socio-cultural barriers to maternal, new born, and child health by providing women the option to deliver by sitting or squatting in health facilities.

Ampadu Delivery Chairs enhance the rotation and descent of the fetus in a difficult birth and give women in labour the extra strength to push by utilizing the helpful force of gravity that characterizes delivery by either kneeling, sitting or squatting. They have been introduced in four health facilities in the Greater Accra Region on a pilot basis since August 2015.

The pilot project has so far been successful without a single complication, morbidity or mortality in the over 500 deliveries done with the chairs.

Mothers who have experienced this intervention expressed satisfaction about the use of the chair and described it as "simple, stress-free and comfortable." Pilot was accepted by medical staff (nurses, midwives and doctors) in the piloting facilities and clients are patronizing. The delivery chair has been used successfully for the following complex cases: Delayed second stage, Intra-uterine foetal death with hydrocephalus (IUFD), Shoulder dystocia, Face to pubis presentations, Big babies, and Footing breech presentation. In October 2016, WAHO adopted it as a good practice in MCH for a scale-up in Ghana and replication across the ECOWAS Sub-Region.

06. Development of innovative devices

PERSONALIZED ELECTROENCEPHALOGRAPHY (EEG) INFORM TRANSCRANIAL ELECTRIC STIMULATION (TES) INTERVENTION FOR COUNTERACTING MIGRAINE [PEIN4COMI]

By Porcaro C.

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Headache is the most prevalent neurological symptom and is experienced by almost everyone at some point in their life. There are major problems for clinicians in treating migraine with available preventive therapies. Firstly, the average efficacy rate of any prophylactic agent does not exceed 50%, and secondly almost all prophylactic drugs are associated with cumbersome and sometimes intolerable adverse effects. Moreover, episodic migraine may evolve to a chronic form that often becomes resistant to treatment, thus feeding medication overuse. Recently, tES has developed into an alternative method of treatment for many pathological conditions, depression, stroke and migraine. In addition, it is now feasible to combine tES with high density EEG (hdEEG), thereby increasing the information that can be gained and the specificity of stimulation. This scheme has been successfully tested in the healthy population by replaying the ongoing electrical activity of the target area (hand primary motor area) back as electrical stimulation. This increases the motor-evoked amplitude by 31% with respect to the baseline, outperforming standard tES.

The main aims of this project are: Aim 1 – to establish robust and personalized neurophysiological markers for better understanding chronic migraine: We will acquire hdEEG both in response to somatosensory stimuli (SSEP) and at rest with open eyes (Rest OE) to: 1.1) investigate whether interictal thalamic dysfunction in episodic migraine patients is still present when migraine becomes chronic; 1.2) identify electrophysiological markers to provide a reading of the neural variations induced by neuromodulation intervention (Aim 2 below); 1.3) verify the impact of neuromodulation intervention on the frequency and severity of attacks.

Aim 2: to develop a new non-invasive and personalized tES intervention that exploits the information recorded by the hdEEG: 2.1) Sham condition will be used to test placebo effects; 2.2) transcranial Direct Current Stimulation (tDCS) targeting the sensory-motor area (C3 electrode) will be used as a gold standard; 2.3) Functional Source Separation (FSS) algorithm will be used to extract the sensorimotor electrical information from SSEP to be directly delivered by subsequent tES intervention.

Potential impact: The EEG informed tES intervention, besides being free from side effects and/or discomfort for the patients, is simple and very low-cost and could be easily made available in any clinical centre.

06. Development of innovative devices

MODELING, ANALYSIS AND CONTROL OF THE “SCARA” MANIPULATOR ARM USING THE “ROBOTICS SYSTEM TOOLBOX FOR MATLAB

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The presented project covers the areas in which robotics has having a major development, with particular attention to the biomedical sector, in which it is possible to define a discipline of its own: medical robotics.

The analysis has been conducted in two ways: the application way and the engineering way, trying to identify which are the physical, mathematical and basic design for the analysis, modeling and description of a trajectory for a mechanical arm. The most relevant problems analyzed are manipulation, trajectory, speed and acceleration of a robotic system, which are behind the functioning of manipulator arms.

For this project, has been studied the problems of the Da Vinci Xi S4000, which is used in the robotic surgery unit of University Polyclinic Federico II in Naples.

The purpose of the work was to model a robotic arm, in particular the SCARA (robotic arm of selective assembly), thanks to a “Robotics System Toolbox” by Matlab that allowed us to plan and execute a trajectory.

To achieve the goal set, the basic concepts regarding Robot Control theory have been analyzed and applied.

It is a sort of trajectory that allows simulating an assistant to robotic surgery. This allowed us to simulate the activity of a robotic instrument during the execution of a surgical intervention.

06. Development of innovative devices

DESIGN AND FABRICATION OF HUMAN BONE (PELVIS,MANDIBLE) BY USING 3D PRINTER

By Mitra R.

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Three-dimensional (3D) printing is an additive manufacturing technique, which allows the fabrication of patient-specific scaffolds with high structural complexity and design flexibility, and gains growing attention. Human bone is very essential for medical study and research. However, human bone preservation is a complex and costly process and the preserved bone erodes with time. This research aims to design and fabricate human bone (Pelvis and Mandible) by Poly(lactic acid) (PLA) material with the same geometry and anatomical structure by 3D printer. The anatomical structure and geometry of Pelvis and Mandible have been collected from CT data. The bone was designed by AutoCAD 3D by using CT data. After comparing designed bones with original bones, designed bones are converted to Stereo-lithographic file by a slicing software (breaks the model surface in slices) and then fabricated by a 3D printer. However, the fabricated bones are exactly similar to the real bones with the same anatomical structure and geometry. 3D printed human bones are cheap, long-lasting and environmentally safe. This 3D printed bone enhances the medical study and research by its degrading behavior.

06. Development of innovative devices

FABRICATION OF A BIO-CERAMIC SCAFFOLD BY USING SPONGE REPLICA METHOD

By Joye Kundu J.

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Hydroxylapatite has its good biocompatibility and similar chemical composition to the mineral part of the bone. It has an important role and various application in bone tissue engineering. Porous hydroxyapatite scaffold has a high surface area, which leads to excellent osteoinductivity as well as reabsorbability and also providing fast bone in growth at the site of injury. In this study highly porous body of a nano structure hydroxyapatite scaffold was successfully replicated by sponge replica method.

Characterization: The compressive strength and the morphological structure of the scaffold were characterized by UTM machine and SEM image respectively. XRD technique was used to investigate the proof of formation of BCP powder.

The result of SEM analysis that, the prepared scaffold has highly interconnected spherical pores with a size in the range of 100-500 micrometer and the compressive strength of the scaffold with the value of 1.425 ± 0.15 mega Pascal, Strut Diameter is 91 ± 53.27 μm ; Porosity 80.57 ± 1.58 % and Standard reference value of porosity is 71 %.

The mentioned properties could make the Bi Phasic calcium phosphate (BCP) ceramic scaffold as a good candidate for bone regeneration application.

06. Development of innovative devices

THE GLOBAL HEALTH IMPROVEMENT REGISTRY: PROTOTYPE INITIATIVE

By Hosea F.

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Currently, the fragmentation, complexity and interdependency of innovations in healthcare creates costly uncertainty, inefficiency and clinical risk for investors, regulators, insurers, government planners, health professionals, and care delivery organizations. Successful healthcare innovations must incorporate multi-disciplinary and multi-stakeholder expertise across the entire lifecycle of the innovation and the systems they interact with. Currently, no single global informational and organizational resource exists to promote such successful innovations at the design stage.

We propose creating a Global Health Innovation Registry, using semantic web data science, to promote convergence among innovators worldwide through multidisciplinary team collaborations and designs based on system-lifecycle expertise.

06. Development of innovative devices

“DESIGN AND DEVELOPMENT OF SENSOR BASED PATIENT POSITION TRACKING DEVICE IN RADIOTHERAPY TREATMENT”

By **Karmaker N.**

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Cancer is the second leading cause of death globally, and is responsible for an estimated 9.6 million deaths in 2018. There are 13 to 15 lakh cancer patients in Bangladesh and two lakh patients newly diagnosed with cancer each year. Patient position is very crucial for RT otherwise Normal tissue will get excessive dose will produce secondary cancer in late effects. Normally Teletherapy is given each day 2-2.5 Gy for 30 days. Though new updated technology has been introduced in commercial available companies like Calypso method, Transponder etc these are very expensive. Also, our RT center in Bangladesh does not have this equipment. The purpose of this research is to reduce the probability of positioning errors during treatment, design and development of low cost patient position monitor device, ensure the patient position monitoring during treatment delivery and use patient position monitoring device for clinical purpose. Low voltage power supply, laser radiation transmitter, laser radiation receiver, alarm, digital display, automatic switching port used in this for complete circuit diagram of patient position monitor device. In this project work, a low voltage power supply is constructed whose output is + 15 V d.c. This output voltage connected to the laser radiation receiver circuit for receive laser radiation. Receiver sensor placed on patient body. Laser radiation transmitter was run by d.c 4.5v rechargeable battery. The laser radiation was set on the receiver sensor area. If patient move and receiver sensor cannot detect the laser radiation signal, the beam will be off by the automatic switching port and also the main device display shows off, audio able alarm gives by buzzer. In future, it can develop eye sensor for patient monitoring and fabrication box. It can be used update laser sensor receiver pad that will help to monitor accurate patient position this device can be used as a pilot project in the radiotherapy departments of the hospitals, others machine company adapt this device and extend cooperation for further development. Different organization should take a step for future development .

Keywords: Radiotherapy, sensor, Laser radiation, Patient position, Healthy tissue, Transmitter.

06. Development of innovative devices

DEVELOPING A LOW-COST MEDICAL IMAGING SOFTWARE PRODUCT FROM RESEARCH PROTOTYPE IN RADIOLOGY

By **K N M.^[1], Prabhu G.^[2], Pcs S.^[1], Kurady R.^[3]**

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There exist several state-of-the-art Medical Image Processing (MIP) applications either in the form of research prototypes or commercially available that are quite expensive and many of them are not affordable by medium and small-scale radiology centers. These MIP software follows software development life cycle (SDLC). However, the same model is not seen in research environment. In many cases, research works are not elevated to commercial product due to lack of planning and absence of SDLC. The objective of our study was to develop a low-cost medical image-processing framework from prototype stage in colon polyp analysis using CT images. This work includes the amalgamation of domain aspects, technology, process, testing, and quality assurance. The framework is developed using Rapid Application Development (RAD) model. Software engineering principles objected oriented design, parallel computing, and a few agile principles are followed in both the research and the development phases. The work includes anonymized DICOM images of different anatomies downloaded from the cancer imaging archive (TCIA), the USA. The domain-based approach of problem-solving and feature-oriented requirements engineering was followed. The prototype was developed by considering the requirements and use cases from Radiologist. The work was carried out on a high-performance workstation with Intel Xeon™ processor, NVidia™ GPU, and 64GB DDR3 RAM. The processing time for different steps were, DICOM reading -3.2±0.22s, DICOM image validation – 0.507±0.421s, applying window settings -6.1815±0.67s, extracting MIP in all the 3 MPR directions – 5.08±0.327s, isosurface extraction using Marching cube algorithm – 52.88±0.91s, a linear smoothing operation – 7.398±0.54s, colon segmentation – 110.6±4.3s, Electronic cleansing – 251.8±8.26s and polyp size measurement – 183.1±2.3s. The results were validated through statistical analysis. Clinical validation is in progress. This framework can be used as an image-processing tool for any imaging modalities and can be customized for the specific needs of the radiologist. We have proved that the RAD model suits perfectly in small-scale research that can be applied to develop a software product. The scope of the future work is, that the framework can be extended to bid data analytics of medical images, for different imaging modalities, and for solving any other problems using radiology images

Terms—Medical Engineering Design, Medical software product.

06. Development of innovative devices

OPEN-SOURCE HARDWARE DESCRIPTION AND BENCH TEST PERFORMANCE OF AN EASY-TO-BUILD AND AFFORDABLE CPAP DEVICE FOR LOW-INCOME COUNTRIES

By Farre R.^[1], Solana G.^[2], Gozal D.^[3], Montserrat J.M.^[4], Navajas D.^[5]

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BACKGROUND: Although precise epidemiological data are scarce, sleep breathing disturbances are prevalent in low-income countries (LICs). Unfortunately, commercially-available CPAP devices may not be readily affordable in LICs thereby discouraging their use. In this context, in-house manufacturing -i.e. medical devices built by healthcare centers to be used for their patients- can be a convenient approach for LICs (Farre et al. Am J Respir Crit Care Med, PMID:30265582). **AIM:** To design and test an affordable CPAP device that is easy to build and requires simple servicing for use in a LIC setting. **METHODS:** The designed CPAP device was based on off-the-shelf materials available via e-commerce. Briefly, a high-pressure blower and its driver, a pressure transducer and a custom-made analog proportional-integral control circuit were identified. The ≈100 US\$ retail cost of all required components should be substantially reduced by wholesale ordering. A low-cost 3D-printer was used to assemble the components into a compact device. The CPAP device prototype was evaluated in a bench simulator (Farré et al. Am J Respir Crit Care Med 168:659-663, 2003) by connecting it to a simulated patient while using conventional CPAP tubing and an intended air leak orifice. The dynamic stability of the nasal pressure provided by the device at different CPAP settings (4, 8, 12, 16 cmH₂O) was measured for several simulated patient's breathing flows (tidal volume: 0.5 L; 10, 15 and 20 breath/min) with and without inclusion of an unintended air leak (30 L/min) at the mask level. **RESULTS:** Nasal pressure fluctuations (peak-to-peak along the breathing cycle) were <1 cmH₂O at the most strenuous condition: CPAP=16 cmH₂O, frequency of 20 breath/min and unintended leak of 30 L/min. In light of the original purpose of this initiative, the device technical information and detailed schematics are available for release under free terms following the open-source hardware approach. **CONCLUSION:** We designed a performant CPAP device for in-house assembly in LIC clinical centers which is low-cost, easy to build, and, most importantly, can be readily serviced and maintained on site. This novel approach should allow for provision of CPAP treatment to LIC patients who otherwise would have been unable to afford this therapy.

06. Development of innovative devices

POSFO: PERSONALISED ORTHOPAEDIC AND SPORTIVE FOOT ORTHOTICS USING INTERNET OF THINGS AND 3D PRINTING

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Disorders of the musculoskeletal (MSK) system are among the major causes of disability. These pathologies are associated with a chronic degeneration and a decreased level of quality of life. Economically, the burden associated with MSK disorders is relevant considering its growing trend (source World Health Organisation) and the final stage of these pathologies that often-required expensive surgical interventions and rehabilitation. In addition, several degenerative conditions originated from disrupted postural behaviour. Many orthoses, such as foot orthotics, have been developed and used as conservative treatments. However, the prescription and the production of these devices showed several technical and technological limitations, especially in the production of customised aids. Therefore, the objective of the POSFO project is to optimise the development of an innovative workflow to produce low-cost and highly accessible personalised foot orthotics. The team defined an innovative workflow to create low-cost, reliable and competitive custom-made foot orthotics using the Internet of Things and 3D printing. It consists of four main phases. The first step is the accurate acquisition of the plantar geometries. Instead of using a bulky scanner or foam boxes, a dedicated app will guide the customer throughout a series of acquisitions. The acquisition process will only need a standard smartphone, or a tablet and the required dataset could be sent from everywhere to the company system. The second step is in the reconstruction process that will not produce any waste material as it will be performed with a reconstruction software starting from the image's dataset. The third phase is the actual modelling that will allow the foot orthotics to match the required geometries and clinical specifications. The fourth and final phase involves the use of a 3D printer that will guarantee the required material properties with a net reduction of both time and cost of production.

The mission of Medere is to create accessible and low-cost custom-made medical devices and medical technology to improve significantly patients' experience and quality of life. Allowing every person to get the best solution, with creativity and innovation, is the engine that pushed the founders during the development of their personal careers.

06. Development of innovative devices

SOCIAL ROBOTS IN HEALTHCARE, A FIVE YEAR ON-THE-FIELD EXPERIENCE AT THE CASA SOLLIEVO DELLA SOFFERENZA RESEARCH HOSPITAL

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Casa Sollievo della Sofferenza is a research hospital with a wide experience in the treatment of elderly people suffering from dementia or with movement difficulties. Thanks to its participation to the MARIO and ACCRA research and innovation projects, both financed under EU H2020, the hospital has gained experience in the design and experimentation of social robots as innovative devices in these fields. With a multidisciplinary approach involving technologists, physicians, and end users in innovative co-creation sessions, robotic services aimed to prevent the functional, physical and cognitive decline of elderly people were developed. Artificial intelligence based algorithms tailored the contents and interaction features to the specific user. One of the developed robotic services supports physicians in the Comprehensive Geriatric Assessment process, resulting in savings of doctors' time to be devoted to meaningful patient care activities. The robots were tested in real settings like hospital wards, senior citizens' homes, outpatient clinics, etc. involving many key players of the healthcare system, that evaluated the impact of social robots in clinical, psychological, ethical and social terms on both patients and caregivers. Preliminary results of MARIO were published in indexed journals and confirmed the improvement of patients' resilience and quality of life, the reduction of cognitive and affective impairment as well as of caregiver burden. The MARIO project has been included by the European Community in the short list of the 25 most influential projects in the Healthy and Active Aging domain, as well as in the European Innovation Radar. ACCRA trials are still ongoing and involve two robots. The Astro robot, designed after the needs that emerged during the co-creation sessions, is intended to help users in their movements and is also capable of measuring users' grasp force to evaluate the level of sarcopenia. Buddy robot helps elderly people on cognitive and social aspects. Furthermore, the hospital put in place case studies and experimentation involving the R1 robot by the Italian Institute of Technology and the Pepper robot by Softbank thanks to the collaboration with Konica Minolta Laboratory Europe. These robots will help patients and physicians in their daily routine. The accomplished results will pave the way for new use cases to demonstrate the suitability of social robots as support tools for healthcare professionals in the care of the elderly.

06. Development of innovative devices

ELECTRONIC SYSTEM FOR CALIBRATION AND GAUGING OF GOLDMANN OCULAR TONOMETER

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Research conducted by the World Health Organization (WHO) at the end of the last century indicated that in 2000 there were about 45 million people with blindness in the world, that is, unable to perform many daily tasks due to visual disability. The same calculations indicated that if global and regional initiatives are not taken, by 2020 there will be 75 million blind people worldwide and more than 225 million people with low vision. According to the Brazilian Society of Ophthalmology (SBO), it is important to note that 90% of these blind and low vision individuals are located in developing countries. However, about 80% of these blindness and low vision cases are preventable or curable. Glaucoma is the second leading cause of blindness in the world, only behind cataract. An important biomedical measurement in ophthalmology is the intraocular pressure (IOP). Elevated IOP is one of the main risk factors for the development of glaucoma and the gold standard for its measurement uses the Goldmann applanation tonometer. This study aims to develop a new electronic method to gauge and calibrate the Goldmann applanation tonometer. Currently, the method used for calibration consists in using a graded metal rod attached to the tonometer where a correlation between the displacement of the rod and the pressure exerted by the patient's eye in the instrument is established. Our new device uses the analog signals received and converts them into visible digital information in an alphanumeric display. The expectation is that we can apply this methodology to various types of applanation tonometers providing a reliable and accessible method to healthcare providers.

Keywords: Glaucoma; intraocular pressure; tonometry; calibration.

06. Development of innovative devices

DEVELOPMENT OF INNOVATIVE SYSTEM FOR NEUROCOGNITIVE AND MOTOR REHABILITATION

By **Miladinovic A., Silveri G., Milos A., Accardo A.**

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Despite the fact that Motor Imagery (MI), the ability to generate the mental correlate of motor and perceptive events in the absence of external stimuli, has been identified and studied for decades, the system for its proper detection and usage in neuro and cognitive rehabilitation hasn't been widely used in clinical settings. Accordingly, MI corresponds to an active process in which the representation of a particular action is mentally reproduced without any external output. A proper non-invasive EEG Brain-Computer Interface can be used for alleviating symptoms of various neurological and psychiatric disorders, and for realization it requires a series of analysis procedures for identifying and classifying the MI particular cerebral signals. In this regard, supporting literature shows that sensorimotor rhythms (SMR) are associated with the cortical areas directly linked to motor channels. Hence, a movement and/or its preparation is detectable distinctive EEG rhythms both happening at the primary sensorimotor area (S1-M1), the supplementary motor area (SMA) and the posterior parietal (PP) one. The peculiarity of SMR relies on the fact that they are naturally connected to the cerebral areas devoted to movements, they are reinforced by training, and they are generated not only in the presence of the action but also with its imagination. Moreover, the mental simulation and the physical execution of an action rely on the same cerebral structures and anatomical-functional systems.

In clinical scenarios, physiotherapists have used MI for neurocognitive and motor rehabilitation in post-stroke, Parkinson's and other patients for a longer time. However, the effectiveness of the therapy is unpredictable because of the uncontrollable conditions (it is unknown if subject performs the task of Motor Imagery). In addition to that, many patients are unable to perform any of the physical rehabilitation tasks for various reasons (paralyses, hearth problems, etc.) and controlled MI is one of the remaining possibilities for their improvement. To overcome problems of uncontrolled MI, the proposed innovative system can measure the active brain responses and give immediate feedback, not only to the operator, but also to the patient, producing a closed loop neurofeedback, ultimately, improving cognitive capabilities and allowing better movement control and muscle recruitment.

06. Development of innovative devices

EARLY IDENTIFICATION OF THE DYSGRAPHIA THROUGH KINEMATIC ANALYSIS OF HANDWRITING

By **Silveri G., Miladinovic A., Ajcevic M., Accardo A.**

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Writing difficulties, which affect an increasing number of school-age children, have a deep impact on performance and communication and can lead to both delays in learning and low self-esteem in everyday life. Dysgraphia, due to uncorrected learning of writing, is the most frequent difficulty and its early identification could allow a more effective therapeutic action, increasing the chances of success and reducing its duration.

In this study, a tool able to identify subjects with graphomotor difficulties using motion-based kinematic analysis has been developed. Digital tablets technology has brought an innovative approach to measure kinematic characteristics of handwriting movements allowing objective quantitative analyses of the writing quality as well as characterization of the handwriting process. In particular the factors concerning the basic elements of writing, such as strokes have been intensively studied considering them as primitives from which complex movements are assumed to be planned and executed.

In this study, the writing was acquired by using both a commercial digitalization tablet (Wacom, Inc., Vancouver, WA, Model Intuos 2.0) and a suitable program based on the Software Development Kit (SDK, LCS/Telegraphics). In order to reproduce a daily school context, a suitable ink pen and a sheet of lined paper of the adequate school grade, placed on the tablet surface, were used. The sampling frequency utilized to acquire the pen displacement was of 100Hz and the spatial resolution was of 0.01mm.

Tests like the reproduction in cursive of a lelele sequence and the copy of a sentence in accurate and fast modalities were used and the handwriting kinematic characteristics were analyzed by using a proprietary program written in MATLAB®. The tool has been validated on the handwritings of dysgraphic and not dysgraphic children (7-10 years old). Different kinematic parameters extracted from their writing were compared in the two groups and, by using principal component analysis and stepwise-fit regression applied to these parameters, a classifier able to well differentiate the two groups, was realized. The device could be employed in the childhood development department within a hospital rehabilitation service.

06. Development of innovative devices

TOWARDS THE DESIGN AND TEST OF A SENSORIZED PACIFIER

By **Giansanti D., Maccioni G.**

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Introduction: Breastfeeding (BF) is considered fundamental for infant feeding and has basic role in nutrition, immunological protection and creation and growth of the infant's orofacial functions and structures [1-3]. Infants in order to perform a correct BF must have suitable oral capacity with suitable strength and therefore dynamic and kinematic functionalities. An infant demonstrates these capacities through two distinct patterns: non-nutritive sucking (NNS), for example when the infant sucks a finger or a pacifier which occurs in the absence eating, and nutritive sucking (NS), which occurs during BF or when eating from a baby bottle. Both NS and NNS patterns are fundamental. The kinematic and dynamic assessment of both NNS and NS tasks could be of aid to investigate problems and/or pathologies related to the orofacial functionality.

Goals: The objective of this study was:

- (a) To design a medical device to assess the NNS.
- (b) To design a bread board to investigate the biofeedback.
- (c) To bench test the medical device.
- (d) To insert the medical device in an experimental study.

Results: At the moment we have implemented step (a-b) and are terminating step (c). In particular we have selected a peculiar sensor (pressure sensor MPX2100, Motorola) capable to assess the dynamic properties as a function of time in the range of interest [1-4]. Regarding step (b) it has also been introduced a led based biofeedback function, to show by means of a led array the activity and strength mapped with a proportional led number. The convincement is that this could be of aid in the nurseries to have a complete online trace/vision of the NNS activity.

Conclusions and work in progress: A medical device to investigate the NNS sucking has been proposed. We are terminating the bench test. The next steps will be focused to the bench test completion and successive phases necessary to insert the device in an experimental study according to the national regulation. The device could be useful in clinics, at home or in telemedicine applications for example in the daily remote monitoring.

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06. Development of innovative devices

PREPARATION AND CHARACTERIZATION OF BIOACTIVE FUNCTIONALIZED SILK-BASED FILMS FOR WOUND HEALING

By **Adhikari S.**

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In this study, an effort has been made to develop a ready-to-use bioactive wound dressing material using natural silk fibroin biomaterial functionalized with drugs and PRP. The flexible silk films were prepared by incorporating 3% dextrose (w/w) in the silk films which acted as a plasticizer. The dextrose modified silk films showed higher water holding capacity than the normal silk films. After evaluating the results of the comparative study done in between the silk films and the dextrose modified silk films, it was found that the flexibility as well as the hydrophilicity of silk fibroin films increased upon the addition of dextrose. Additionally, two more types of dextrose modified films were prepared, the PRP coated dextrose modified films and the drug coated dextrose modified films. The films were microscopically examined for detecting cytotoxicity and the results showed that the films were not toxic. An in-vivo wound healing test on mice models indicated that the PRP coated and the drug coated films resulted in a good wound recovery effect, similar to a commercial wound dressing material. The increased hydrophilicity of these films along with the combined results of drugs and PRP have balanced the moist environment at the wound site, which improved the wound healing compared with the other types of films. This systematic approach to wound healing biomaterial wound dressings may demonstrate a useful strategy to select formulations for further study towards new treatment options for chronic wounds in the future.

Keywords: Functionalize, Hydrophilicity, Pathological, Proliferation

06. Development of innovative devices

SONEHEALTH IMPROVE THE FIRST DIAGNOSIS WITH THE CLASSIC STETHOSCOPE

By Bonanno M.

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SONE health aim to improve the first diagnosis made with the Classic stethoscope! Thanks to devices that digitize the sounds detected by any classic stethoscopes with the aim to improve it (by amplifying and filtering), and finally send it to ICT devices:

- SONE remote: add on device for any classic stethoscope: <https://www.sonehealth.com/sone-remote/?lang=en>
- SONE pro: electronic headsets for Littman stethoscope: <https://www.sonehealth.com/sone-pro/?lang=en>
- Sound Amplifier 32x; 4 filters for “Lung and heart tones; Guarantees hygiene; Bluetooth communication to software on app.

Those solutions are able to digitize the natural sound exactly as it is heard by the examiner; are protected by two PCT patents, GRANTED in USA, EUROPE and in process to be granted in CHINA;

- Through a SW application, it allows to record and share auscultation among specialists, with the aim to improve diagnosis and monitoring of pathologies and perform Remote Patient Monitoring (RPM) services.
- And associated with a predictive software for recognition of abnormal sound, will be a strong help in a first diagnosis.

All the Electronic stethoscope on the market, depends critically on the electro-acoustic properties of the sensors used to acquire the signals of interest, and this is reflected in no existing acoustical standards for characterizing electronic stethoscopes; This lack, reduce the trust of physicians in an electronic based auscultation; they need to be trained for the sound electronically transduced. This project has the ambition to allow a better diagnosis of COPD and valvulopathies. Furthermore, SONE will strengthen Remote Patient Monitoring services. European data show the business opportunity: at least 1 out of 5 people suffers from chronic diseases suitable for homecare and 4 out of 5 citizens classify medical errors as an important issue. Patient anxiety, due to uncertain diagnosis, is reflected in expensive additional testing: the average price for an echocardiogram range from \$1,000 to \$3,000. The Global market demand of digital stethoscope from 2020 until 2022 is of 8 Million units, and the market of classic stethoscope in the same period is of 80 Million; SONEhealth aim to address market share linked with the sales of classic stethoscopes. The users are hospital and clinics; cardiologists, general practitioners, and students; and company providing RPM services.

06. Development of innovative devices

CATALYSTS OF MEDICAL DEVICES INNOVATION PROCESS

By Cardoso De Morais Oliveira V.[1], Valadares Oliveira E.J.[2], Weibel N.[3]

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Innovating in the medical device sector differs from other segments, just being new is not enough. Safety, effectiveness, benefit, cost, and access must also be addressed. Compliance factors (market regulation, reimbursement policies, and prices) also act as modulating agents in the innovation process. This work seeks to address drivers that may impact the development of innovative medical technology, considering socioeconomic and compliance factors that can influence the process. Three approaches can be used to understand innovation in the medical devices sector:

- a) The motivation of the innovation, whether it was demanded (solution for a new need) or compelled (evolution of scientific knowledge, clinical practices, and the skills to produce new tools);
- b) Level of discontinuity imposed by the innovation: disruptive or incremental;
- c) Impacts and consequences of innovation, such as the impact on the patient benefit versus the cost of innovation.

One of the leading economic indicators of health is its spending and behavioral trends. The USA, for example, have the highest health spending in the world. In 2017, the USA spent US\$ 3.5 trillion. For comparative purposes, in 2017, all world spending on health was approximately US\$ 7.7 trillion, among US\$ 1.7 trillion in Europe, same for Asia/Australia, and US\$ 350 billion in Latin America. Considering only the medical devices market, the USA also appears as a leader, accounting for 40% of the world market (\$ 156 billion in 2017) and exports exceeding US\$ 41 billion in the same year. Specifically, for the medical devices sector, the following technological trends can be indicated: biomaterials, biosensors, medical software, artificial intelligence, data analysis via Big Data. Technology giants such as Apple, Amazon, Microsoft, and Google begin to enter the healthcare market by introducing new solutions that challenge traditional operations, supply chains, and sales channels. The incentive to the innovation involves the strengthening of relations between government, industry, and academia, reinforcing here the triple helix model of innovation, requiring for the medical devices sector, a redefinition of how technologies and new business models are developed. Understanding, and defining new sectoral strategies is fundamental for the development of new products and business, which can promote more transparency, access, safety, the efficacy of medical devices technology, accelerating its access to the market.

06. Development of innovative devices

IMPORTANT FACTORS IN DEVELOPING INNOVATIVE MEDICAL DEVICES IN JAPAN

By **Fukuta K., Yoshioka J., Ifuku T., Igeta H., Honma T.**

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As a recent trend in Japan, collaboration between medical practice and medical industry companies is accelerating in developing medical devices. Necessary factors leading to this advancement, including national strategies, will be described. The first factor is identification of the unmet needs in the clinical setting and finding a co-developer who is able to address the issue. Clinical engineers work beside patients to operate and monitor medical devices, and maintain for contributing to the improved clinical safety. Consequently, for instance, our colleague, Mr. Yoshioka has contributed in improving the safety of the oxygen pressure regulator by developing an alarm system with a medical device manufacturer. As described, it is important that the challenges and needs in the medical field be connected with technologies, and the Japanese government is also promoting medical-industrial cooperation development linking medical professionals and companies.

Secondly, appropriate knowledge of regulation is necessary for developing new medical devices. Medical devices are regulated under the Pharmaceuticals and Medical Devices Act and require prior approval. It is classified into 3 categories according to the potential risk to human life and health or their side effects; high-level control, requiring control and general devices. Also, different types of approval exist: approval, certification, and self-certification. It is important to know in advance what type of approval is required, as it is directly related to obtaining acquisition time and fee. As a government, new approval schemes were established to speed up the release of new and innovative technologies.

Thirdly, diagnosis and treatment are covered under universal health insurance, and this allows a uniform medical service fee to be applied for all medical institutions. Expenses related to medical devices are included in it and it is assessed in 2 categories, either price embedded in the technology fee or the price of a specific insurance medical devices. Especially in the case of specified insurance medical devices is, in principle, assess fees by concept of functional classification and similar price method so that it is important to check existing assessment from the beginning of development when considering early collection of development costs. In summary, medical device development is becoming common, and it is important to consider these factors for innovative medical device development in Japan.

06. Development of innovative devices

SPE3D-APP PROJECT: 3D PRINTING AND APP. A SUPPORT FOR DIFFERENT ABILITIES AND CLINICAL PRACTICE

By **Simonetti M.**

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SPE3D-App is a project by ITS Volta (www.itsvolta.it) in the ITS4.0-Program promoted by the MIUR in collaboration with the Ca'Foscari University. The design idea is inspired by the absence of industries producing ergonomic systems for driving electric wheelchairs while supporting the personal needs arising from specific disabilities. It was decided to realize Customizable and Ergonomic Supports (in Italian: Supporti Personalizzabili Ergonomici) in 3D printing and APP that allowed to support clinical practice for the measurement of angles of mobility of body joints. This is the basis of project name: SPE3D-APP. The design methodology that supported the entire production process is based on "Design Thinking". This modern approach to innovation relies on understanding the effective needs of the users with effective and low-cost prototyping tools as well as relevant models of economic assessment.

The use of the additive manufacturing/3D printing turns out to be the suitable technology for design, modelling and realizing customizable prototypes unique in their ergonomics. The implementation of APP responds well to the needs of the clinical staff (physiatrist and physiotherapist who often use manual goniometers). These will be installed on modern smartphones which are natively equipped with the necessary measurement sensors (accelerometers, gyroscopes, etc). Through 5 phases of Design Thinking, with the direction of Marco Simonetti (project leader), with the collaboration of the Diego Zabot (project work), supported by R3place (innovative start-up in the 3D printing industry) and with the participation of students of "Engineer Technician for Medical Informatics and Bioinformatics solutions (2016-18)", two 3D printing prototypes and two APP were created.

The first prototype was the new custom joystick to improve the driving experience of a young male with mobility impairments (29yo). The second prototype is a support to fix a smartphone on the back side of the hand. The first APP has been designed to compare the trajectories performed with the old joystick in respect to the new prototype created during the wheelchair driving.

The second allows measuring, by inserting the smartphone in the appropriate printed support, the angles of movement of the wrist (flexion-extension, adduction-abduction, pronation-supination). The test phases gathered the satisfaction of the final user and the physiatrist, involved in the verification of digitally performed measurements.

06. Development of innovative devices

D-SHOE: A SMART SHOE TO DETECT WALKING DYSFUNCTION

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Walking disorders are one of the most common problems encountered in neurological and orthopedic patients as well as in elders. Walking disorders are an established risk factor for falling because of impaired stepping and postural stability. For detection of causes of risk of falling or fall phobia needs clinical assessment of walking. Walking involves repetitive sequences of gait cycles. Each gait cycle is divided into stance and swing phases. Each gait phase has functional objectives and goals. These goals and objectives achieve three basic tasks. These tasks are weight acceptance, single limb support and limb advancement. Failure to achieve any basic task leads to any musculoskeletal disability or problem. Aim of this study is to describe and validate the algorithm for the detection of musculoskeletal disorder. Musculoskeletal disorders can be studied by timing of gait phases. Accurate gait phases duration are to be recorded by using foot switches. The system consists of network of foot switches. Foot switches are placed beneath the soles of the shoe. Four switches are mounted on heel, first metatarsal, fifth metatarsal and thumb positions of both shoes. In this study, possibilities of detecting duration of gait phases are heel strike, loading response, midstance, pre-swing and swing. Duration of each gait phase are served as an input for real time analysis. Foot switches signals are fed in to Arduino mega 2560 which serves as a data acquisition board for importing data to LabVIEW 2018. In LabVIEW, an algorithm is implemented to calculate, analyze and predict walking abnormality reliably. Five (5) healthy participants (3 males and 2 females) belonging to the age group of (21-26 years) were recruited from the Hamdard University for the functional walking analysis test. The response was found accurate results. A smart shoe platform helps to improve bio-mechanist practices, to recover walking patients, to improve their treatment plans. Through smart shoe, bio-mechanist can quickly collect reliable, repeatable profile data comprises of walking phases duration, report generation and diagnosis documentation.

06. Development of innovative devices

ANALYSIS OF THE EMERGENCY NEONATAL TRANSPORT CLINICAL RECORDS BEFORE AND AFTER THE INTRODUCTION OF SHOCK ABSORBING STRETCHER SUPPORTS

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Introduction: To improve the technological equipment of the Emergency Neonatal Transport Service (STEN), OPBG adopted a hydropneumatic system with adjustable tilting, capable of reducing the effects of vibrations and impact on the infant. This device is necessary for the protection of both patients (safe use of the medical equipment, which lays on the shock absorbing support) and healthcare professionals (ease of the incubator loading/unloading procedure). This project analyzes the physiological parameters of STEN patients for a statistical comparison of data before and after the introduction of the shock absorbing stretcher supports, to evaluate their potential clinical benefit.

Methods: Both the parameters indicating the stable condition of patients during the transfer (Breath Rate, BR; Temperature, T; Systolic Pressure, SP; Diastolic Pressure, DP) and the “confounding” variables, i.e. parameters with potential effects on the aforementioned indicators (Body Weight, BW; Gestational Age, GA), were appropriately selected. An equal number of transports before (PRE) and after (POST) the introduction of the shock absorbing supports was considered for the comparison (n=778). The variation of the selected indicators following the transfer (Δ BR, Δ T, Δ SP, Δ DP) was evaluated by means of a regressive analysis: predictive values of the sample means (corrected to account for the effects of the “confounding” variables) were compared via t-test ($\alpha=0.05$).

Results: Δ BR: means equal to -0,03 (PRE) and -0,96 (POST) acts/min. Δ T: 0,014 °C (PRE); -0,011 °C (POST). Δ SP: 0,21 mmHg (PRE); -0,10 mmHg (POST). Δ DP: -0,12 mmHg (PRE); 0,83 mmHg (POST).

Conclusion: Significant differences between PRE and POST conditions were not found regarding T, SP and DP. A statistically significant reduction of BR was found; however, the difference was not meaningful from a clinical point of view. Possible developments of this project are: the continuation of the statistical analysis, with the increase of the samples; the use, on the ambulances, of devices capable of measuring the swings acting on the incubator (i.e. accelerometers), to evaluate their correlation with the selected indicators.

06. Development of innovative devices

NEEDLE FREE BLOOD TYPING

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In conventional method, we can determine blood group using invasive method. This is time consuming because of chemical reaction between blood and chemical reagent. Our proposed idea is using IR light source on the patient fingertip we can determine the Blood group base on the absorption Beer Lambert's Principal.

In human classification of blood group is ABO and its define antigens and antibodies present on the surface of RBC in the blood Basic principle involved is interaction of antigen and antibody and subsequent agglutination of RBCs. When there is no interaction between the antigen and antibody agglutination does not occur.

Light from the source passes through the RBC of the blood, epitopes of antigens, and thereby allowing light with a distinct wavelength to pass/deflect/diffract/reflect completely.

This deflected light is detected with the help of sensitive photodiode which is then interfaced with the control unit to get output into respective voltage. This process is quick, convenient and economic for blood group detection in hospital, clinic and during emergency.

06. Development of innovative devices

DESIGN OF AN INNOVATIVE REHABILITATION PLATFORM USING A ROBOT, VIRTUAL REALITY AND WEARABLE SENSORS

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Description of the project: Work reintegration following a trauma or illness is a multidimensional process that involves both physical and psychosocial aspects [1]. The recovery of upper limb abilities is an important factor for work reintegration, especially for those tasks requiring strength, movement control and arm dexterity [2] - [5]. As it is well known, robot-assisted rehabilitation training have shown improvements in terms of muscle strength and motor coordination recovery in neurological patients [6]. But their impact in terms of activities of daily living (ADLs) is currently rather limited, especially for workers reintegration [6]. Currently the existing rehabilitation programs aimed to work reintegration are poorly oriented to quantitative and personalised assessment of residual abilities and to the recovery of skills for worker re-employment. In order to overcome these limits, a new robotic platform based on a robotic arm, wearable sensors and virtual reality scenarios is developed.

Objective: The goal of the project is to propose an innovative robotic platform (RoboVir), integrated with wearable sensors and virtual reality scenarios for upper limb rehabilitation with visuomotor coordination in occupational contexts.

The final users that will benefit will be:

- a) the health care professionals involved in upper limb rehabilitation
- b) the workers who have suffered injuries of the upper limbs in their work and who need rapid rehabilitative recovery paths and re-insight into the work environment

Results: The key elements of the designed and developed platform are the following : A) a commercial end-effector robotic arm (Panda robot, Franka Emika GmbH) with 7 degrees of freedom ; B) wearable customized foot insoles; C) virtual reality (VR) with two serious games and D) a commercial hand tracking device. The robot is controlled by using a customized adaptive control based on the impedance-based technique in order to interact gently with the user. The integrated components permit both the visuomotor coordination control and the balance monitoring.

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06. Development of innovative devices

A MOBILE APP FOR PREVENTING OF EXERCISE-INDUCED HYPOGLYCEMIA IN TYPE 1 DIABETIC PATIENTS

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There is an increasing need for technology solutions to increase self-empowerment and self-management of chronic patients. Nutrition and physical activity are important parts of a healthy lifestyle and management of diabetes. Physical activity greatly influences blood glucose levels, therefore for type 1 diabetes (T1D) patients is important to adapt their diet and therapy in order to avoid exercise-induced hyperglycemia and hypoglycemia. Existing guidelines for minimizing the risk of hypoglycemia are not well-defined and it represents one of the major barriers to physical activity and it limits volitional exercise in T1D patients.

To overcome this problem in T1D subjects, an algorithm called ECRES was proposed to estimate patient-exercise tailored glucose supplement required to maintain safe blood glucose levels during physical activity (Francescato et al, Med Sci Sports Exerc 2011). The algorithm is based on patient's habitual therapy and diet, and accounts for his/her insulin sensitivity (Francescato et al, J Diabetes Sci Technol 2019). Actual exercise intensity and duration, patient's physical fitness level, and the timing of the activity relative to the last insulin bolus, are used by the algorithm, allowing to estimate the carbohydrates supplement for any time of day the exercise is performed. The method was successfully tested during short (Francescato et al, Curr Diabetes Rev 2011) and prolonged exercise (Francescato et al, PLoS ONE 2015); Buoite Stella et al, Can J Diab 2016), estimating minor amounts of CHO supplement with respect to a classical approach, while maintaining glycaemia within safe levels (Ajčević et al, IFMBE Proceedings 2019).

An implementation of the ECRES algorithm as a mobile app for the self-management of type 1 diabetes is illustrated. The developed application provides relevant feedback to patients on carbohydrate intake needed to carry out a planned physical activity, in a safe manner. Furthermore, application provides other important features, for self-management of this chronicity: entry of blood glucose values, display of diabetes-related data, such as blood glucose readings and their analysis, carbohydrate intake, insulin doses, and easy data export. The app has the potential of overcoming the overall scarcity of knowledge around exercise management; it might be an intriguing tool to help patients avoiding exercise-induced falls of glycaemia, and thus encourage them to increase their physical activity.

06. Development of innovative devices

ARAMIS- AUTOMATIC RECOVERY ARM MOTILITY INTEGRATED SYSTEM». ROBO-MECHATRONIC SYSTEM FOR THE NEUROREHABILITATION AND FUNCTIONAL RECOVERY OF THE PARETIC UPPER LIMB IN POST STROKE PATIENTS

By Pignolo L.

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ARAMIS is a concept robot and prototype for the neurorehabilitation of the paretic upper limb after stroke. A system designed to take advantage on the arms functional interaction, it operates two computer-controlled, symmetric and interacting exoskeletons that compensate for the inadequate strength and accuracy of the paretic arm movements and the effect of gravity during rehabilitation.

Patient, operator and robot interact. The training exercises and rehabilitation protocols can be personalized in a virtually unlimited variety of modalities and are adjustable during treatment whenever required. ARAMIS* can measure the shoulder, elbow and forearm residual motor function in baseline and record quantitative indices of motor recovery during/after treatment

Developed in the research laboratories of RAN at the S. Anna Institute of Crotona, since 2008, first prototype, and now is operative the 4Th evolution of the system.

The four prototypes have been tried, over the years, on over 130 patients. The Aramis system is based on the concept of also using the undamaged nervous structures of the homolateral hemisphere, by proximal-distal recovery. The program is set by the therapist. Once inside the robot, the patient starts the session in safety and requires no further help from the therapist. The overall time for this stage is no more than 5 minutes, thus leaving the therapist free to get on with other things. It only takes a day to train staff since the software interface has been designed to be user friendly for all operators. During treatment the therapist assesses the level of recovery achieved and can change mode by proposing active exercises for daily living activities in specially designed 3D virtual scenarios.

06. Development of innovative devices

MECHATRONIC HOSPITAL BED FOR STATIC AND DYNAMIC POSITIONING, AND PASSIVE MOBILIZATION, OF THE ENTIRE BODY IN ACUTE POST STROKE PATIENTS

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The level of motor function recovery, after stroke, mostly depends on the urgency measures that are taken in the first hours to avoid the disastrous consequences of incorrect positioning, which should also be dynamic, and mobilization of all the segments. This should be performed during the first 24 hours, but currently requires the constant intervention of an operator. However, a study published in *Stroke* in 2004 described the condition of the patient in the first 14 days as “Inactive and Alone”: patients spend 50% of their day in bed, 28% sitting, and only 13% employed in tasks that might prevent complications from immobilization and improve motor recovery. The patient is alone for about 60% of the time.

A mechatronic bed has been designed to fulfil all these needs. The mechatronic bed, called *Ulisse*, is a fully automated device, managed by a centralized control, which enables all the necessary functions and early rehabilitation to be performed 24 hours a day without the constant intervention of an operator whose only task is to select the treatment program according to the patient’s evolution

During first phase after damage, wide 24 hours, *ULISSE* allows to perform a right static and dynamic positioning, more than practicing the mobilization of all segments.

06. Development of innovative devices

A DEVICE FOR MONITORING CIRCADIAN RHYTHMS VIA WEARABLE SENSORS. A PILOT STUDY

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Circadian rhythms are physiological and behavioral processes that typically recur over 24-h periods. Circadian alteration has significant side effects in our life. Among many, it could lead to cardiovascular diseases, cancer and sleep disorders, disrupting quality of life. Moreover, recent researches proved that patients with major alterations in circadian cycles are significantly less likely to survive to cancer treatments. Currently, the methods for circadian measurements are not suitable for continuous and simultaneous monitoring at home. Circadian rhythm in humans can be assessed by measuring the circadian rhythmic profile in serum level of melatonin and cortisol, via laboratory tests, which are expensive and not easy to be performed at home. Thus, there is the need to develop a new technology to track the state of a person’s circadian clock(s) in real-time. Therefore, the combination of wearable sensors, biomedical signal analysis and artificial intelligence techniques could represent a valid solution to track alterations in internal clock transforming medicine from primarily intervention-focused to predictive and preventative.

Several cortisol and melatonin indices are commonly used in the literature to determine circadian alterations. In particular, peak-to-trough difference is one of the most used indices to assess rhythm alterations in cortisol profiles, whereas the onset of melatonin secretion under dim light conditions (DLMO) is the single most accurate marker for assessing the circadian pacemaker.

To prototype and validate a technology for monitoring circadian cycle in real-time, healthy participants and cancer patients were recruited in this study (REGO-2018-2205 & REC-14/WA/0033). Subjects were asked to wear two different wearable devices. The first wearable device, the *Zephyr BioPatch*, recorded ECG, breathing rate and 3-axis accelerations. The second one was a wireless data logger, the *iButtons*, which recorded body temperature. In this study, cortisol and melatonin were used as markers of circadian cycle. For each subject, behavioural and physiological signals were acquired for two consecutive days by wearable devices, and two days’ worth of salivary samples were taken. Preliminary analysis shows promising results to automatically detect circadian alterations based on Heart Rate Variability features and temperature data extracted during periods where activity is controlled for. Some moderately successful classifiers were produced.

06. Development of innovative devices

TOWARDS THE AUTOMATION OF PBS PROTON TREATMENT PLANNING

By **Alparone A.^[1], Vecchi C.^[1], Zara S.^[1], Placidi L.^[2], Righetto R.^[3], Schwarz M.^[3]**

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Purpose: To develop an automatic planning process for intra-cranial PBS proton treatments.

Materials and methods: Phase one consists in the automatic selection of all clinically feasible gantry and couch angles setup (GCAS), based on the target localization. This is achieved either via a class solution (CS) or via a computation of heterogeneity index (HI) of the possible beam paths. CS allows the user to select the anatomical region and therefore a predefined setup suggested by experts. Selecting AHI, all available GCAS, based on the heterogeneity index extracted for each beam path angles, are listed. The user may then select from 2 up to a maximum of 4 fields, with a minimum separation of 30°, as well as the use of range shifter for each field. Target homogeneous dose coverage is then obtained by either PBS single field or multiple field optimization.

In the undergoing phase two, genetic algorithm (GA) gets as input the optimal GCAS from the CS and AHI option and, in addition to target coverage, includes OAR sparing. GA is characterized by a fitness function that evaluates the individual's adaptability using PTVs coverage and equivalent uniform dose for OARs as hippocampus, brainstem, spinal cord, optical chiasm and nerves. User can decide to use both phase one and two results as input or insert manually the GCAS.

Results and future work: Phase one lead to a fluid and intuitive workflow to achieve the best GCAS, based on the CS or AHI option, and a clinical acceptable homogeneous target dose coverage. The upcoming and conclusive results of phase two look promising: a clinical validation of the GA proton auto-planning for intra-cranial tumors is ongoing. Even though dependent on the target size and the number of OARs included in the optimization, the required time for optimised/calculated a plan is roughly 30 min.

06. Development of innovative devices

REMS TECHNOLOGY: EARLY DIAGNOSIS OF OSTEOPOROSIS AND RISK OF FRACTURE

By **Conversano F.^[1], Pisani P.^[1], Rizzo F.^[2], Ciardo D.^[2], Leone C.^[2], Casciaro S.^[1]**

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Nationally and internationally patented, REMS (Radiofrequency Echographic Multi Spectrometry), is an innovative Italian technology which allows the early diagnosis of osteoporosis, the bone health monitoring and the evaluation of the fracture risk on the axial reference sites (proximal femur and lumbar vertebrae) by using a non-ionizing approach.

Dedicated algorithms make it possible to realize a highly sensitive spectral and statistical analysis of the native raw data obtained from simple echographic scans of lumbar or femoral sites. The comparison with spectral reference models (healthy and osteoporotic patient's spectra model) enables the calculation of the bone mineral density (BMD) by using a fully automatic data elaboration process. REMS technology has also been validated on multicentric level on thousands of patients [1]: both the high-rate performance in identifying the osteoporotic patients (sensitivity and specificity > 90%) and the elevated precision (RMS-CV: 0.38% for the lumbar spine and 0.32% for the femoral site) have been shown.

During the same echographic scan, REMS technology also provides the innovative parameter Fragility Score that automatically estimates the bone fragility and the risk of fracture based on the quality of the inner bone micro-architecture by comparing it against spectral models of reference obtained from fractured and non-fractured patients.

It is well known that osteoporosis may also affect young people and children, and that its worsening may only be halted by a prompt diagnosis and treatment: new applications of REMS technology will allow the calculation of the bone mineral density as well as the risk of fracture in paediatric patients. Furthermore, REMS technology will enable the examination of muscular tissue by timely monitoring muscular mass loss in order to detect pathologies such as sarcopenia, strictly linked with bone frailty and fractures.

Finally, thanks to the non-ionizing approach, REMS technology is feasible for mass population prevention programs and for rising population awareness towards the bone health in order to reduce osteoporosis impact both on the socio-economic level and on the overall citizenship health level, promoting a healthy and active aging. The issue of population aging, if neglected, may lead to an increased impact of chronic diseases not only on the single subject, but also on the National Health System and, as a consequence, on our society.

06. Development of innovative devices

RESEARCH ON A FLEXIBLE NANOSENSOR WITH VISUAL DETECTION FOR RADIAL ARTERY PUNCTURE GUIDANCE

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Radial artery puncture is the most commonly used pre-treatment method for arterial blood gas analysis and dynamic blood pressure monitoring. However, this method mainly relies on the experience of physicians. The lack of experience, thin patient's brachial artery, etc., will all hinder the puncture, even causing physical and psychological damages to the patient. Therefore, there is a need for a convenient and rapid method for guiding the radial artery puncture. The most popular method of guidance today is ultrasound-assisted radial artery puncture. The method is relatively intuitive and greatly improves the success rate of radial artery puncture. However, considering the inconvenience of instrument operation with ultrasound equipment, new visualization methods are good alternatives to overcome the shortcoming.

This paper aims to introduce a flexible pressure sensing device based on nanomaterials according to the actual clinical needs above. A sensor was constructed with flexible nano-arrays by using polymethyl methacrylate (PMMA) as the base for nano-arrays. The flexible support materials combined with nano-processing technology for micro-array etching and nano-compositing. Then graphene derivatives and gold nanoparticles worked as sensing layers with high pressure sensitivity. With nano-array design and nanomaterial, it can fully touch the wrist of the person, better sensing the pulsation of the radial artery, and then indicate the position of the artery. At the same time, the arm support part is designed according to the characteristics of the human arm and the radial artery puncture needle, and the sensor is combined to form the whole sensing device for further improving the success rate of the radial artery puncture. Such kind of sensor can indicate the position and orientation of the artery in vitro by utilizing the flexibility, high sensitivity to pressure, compression and discoloration of nanomaterials such as gold nanoparticles and graphene, and combining nano-processing technology with sensing technology. A visualized radial artery puncture indication system based on nanomaterials was constructed to visualize the arterial vessels of the radial artery puncture target area, guiding the anesthesiologist to perform radial artery puncture. Based on the device, the blood pressure and heart rate can be further monitored in vitro, and the integration of the auxiliary and the detection can be achieved.

06. Development of innovative devices

HTA-BASED FRAMEWORK FOR INNOVATIVE DEVICE DEVELOPMENT

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BACKGROUND: According to the WHO, HT Assessment (HTA) purpose is to “inform technology-related policy-making in health care”. As such, HTA methods can be used either in the hospital context for managerial decisions, or in the governance of national health systems or else be tailored for early assessment of medical devices in development (Early-HTA). During the new product development process, medical companies use Early-HTA methodologies for strategic considerations, economic evaluation and/or clinical considerations. This paper presents an HTA-based framework for innovative device development to foster new patents and innovative undergraduate projects. **METHODS:** The proposed methodology was composed from reviewed technical literature on HTA topics, papers from scientific community as well as reports from authoritative sources: guidelines from the Brazilian Ministry of Health, reports from the European Network for HTA, publications from the Ad-HopHTA and MedTechHTA projects (Adopting Hospital Based HTA and Methods for HTA of Medical Devices). The devised framework was, then, applied in 3 case studies of undergraduate final projects of medical device development: non-invasive blood pressure measurement; transepidermal water loss quantification; wireless adaptor for ECG recorder. Final results were evaluated according their adequacy for new intellectual property application. **RESULTS:** Our framework has 6 stages (A-F). It starts with a preliminary (scope) review of scientific papers (Phase A). A systematic review of literature (Phase B) is then conducted, with extraction of all relevant product, population and methodological information. These data are used for: (B-1) delimitation of possible use scenarios; (B-2) pooling of commercially available devices; and (B-3) definition of device main requisites and core functions. Deliverables A-1 and B3 are combined for elaboration of query terms and search in major patent databases (Phase C), to obtain related technical products (C-1). In Phase D, deliverables B-1, B-2 and B-3 are used for design analysis and selection in matrices (Requisites mapping; Function mapping; Pugh Matrix: respectively D-1, D-2, D-3). All Class C and D deliverables are used in the prototype informational and conceptual designs, respectively Phases E and F. Case studies show great concordance among framework deliverables and data needed for patent applications.

06. Development of innovative devices

3- D VASCULOGRAPHY : NON-INVASIVE, AFFORDABLE AND SAFE SOLUTION FOR CARDIOVASCULAR ASSESSMENT

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3-D vasculography produces a complete cardiovascular functional physiological profile of the patient consisting of over sixty vital functional parameters beat to beat that directly aid in diagnosis and treatment of cardiovascular diseases in a rural society, cost effectively. Technique: A multi-variable mathematical model specific to each individual patient can be designed to obtain the nominal basal nonlinear hemodynamic behavior. By superimposing the measured data obtained from the individuals on a predictive model, a pattern, called 3D-Cardiovasculography (CVG), can be generated. With use in screening thousands of patients over last 10 years, it was observed that Coronary Artery Disease (CAD) characteristically altered the CVG pattern. These alterations were carefully analyzed using artificial neural networks and back propagation neural dynamics and the exact status of the coronary insufficiency was reconstructed on a realistic-geometry coronary model. A strong correlation was found to exist between functional structures and structural functions. It is now feasible to use such modelling and vasculographic techniques to detect the primary presence of CAD and to assess its severity. It also early detects other cardiovascular abnormalities, pulmonary pathology and renal microcirculation in mass screening of patients at rural levels. Conclusion: In an earlier study conducted, with 300 cardiac patients, the correlation between coronary angiography and vasculographic technique was established as: Sensitivity: 90.5%, Specificity: 92.1%, Positive Predictive Accuracy: 98.4%, Negative predictive Accuracy: 75.6%.

Thus, the 3D Vasculography test can be applied for primary mass screening of people in the Urban and Rural settings, for cardiovascular diseases specially Coronary artery disease.

06. Development of innovative devices

CATALYSTS OF MEDICAL DEVICES INNOVATION PROCESS

By Ramirez Lopez L.J., Rodriguez J.

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We have designed a new Holter that measures heart's activity for over 24 hours, implements a new prediction methodology, and generates alarms as well as indicators to patients and treating physicians. A new methodology Various diagnostic advances have been developed in clinical cardiology thanks to Holter implementation; however, their interpretation has largely been conditioned to clinical analysis and measurements adjusted to diverse population characteristics, thus turning it into a subjective examination. This, however, requires vast population studies to be validated that, in turn, have not achieved the ultimate goal: mortality prediction. Given this context, MD Javier Rodríguez, Insight Group director, developed a mathematical methodology that assesses cardiac dynamics through entropy and probability, creating a numerical and geometrical attractor which allows to quantify the normalcy of chronic and acute disease as well as the evolution between such states. This has been shown in different contexts with 100% sensitivity and specificity results. To develop this methodology, lowest and highest heart rate values are taken from Holter paired records in ranges of 5 beats/min consecutively recorded, from which its frequency of occurrence is assessed to create the new attractor. Afterwards, the probability of occupation is assessed vis-à-vis the totality of each range so that probability results from the division between the heart rate ordered pair and the totality of heart rate recorded pairs.

Finally, equation 1 is solved with regard to the S/k entropy relation to group summands corresponding to associated probabilities for occupation rates per unit (1-9), tens (10-99), hundreds (100-999), and thousands (1.000 to 9.999), thus adding to subsequently assess existing proportions between summands to the totality (S/k proportion), as well as proportions between hundreds with regard to thousands as well as tens with regard to hundreds per specified region.

Device Holter device which implements:

- Cloud data storage.
- Data access through password and user.
- Available monitoring per hour of measurement.
- Continuous monitoring to 2 or 3 ECG derivations.
- 3 or 12 electrode measurement.
- Firmware including new prediction methodology (explained above).
- Patient, treating physician and family member visual alarms recorded in database.
- Status: functional prototype.

06. Development of innovative devices

A BCI CONTROLLED SOFT FINGER EXOSKELETON FITTING PATIENT'S NEEDS

By **Cafolla D., Pavone L., Sebastiano F.**

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Soft robotics are robotic systems made of materials that are similar in softness to human soft tissues. Recent medical soft robot designs, including rehabilitation, surgical, and diagnostic soft robots, are categorized by application and reviewed for functionality. Each design is analysed for engineering characteristics and clinical significance. One of these innovative approaches can include soft robotics since it has high performance potential in situations where the kinematic parameters of the system are not defined in advance making it suitable for a tailored finger exoskeleton fitting patient's need.

Brain Computer Interface (BCI) technology is a set of tools that allow a user to control an external device using only his brain, with no muscle's involvement. In the last years, it became attractive in the field of assistive technologies, especially for motor rehabilitation. The field of assistive technologies for motor rehabilitation is taking advantage by the introduction of electrophysiological signals to control robotic devices. One of the most used control signals for BCI applications is the ElectroEncephaloGram (EEG). EEG-based brain-computer interface (BCI) has shown its effectiveness for the purpose of enhancing robot-assisted rehabilitation training.

User's intent is generally interpreted extracting distinguished features of EEG signals, called Event-Related Potentials (ERP), which occurs in the brain in response to specific cognitive, motor or sensory processes. One of the most used ERP used in BCI applications is the sensorimotor rhythm (SMR), elicited during motor imagery tasks. SMRs are very well-known rhythms in the brain observed in EEG signal around 8-12 Hz or 18-26 Hz over sensorimotor cortex. SMR increase immediately after an active movement is performed and decrease before and during the execution of the movement itself. These phenomena are called event-related desynchronization (ERD) and event-related synchronization (ERS), respectively.

This method introduces a BCI controlled soft finger exoskeleton for patient's needs modelled around one specific user finger with the help of a 3D scanning procedure maintaining a light structure and the easiness to wear. The designed finger exoskeleton is controlled by an EEG-based Brain Computer Interface (BCI) system helping people to faster recover from motion impairments or to restore grasping skills in people with permanent motor disabilities.

06. Development of innovative devices

BREAST PHYSICAL PHANTOMS FOR CONVENTIONAL AND PHASE CONTRAST BREAST TOMOSYNTHESIS

By **Daskalaki A., Dermitzakis A., Malliori A., Pallikarakis N.**

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While software phantoms are very important in investigating new imaging modalities, physical phantoms are indispensable tools for image quality evaluation and dosimetric studies in x-ray breast imaging. Rapid prototyping and 3D printing techniques, provide today the possibility to produce such customized phantoms in the lab, with very precise and fit to specific purpose characteristics. This project is aiming in the development of breast phantoms, using 3D printing techniques combined with purification processes, specialized for phase contrast breast tomosynthesis. The physical phantoms will be produced in three basic steps. First, a type of mold, in a semi cycle form with complex geometries internally, is constructed using high resolution rapid prototyping (3D printing). A single material with glandular equivalence is used to form a mold of 5 cm radius and 4 cm thickness. During the second step a liquid material with adipose equivalence is purified and used to fill the empty spaces of the complex mold. The investigated materials are going to be PLA and resins for the glandular equivalent material and paraffin and epoxy-based resin for the adipose part. Finally, 3 different types of abnormalities are embedded. Nylon spheres with sizes 4.8 mm, 3.2 mm and 2.4 mm representing masses, nylon fibers with sizes 0.9 mm, 0.7 mm and 0.5 mm, and CaCO₃ powder representing microcalcifications (μ Cs), are used for this purpose. During the solidification process, four layers of the above-mentioned abnormalities are embedded. The investigated materials were selected based on their radiographic and refractive properties. A comparison of the refractive indexes δ and the attenuation coefficients μ between breast tissues and the mimicking materials has been calculated according to the equation $\delta\text{Diff}=(|\delta_B-\delta_M|/\delta_B)*100$. Where B represents the values of breast tissue and M the values of mimicking material. The final phantoms will be used to acquire conventional BT images and phase contrast images with micro-focus x-ray tube. The production of such phantoms enables qualitative and quantitative image quality assessment and dose analysis in the case of phase contrast breast tomosynthesis. Also, they may provide an important tool for researchers to optimize and improve different imaging techniques under real conditions and to evaluate and compare various breast imaging modalities in terms of clinical performance.

06. Development of innovative devices

DEVELOPMENT OF AN ULTRASOUND PHANTOM FOR INVESTIGATING BRAIN TISSUE PULSATIONS

By De Vries G.^[1], George S.^[2], Ramnarine K.^[2], Turner P.^[2], Chung E.^[2]

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Doppler ultrasound can be used to investigate how pulsatile flow in the major cerebral arteries contributes to the motion of surrounding brain tissue [1-3]. The aim of this study was to develop an arterial brain tissue pulsation phantom to aid development of an ultrasound method for measuring brain tissue motion. To mimic the contribution of major artery pulsation to brain tissue motion, physiologically realistic pulsatile flow was generated within a silicone anatomical replica of the major cerebral arteries. The vascular replica was surrounded by a polyvinyl-alcohol material intended to mimic the elastic and acoustic properties of brain tissue [4]. For comparison with phantom measurements, tissue velocities were measured in healthy volunteers using a Nihon Kohden Transcranial Doppler prototype device. Data were analysed in MatLab to estimate brain tissue displacement over the cardiac cycle; each recording provides information on tissue displacements in the direction of the beam for 30 overlapping 3 mm Doppler gates spaced 2 mm apart; corresponding to a depth range of 22-80 mm. To compare the path of the ultrasound beam with brain anatomy, volunteers also underwent 3T MRI. 'Tissue' motion waveforms in the phantom were similar to those of healthy volunteers (Forehead-Phantom: 2 – 165 μm , Healthy Volunteer: 2 – 183 μm). Localised changes in pulsation amplitude, phase shifts and asymmetry in pulsation waveforms were reproduced. This arterial brain tissue phantom mimics tissue motion due to vessel pulsation, excluding ventricular flow, tissue perfusion and intracranial pressure. Further work is underway to improve the phantom to investigate the impact of parameters such as intracranial pressure, arterial blood pressure, and cerebral compliance on Doppler brain tissue pulsation estimates.

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06. Development of innovative devices

THE NEW CARDIAC DIAGNOSTIC PREDICTION APPLIED TO A DESIGNED HOLTER

By Ramirez Lopez L.J., Rodríguez J.

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We have designed a new Holter that measures heart's activity for over 24 hours, implements a new prediction methodology, and generates alarms as well as indicators to patients and treating physicians. A new methodology Various diagnostic advances have been developed in clinical cardiology thanks to Holter implementation; however, their interpretation has largely been conditioned to clinical analysis and measurements adjusted to diverse population characteristics, thus turning it into a subjective examination. This, however, requires vast population studies to be validated that, in turn, have not achieved the ultimate goal: mortality prediction. Given this context, MD Javier Rodríguez, Insight Group director, developed a mathematical methodology that assesses cardiac dynamics through entropy and probability, creating a numerical and geometrical attractor which allows to quantify the normalcy of chronic and acute disease as well as the evolution between such states. This has been shown in different contexts with 100% sensitivity and specificity results. To develop this methodology, lowest and highest heart rate values are taken from Holter paired records in ranges of 5 beats/min consecutively recorded, from which its frequency of occurrence is assessed to create the new attractor. Afterwards, the probability of occupation is assessed vis-à-vis the totality of each range so that probability results from the division between the heart rate ordered pair and the totality of heart rate recorded pairs. Finally, equation 1 is solved with regard to the S/k entropy relation to group summands corresponding to associated probabilities for occupation rates per unit (1-9), tens (10-99), hundreds (100-999), and thousands (1.000 to 9.999), thus adding to subsequently assess existing proportions between summands to the totality (S/k proportion), as well as proportions between hundreds with regard to thousands as well as tens with regard to hundreds per specified region. Device Holter device which implements:

- Cloud data storage.
- Data access through password and user.
- Available monitoring per hour of measurement.
- Continuous monitoring to 2 or 3 ECG derivations.
- 3 or 12 electrode measurement.
- Firmware including new prediction methodology (explained above).
- Patient, treating physician and family member visual alarms recorded in database
- Status: functional prototype.

07. Design of health facilities

NEW HOSPITAL CONSTRUCTION EQUIPMENT PREINSTALLATIONS PLANNING

By **Gonzalez G., Pestaña R., Meirovich C.**

Meirovich Consulting, Madrid, Spain

The final objective of this presentation is to make the audience aware of the importance of preinstallations in a new hospital project.

Medical Equipment Planning is not only preparing a list of equipment and a set of technical specifications for the procurement of the new equipment.

It is also about guaranteeing the proper installation of the equipment once it is procured. By proper we mean not only that the equipment may be turned on and off but that the equipment is a proper position for users and or patients, that there are no loose cables, that the path to get to the device was not blocked for a handicapped person, that the room keeps its required clinical space, that are not safety issued due to hanging tubes or open walls.

In this presentation we will show a few examples and situations found during construction in some of the areas of the hospital (Kitchen, Laundry, CSSD, Morgue, Laboratory, Imaging Diagnostics (MRI), Nuclear Medicine (LINACs) and Operating Theatres) and the way we proposed to approach a solution to them.

07. Design of health facilities

EMERGENCY RELOCATION OF A CARDIO-SURGICAL HEALTH FACILITY DUE TO WAR

By **Djankou T.L.^[1], Ngong A.S.^[1], Albonico V.^[2]**

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The promptness of a patient's recovery in a healthcare facility depends immensely on how accurate the engineers were during the construction phase. How precise international standards are implemented in various engineering sectors of the hospital is of capital importance. It is therefore of prime importance to choose an experienced contractor to implement a healthcare project.

In November 2016, a social unrest broke up the two English speaking regions of Cameroon (North West and South West regions). The Cardiac Centre Shisong happens to be in one of these regions. The crisis persisted and grew into violent and deadly confrontations between separatist fighters and the military leading massive internal displacement of citizens. It is to this effect that the cardio-surgical unit of the hospital relocated to a safer city to reach out to the ever-growing number of patients.

CHALLENGES ENCOUNTERED HINDERING THE SMOOTH TAKE OFF SURGERIES IN THE CHOSEN CLINIC

- The presence of 2 split type air conditioners instead of an air handling unit. Among the 2 air conditioners none was working correctly.
- Absence of piping for medical air in the operating theater.
- Absence of piping for anesthetic gas scavenging system in the operating theater.
- Presence of only three electricity sockets in the operating theater.
- The presence of a 2 bed poorly designed intensive care unit.
- Poor disposition of oxygen cylinders and supply network.
- Absence of a centralized vacuum system.
- Absence of medical gas alarm system.

MEASURES TAKEN TO UPGRADE THE FACILITY SO AS TO ACCOMMODATE THE CARDIO-SURGICAL SERVICE.

- Repaired and cleaned air conditioners rather than purchasing an air handling unit.
- More sockets for oxygen and medical air were added in the theater.
- Installation of piping for evacuation of anesthetic gas from the machine.
- Installation of a 2 cylinders by 2 ramps with a switch over mechanism between both ramps and connected to a medical gas alarm system.
- Construction of a building to accommodate the intensive care unit.

LIMITATIONS OBSERVED IN THE CONSTRUCTION OF THE INTENSIVE CARE UNIT

- No provision of a sluice room
- Poor drainage of rain water from the roof leading to the proliferation of fungi growth.
- Poor demarcation of sterile zone, hence communication of construction site with the intensive care unit.
- Poor implementation of oxygen distribution system leading to frequent rupture in oxygen supply to services.

07. Design of health facilities

CE'S DEVELOPING A MULTI-SKILLED HOLISTIC ROLE IN FACILITY DESIGN AND BUILD, AND PROJECT MANAGEMENT

By Grainger P., Kearney B.

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When three inner city multidisciplinary Dublin hospitals merged, this merger saw the translocation of staff and patients and the integration of respective hospitals operational infrastructures, policies and ethos to a green field site on the suburbs of Dublin. The work brief of a group of clinical engineers was developed to lead and manage significant aspects of this project whilst working directly for the New Hospital Board Project Office. Associated project management work spanned a period of five years. It was not necessarily the nature of any individual task performed during this project that extended the day-to-day role of the Clinical Engineer, it was, more importantly, the scale upon which many of these tasks were undertaken and the breadth of engineering skills required. Design related hardcore civil, mechanical, environmental and electrical engineering issues had to be solved in conjunction with external consultant engineering firms. All aspects had to be project managed or "driven" by a team of Clinical Engineers. The CE's encountered a cross of medical device equipment issues in conjunction with heavy fundamental engineering build construction challenges. Such examples are:

- The ergonomic design of a physiotherapy department with consideration given to the structural Faraday Cage.
- Railway track vibration effects on large x ray diagnostic equipment?
- Positioning, support and anchoring of ceiling mount anaesthetic booms, monitors, microscopes in consideration of support and degrees of stability and load distribution.

Furthermore, the Clinical Engineering role became an integral component of clinical support as patient care needs were tended to in the design of the new facility. This presentation reviews the role of the Clinical Engineer extending into a broader multi-skilled holistic engineering function of Project Management in Facility Design and Build at "Project and Design Committee" level. It also reviews the subsequent scientific opportunities for those clinical engineers involved after having developed a deeper and closer relationship with the user (medical, nursing and paramedical staff). Since this Hospital Project, in Ireland more Clinical Engineering personnel are working in a formal Facility Project Management Role - encouraged under the National Development Plan. Further examples of role diversity such as the management of Acute Hospital site utilization and facility Development Control Planning will be presented.

07. Design of health facilities

THE ROLE OF THE CLINICAL ENGINEER IN HOSPITAL ELECTRICAL INFRASTRUCTURE

By Mcgrath C., Grainger P., Kearny B., Shrolik O.

BEAI, Naas, Ireland

Background: Clinical Engineers in hospitals worldwide have a long history of safeguarding patient safety and well being, using their skills, expertise and experience to maximise electrical safety, reliability, and continuity of clinical services. In most healthcare settings, the Clinical Engineering contribution to patient safety is limited to Medical Devices, and the main healthcare facility electrical power infrastructure is left to Electrical Engineers and technical staff.

Clinical Engineers can bridge this gap between the medical device and electrical infrastructure fields with successful results. Clinical Engineers can play a major role in the provision of safe and reliable healthcare electrical power systems through several means including: examining existing systems, working on project teams delivering new electrical infrastructure, and playing a leading role in the development of electrical standards for Medical Locations.

Project Aims:

- Conduct analysis of existing power systems within healthcare facilities, identifying flaws and risks to patient safety, taking into account electrical safety, reliability of supply, and the resilience of the infrastructure in the event of component failure.
- Working alongside Electrical Engineers, outside Consultants and Technical Services staff to provide specifications and requirements for new infrastructure to be installed in healthcare facilities.
- Work alongside Hospital Clinical and Technical Services staff to plan for works on Hospital electrical systems by contractors; providing Clinical Engineering services to ensure a minimal disruption to Clinical Services during works.
- Contribute at both a national and international level to the development of standards governing electrical power systems used in Medical Locations, applying Clinical Engineering expertise and experience in the area to lead the development of revised standards with Patient Safety to the fore.

The numerous works illustrated within this presentation were completed over the period 2016-2019. This presentation will demonstrate the background of each project, the goals, the roles played by Clinical Engineers on the project team, and the results of each project as well as future projects planned and potential further work.

08. Technologies for home care

DIGITAL HEALTHCARE IN HOME CARE: IOT FOR THE IMPROVEMENT OF TECHNOLOGY MANAGEMENT AT PATIENT'S HOME

By Mesoellea G.^[2], Mesoellea A.^[1]

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In healthcare, the world of home care has always had difficulties in developing ICT solutions and technologies. The era of industry 4.0 and new technologies can help improve home care and, for this reason, there is a strong need to computerization, which grows with the increase in demand for home care. The elderly population, but not only, takes care of diseases that must necessarily be treated outside hospitals, both for reasons of sustainability, and because these are not the most appropriate places to treat certain conditions. However, the response of IT has always been weak: in fact, telemedicine is often been considered as something additional to manage. Therefore, it has to change approach since the continuous computerization of clinical data can lead to two great benefits: improvement of the medical services dedicated and customized on the specific needs of the patient, where both the standardization of hospitalization procedures and an effective and efficient management of electro-medical equipment used in home care are lacking. In fact, the only reference currently available is the guideline drawn up by Assogastecnici, which aims to provide a method for the correct management of medical devices normally used in homecare activities. It is also known to all that, the management of home care devices is an extremely complicated process, because of the vastness of data to be managed and the distribution of these devices over an entire territory. Therefore, the traceability of the equipment is fundamental to allow an optimal management for the benefit of the patient but also of the health organizations. Computerization may be the key to being able to map the scattered technologies in the area, linking them to the patient's data and then going to simultaneously manage the patient's clinical history and the maintenance history of the equipment, exploiting software that already exist today. It would be enough to integrate and implement software all together. Therefore, creating an interface between the SIC management equipment maintenance software and the computerized medical records management system would allow to monitor patients and equipment over time throughout the territory. Finally, a critical issue to work on is the presence of the risk of confined spaces, as homes often do not guarantee ample workspace and, finally, the presence of electrical system do not suitable for the medical devices that are used in patient's homes.

08. Technologies for home care

ARC-INTELLICARE, A HOME-BASED PLATFORM FOR AN INTEGRATED REHABILITATION CARE: THE ITALIAN CASE STUDY

By Lai S.^[1], Mantoan A.^[1], Sernissi F.^[1], Moro L.^[1], Brondi R.^[1], Avveduto G.^[1], Panero R.^[1], Ponzo E.^[1], Abbiate I.^[2], Revel A.^[2], Odoni R.^[2], Ascari L.^[1]

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The introduction of innovative technologies for the delivering of care at patients' home is highly advocated to make it more accessible after hospital discharge, while limiting healthcare costs. However, home-based solutions are still scarcely adopted due to several obstacles, such as: (i) need to design and implement new care pathways including their adoption; (ii) lack of evidence to support reimbursement mechanisms; (iii) poor or no integration with hospital IT services. The aim of this work is to introduce a new platform for home-based rehabilitation, ARC-Intellicare (ARC), and the related pathway proposed within the clinical investigation ARCANGEL (ClinicalTrial.gov ID: NCT03787433). This trial is currently being conducted on stroke survivors at the Local Health Unit ASL TO3 (Turin, Italy), and at the Northern Health and Social Care Trust (N. Ireland), to assess the feasibility of introducing ARC in the clinical practice, users' acceptability and Health Economics data. ARC aims at supporting and motivating the patients in following their rehab program, by providing monitoring and real-time performance feedback during the execution of functional exercises prescribed by therapists. This is possible thanks to a locally running machine learning engine that analyzes inertial data collected from patients' limbs from up to 5 wearable sensors hosted into wrist, ankle and neck biocompatible straps. A tablet serves as interface for the patient via a user-friendly App and can be charged with the sensors into a base station. A web portal is available for healthcare coordinators to manage ARC devices and an HL7 communication layer will provide integration with hospitals' Electronic Medical Records. Patients are introduced to the use of ARC during training sessions offered by skilled therapists. Thus, they can continue their rehab program at home, under remote supervision. Therapists are equipped with a dedicated tablet and App, allowing them to visualize patients' performances, and to update their rehab program. ARC offers also a cognitive functionality that guides patients step-by-step executing predefined activities of daily living. Currently, 34 patients have been screened at the ASL TO 3, 18 have been recruited and 10 of those are using ARC at home with positive feedback and a good level of satisfaction. ARC is GDPR compliant and will be certified as Medical Device Class I for post-stroke rehabilitation intended use after ARCANGEL study completion.

08. Technologies for home care

DESIGNING SAFE & SUSTAINABLE COMMUNITY PATIENT CARE COORDINATION TELEHEALTH HUBS W/COLOUR PETRI NETS

By Sloane E.^[1], Gehlot V.^[2], Wickramasinghe N.^[3]

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Modelling and simulation (M&S) tools are powerful engineering planning tools that enable prediction of system performance. If telehealth/mHealth is to scale successfully to meet population needs, safe and sustainable performance must be assured. M&S tools can be used to predict how many remote clinical support staff are needed to cover complex mixtures of patients with varying risk, frequency and complexity of problems. Too many patient alerts or alarms can overwhelm an ill-configured staff/system layout, leading to unsafe, unresponsive, and unacceptable performance. This project is based on a proven, open source M&S tool, Coloured Petri Nets (CPN). The authors propose collaborative research and application efforts to build libraries of shared modelling tools to accelerate design, implement, and deploy much-needed homecare telehealth networks.

Over the past several years, models and papers illustrating baseline CPN community telehealth applications have been presented at academic healthcare, informatics, and business conferences. The applied nature and skills of the Clinical Engineering discipline are ideally suited for a collaboration to expand from research to specific hospital/community clinical trials and application. Existing CPN models are offered by the authors to any researcher who would like to begin application in a local context. A sharable, open-source library of CPN models for telehealth community hubs will be discussed and recommended.

08. Technologies for home care

A SENSORIZED EXERCISER IN LUNG REHABILITATION: TOWARDS THE INTEGRATION IN THE HEALTH-CARE

By Giansanti D., Maccioni G.

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Respiratory rehabilitation aims to modify the impact that the respiratory disease has on the patient's quality of life, reducing the severity of the symptoms and improving their ability to adhere to the activities of daily life. Following an initial assessment, they are prescribed (a) different forms and modes of physical exercise and (b) exercise of pulmonary musculature to improve individual performance and the consequences of the symptoms of the emotional sphere related to the pathological condition. At the moment the devices for pulmonary exertion/stimulation, even if gamified, give out qualitative information and are not provided with electronics and/or are not connected to the network. There are a lot of commercial gamified lung exercisers based on chambers with balls. In the exercisers with three chambers the balls rise according to the flow intensity (1 ball=400 cc/s ; 2 balls=800 cc/s ; 3 balls=1200 cc/s). The objective of this study was to design an electronic and PC based lung exerciser capable to (A) show a biofeed-back (B) to store data to (C) remotely exchange information in telemedicine applications. We have designed a prototypal exerciser/stimulator system for expiration improvement through the execution of gamified exercises. The system comprehends (a) an electronic device for the expiration flow measurement; (b) An USB 6008 A/D converter (National Instruments, USA) for the integration to a PC. (c) A biofeedback software application on the PC with a gamified representation of the flow, allowing also the data storing; designed by means of Labview 10 (National Instruments, USA). The core element of the hardware is a hot-wire-measurement sensor: the anemometer component Mini Anemometer 490 (Kurtz Instruments inc, USA). The biofeedback software shows three tanks, filled according to the flow intensity: (1 tank=400 cc/s; 2 tanks=800 cc/s; 3 tanks=1200 cc/s). The system has been successfully bench tested. We have planned to introduce it into a full clinical use. In particular the plan is to use it at the patient's home alone or in combination and integrated with an equipment which performs an automatic walking test [2-3]; this could fully insert the system in a telemedicine and e-health application.

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08. Technologies for home care

DEVELOPMENT OF A BIOMECHATRONIC DEVICE FOR MOTION ANALYSIS THROUGH A STEREOSCOPIC VISION MODULE DEVELOPMENT OF AN AUGMENTED REALITY INTERFACE FOR ADAPTIVE AND CUSTOMIZED MOTOR REHABILITATION IN A CLINICAL AND DOMESTIC ENVIRONMENT

By **Priester F.^[1], Fregola S.^[2], Gallo A.^[2], Merola A.^[3]**

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The purpose of the activities carried out is the development of an augmented reality PC interface for neuromotor rehabilitation using optimized body motion capture algorithms and new motion analysis methods. It allows the patient interaction with an environment in augmented reality able to adapt itself to the subject performance evolution during therapy and to the individual characteristics of the patient. The interface is based on the use of an RGB-Depth camera (Kinect Microsoft, ZED 2K, ORBBEC) for body motion capture. Methods have been developed to implement an algorithm able to identify the body junctions, to define the abduction and adduction movements of the limbs and to estimate the orientation of the anatomical parts in the space. They incorporate the calculation of the value of the detected angle and the control of the trunk and shoulder posture during movements. It is a system capable of recognizing and signalling an incorrect position of the patient's body that could affect the objective of the exercise to be performed, in order to maximize the effectiveness of the treatment based on the user's potential, increasing the chances of a better biofeedback. In the results obtained by performing tests for various exercises, the points identifying the joints have been detected correctly, achieving good precision. In support of what has been said, the use of these exercises was found in the rehabilitation protocols aimed at the recovery of mobility following trauma and in the case of surgical interventions. The work carried out is a valid tool for patients affected by chronic disability, but it could be extended to neurodegenerative diseases in the early stages of the disease. Thanks to an interactive model, patients can overcome the difficulties in interaction with the most common IT tools and technologies, they can perform rehabilitation sessions independently being supported and encouraged during the rehabilitation process at the same time. The physiotherapist can also check in real time the results and customize the care pathway. The key points are: Making rehabilitation motivating the patient, keeping a "player" profile optimizing costs with the possibility of low-cost remote assistance and telemedicine. This project allows to create a home care technology able to perform home rehabilitation.

08. Technologies for home care

OBERON MODEL FOR THE INTEGRATED MANAGEMENT AND ASSISTANCE OF CHRONIC PATIENTS IN VS AND MCS

By **Mauro A., Raso M.G.**

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The third-level home care service called "Oberon" accredited with the Regional Health Service in August 2018 was born as a project, presented by the Calabria Region to avail of the resources allocated for the priority objectives and of national importance and approved by the Ministry of Health in May 2010. The project aimed at activating a managerial experimentation, the only one in Italy and presumably in Europe, for the assistance of chronic patients in Vegetative State (VS) and Minimally Conscious State (MCS) for the entire regional territory of Calabria. For the implementation of the activities of the various phases of the Executive Plan, Istituto S. Anna in Crotona was identified as the executor and all the Provincial Health Centres of Calabria (Catanzaro, Cosenza, Reggio Calabria, Vibo Valentia) as partners for the provision of some of the planned home services. The service defines the integrated assistance for chronic patients in VS and MCS even fluctuating with a different aetiology and is based on what was defined with the experimental phase. It obtained the UNI EN ISO 9001:2015 quality certification in August 2018. It provides an innovative home-based hospitalisation through a public-private integration guaranteed by the automated remote monitoring of vital parameters and home visits by a remote team. Furthermore, teleconsultation is guaranteed through video calls aimed at assessing the patient's general conditions and supporting the family. This function is carried out by the Istituto S. Anna operating set up at the facility located in Poggio Pudano, called Special Operating Unit. The service also provides a consultation by telephone through video calls aimed at verifying the patient's general condition (skin reddening, and so on) and to support the patient's family. Technical assistance is also guaranteed ensuring that the equipment installed at home operates continuously. The remote team comprises a specialist doctor, a professional nurse, a rehabilitation therapist and a home assistant for the vegetative state (the ADOSV in Italian) and visits for which the frequencies vary depending on the patient's clinical conditions. The doctor and the home assistant for the vegetative state are made available by the S. Anna Institute while the Nurse and Therapist are assigned by the Provincial Health Centres. Remote monitoring is guaranteed by installing sensor devices at home and connected with the UOS (Special Operating Unit) via web.

08. Technologies for home care

BIOMEDICAL ENGINEERS ROLE SUPPORTING COMMUNITY BASED MEDICAL EQUIPMENT IN IRELAND

By Hackett L.^[1], Grainger P.^[2], O Toole A.^[1]

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This presentation aim is to provide the conference delegate with an understanding and appreciation of Medical device equipment support structure and the ever increasing importance of the role of community based Biomedical Engineers in the complex and challenging community setting in Ireland. Since this structure is designed and implemented in modular form part or all of the structure can be used in any area to support medical devices in Community. The effective management and support of medical equipment is an important function in any community based health care area, due to the diverse nature of the community service it is a greater challenge to provide effective support to equipment than in an acute hospital environment. Effective support to Medical Equipment in the community supports and improves acute hospital bed management, and it also has a positive impact on patient comfort and wellbeing while ensuring all medical equipment is maintained and supported to best international practice in compliance with Manufacturers recommendations national policies and international legislation. It improves performance for our colleagues across the various multidisciplinary teams. Compliance with regulations reduces the ever increasing cost of litigation which was damaging the reputation and increasing the cost of providing the service. The presentation will also demonstrate the changes over the last 15 years in the type of equipment and technology in use within the community setting, the various and varying locations of equipment and the resources and different models of service required to manage and maintain this portfolio of equipment in an area where more complex and acutely ill clients are being cared for thus increasing challenge on the Biomedical engineering resources. It will also look at the different skill sets required by Biomedical engineers in the community compared to the Acute Hospital setting. It also looks at new technologies – maintaining awareness of market place innovation which can improve client comfort and improve overall efficiency.

08. Technologies for home care

VIDEODIALYSIS: A VIRTUAL CAREGIVER FOR A NEW TYPE OF ASSISTED PERITONEAL DIALYSIS

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BACKGROUND: Peritoneal Dialysis (PD) is a form of home dialysis managed by the patient or caregiver. However, its use is limited by a number of social, physical, cognitive and psychological barriers to self-care in elderly patients (pts). In order to overcome these barriers to self-care PD, we created a virtual caregiver to provide remote care. From 2002 to 2008, a Sony videoconferencing device was used as technological support. Then in 2009 a new system called Videodialysis (VD) was introduced (VD-Mod1), and this was improved technologically in 2015 (VD-Mod2-eViSuS). The paper reports our experience from 01/10/2001 to 30/04/2017.

VIDEODIALYSIS: The basic components of VD are:

1. A Remote Station (RS): a video camera, monitor, microphone and technological box for connecting to the phone network, pre-assembled in a self-contained structure to make it easy to transport and activate at home without technical assistance.
2. A Control Station (CS): a webcam, high resolution monitor and software allowing up to 6 pts to be followed at the same time; photos can be taken and stored, and a switch and pointer improve interaction with pts/Caregiver (CG).
3. Connectivity: the connectivity in VD-Mod1 using ADSL/SHDSL lines has been completely changed in VD-Mod2-eViSuS to create an internet network connecting the RS and CS by both landline and mobile phone. Governance of the VD-Mod2-eViSuS is tasked to a Cloud Control Center.

RESULTS: VD was used for 26 pts (71.9±8.9 years - 3.7 barriers/pt). In 20 cases it was used to guide the pt, and in 6 cases the CG. During a 527-month follow-up (20.3±17.9), the number of connections was >40,000. VD was interrupted in 20 pts, due to death (9), Tx (1), transfer to HD (2), transfer to PD assisted by a self-sufficient independent CG (8) on account of clinical deterioration. The incidence of peritonitis (1/48 pt.mths) was no different to that of non-VD pts. The aspects pts appreciated the most were the contact with staff, security, help with care and not weighing on family members. During the study VD was also used on clinical grounds, and for reasons of difficulties in transporting and training pts and CGs, with a significant reduction in the number of hospital visits.

CONCLUSIONS: VD is a reliable, safe system which requires no technological know-how and is easy to use when self-care is not possible due to social, physical, cognitive or psychological barriers.

08. Technologies for home care

AUGMENTED-REALITY-BASED COGNITIVE SUPPORT IN ACTIVITIES OF DAILY LIVING

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The change in the age profile of the population is causing a significant increase in the number of people with dementia [<https://www.alzheimers.net/resources/alzheimers-statistics/>]. We propose a cognitive support intervention based on Augmented Reality (AR) technologies. Several studies [Lopez-Martinez A et al. 2011; Serino S et al. Front Aging Neurosci 2017] have used Virtual Reality (VR) for cognitive stimulation, with the aim of decreasing the rate of intellectual decay and potentially reversing age-related cognitive decline.

Compared to VR, Augmented Reality (AR) is easier to use, as it does not isolate the user from his/her environment. For this reason, we have developed an application based on AR markers to assist patients in their daily activities, at home and also away from home.

The proposal's target is the person with cognitive disabilities; in principle, even people with dementia could use this platform as a support in carrying out typical daily activities.

The aim of the AR system is to show (symbolically and/or textually) hidden points, such as rooms behind doors or objects in cabinets, or to warn that contact with an object can be dangerous, such as electrical sockets, an oven, ... We have placed specific markers on physical objects of interest, as suggested by the National Institute on Aging (a division of the NIH, US). Each of these markers is associated with information, so that it can be considered as an augmented object (AO) (visible object with additional information such as text, images, ...), which can be programmed according to the preferences and needs of the subject. The user wears commercial-type eyeglasses, with an embedded display and an integrated video camera: when a marker falls within the field of vision of the latter, the system makes the AO-associated content visible to the user through the display, at the position of the marker.

The home environment integrated by AR can be useful for patients for a safe exploration of the home environment itself. Moreover, besides preventing incidents during daily living activities, this type of patient empowerment, in perspective, can increase the level of physical activity, which has now been identified with certainty as a protective factor against the progression of neurodegenerative diseases (e.g., Kou et al, 2019, doi:10.3390/ijms20071591).

08. Technologies for home care

DIAGNOSTIC IMAGING AT HOME IN URGENT, LOW ACUITY SITUATIONS: A POSSIBLE ROLE FOR PARAMEDICS?

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In Ontario, as in other parts of Canada, marginalized and vulnerable populations, such as the elderly and individuals with mental health or addiction concerns, have been identified as having the greatest difficulty accessing quality, comprehensive medical care. In general, access to care after-hours is also insufficient. Inevitably, when acute illness or chronic disease exacerbations arise, these individuals end-up in hospital emergency departments in order to access required primary care and resources including medical assessment (e.g., diagnostic testing) and treatment (e.g., intravenous therapies). Research studies that examined paramedic call and hospital data have shown a majority of patients transported to hospital emergency departments by paramedics were not admitted into the hospital. A large proportion of these patients were further identified as needing radiography services. This research explores available evidence surrounding the need for provision of radiography services pre-hospital, in addition to implementation considerations (e.g., barriers/facilitators, feasibility, options) for paramedics to be involved in radiography service provision. Research methods include an analysis of 9-1-1 call and hospital data, and semi-structured interviews and focus groups with key informant experts in the healthcare system (e.g., paramedics, primary care providers, technologists, and administrators). It was hypothesized, if radiography services could be provided at home, having this diagnostic result could aid clinicians in assessing a patient's medical condition and help guide decision making when determining possible patient care approaches and disposition. Preliminary research results found, overall, a majority of care providers felt having access to diagnostic testing at home would support the provision of urgent care out-of-hospital. However opinions differed on the acuity level of target populations to be treated. Quantitative results also showed different diagnostic tests being used for different population age groups with older patients requiring a combination of lab tests plus radiographic imaging. These study results will help York Region Paramedics explore further possibilities for better supporting their clients and future opportunities for scope expansion.

08. Technologies for home care

DEVELOPMENT OF IOT-BASED PATIENT HEALTH MONITORING AND MANAGEMENT SYSTEM

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The present healthcare system is faced by two basic challenges when it comes to patient health monitoring; the need for the health care provider to be close to the patient physically and the immobility of patients when they are restricted to hospital beds or when wired to large machines, thus the need for a mobile health monitoring device for patient as an improvement to the existing health care system. In this research, a wireless-based mobile healthcare monitoring system that can provide real time online information about the physiological conditions of a patient is being designed and implemented. The IoT-based health parameters monitoring system measures and monitor two important health parameters (body temperature and pulse rate) in order to accurately describe the status of the patient's health and fitness. The measured parameters are saved on an online database developed using MySQL for storage and record keeping. Warning messages about the patient's critical health status are sent as SMS alert and Gmail notification to the healthcare professional's mobile phone, which then uses the information contained in the notification received to provide the necessary medical advice to the patient. The management and information retrieval on the system is enhanced through the developed Mobile App deployed on the mobile phone of the health practitioner and the patient.

09. International standards and regulations

MEDICAL DEVICE POST MARKET SURVEILLANCE AND QUALITY CONTROL

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Medical device safety is one of the leading topics in the world and most certainly the most important aspect of health care. International regulations are the ground stone for ensuring both safety and reliability of measurement of medical devices. Post market surveillance is as important as pre-market approval because it is the only way to keep the devices functioning in their full capacity. Quality control involved in all steps of marketing of medical devices is subjected to various regulations depending on the part of the world where they are used in but all of them share the essence of standardized inspection of medical equipment leading to its traceability and functionality. The need for implementation of an interdisciplinary supervision mechanism for medical devices that relies on scientific evidence-based methodology is recognized. As a result of this mechanism medical professionals will be able to justifiably rely on medical device safety and performance. This paper presents a legal metrology framework implemented in Bosnia and Herzegovina which ensures effective post market surveillance and quality control.

09. International standards and regulations

HIGH-LEVEL REGULATION OF CLINICAL ENGINEERING ACTIVITIES IN TURKEY

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Medical devices are considered among the expensive items of the health system. The competent authority is also responsible for safety placing on the market and the use of medical devices. In Turkey, private companies provide calibration services, except in-house activities by health care facilities. There is not any particular regulation on this issue beyond the quality system mechanism of healthcare facilities. In this respect, we introduced a national regulation that presents general rules and a stepwise approach to regulate the calibration service market.

The purpose of this regulation is to regulate the procedures and principles regarding the necessary test, control and calibration services that are provided to protect the patients, users and third parties during the using period of the medical devices from any possible threats against their health and safety. This regulation covers the procedures and principles regarding the trainer or users, the application, authorization, monitoring, and audit of the agencies to conduct the test, control and calibration, maintenance and repair of the medical devices during the operating time, the personnel of these agencies and their qualifications. In this regulation, medical devices are divided into 18 sub-categories regarding the similarity of them in the term of technological properties and needed calibration procedures. All actors in this field are defined such as responsible manager, technical expert, calibration conformity assessor, and training center. Training program and content are defined for every sub-category. There are three main stages to implement this regulation. The first step is authorization for training centers, second is having a license by calibration experts and third is the authorization of calibration service providers that employ certified technical experts.

In addition, we have developed a national medical device tracking system, Product Tracking System, which includes a clinical engineering sub-module. In this module, we are able to track all clinical engineering activities such as calibration and maintenance through the integration of healthcare facilities and service providers into the system.

09. International standards and regulations

GUIDELINE FOR ADDITIVE MANUFACTURING CENTERS IN CLINICAL INSTITUTIONS

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Healthcare is moving toward a high personalization of the diagnostic and therapeutic path. In this context Additive Manufacturing (AM) technology is playing an emerging role for the production of custom made devices, as patient-specific phantoms or surgical guides. AM is based on a layer-by-layer process which, by reducing the geometrical complexity of the model, enables the production of complex shapes in fewer time than any other technology. AM can be best exploited for the production of low volumes of highly personalized products, perfectly suiting the manufacturing of patient-specific products. Custom made medical devices are regulated by the upcoming EU Medical Device Regulation 2017/745 (MDR) and, under some requirements, can be manufactured by health institutions for their own patients. In the last 10 years the number of studies concerning the application of AM to medicine has exponentially grown, as evidence of a raising interest that is being translated into clinical application, still without a standardised approach. Clinical implementation challenges arise from the complex informational and productive workflow, that starts from the acquisition of the diagnostic images and ends at patient treatment, involving multiple technologies and different professional skills.

To ensure an orderly flow and ultimately patient safety, we believe that best practices should be implemented from the ideation of the clinical center to the practical routine operations.

The guideline proposes best practices in the set-up and management of a clinical center of AM, in compliance to the standard ISO 13485 and MDR. A risk based approach is used to classify the custom made devices in three classes: phantoms, surgical guides and implants. For each class, we provide criteria for the choice of materials, production and post production equipment, and procedures for quality control and traceability. We propose a process flow for the whole patient management, to identify responsibilities of each professional and steps for production and control. This flow, once managed in the clinical routine, allows complete traceability of the device. For each step, we propose efficiency indicators that are both measurable and significant for the technology assessment. The guideline will allow better communication among professionals, better equipment management and easier and more effective collection of indicators of HTA and of patient outcome.

09. International standards and regulations

MEDICAL EQUIPMENT RADIATION SAFETY COMPLIANCE STUDY AMONG 12 STATES/UT IN INDIA

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Background: Indian Public health standards emphasize on radiation-based diagnostic facilities as essential from Community health center to District hospital. For ensuring radiological safety as well as environmental safety in India, it is mandatory for all the users of x-ray equipment, to obtain license from Atomic Energy Regulatory Board (AERB) for doing any of the diagnostic radiation-related activities.

Objective: The aim is to estimate the percentage AERB compliance of x-ray equipment in Public Health facilities till Secondary care in 12 States/UT in India.

Methods: Comparative analysis of x-ray equipment from state equipment maintenance dashboards and approved equipment for operation from AERB website. Therefore, Percentage of AERB compliance= (number of approved equipment in state/number of total equipment in state) X 100

Result: It is found that out of 12 only 3 states (D&N Haveli, Daman and Diu and Puducherry) are having more than 50% compliance. Andhra Pradesh is having 32% equipment approved for operation from AERB whereas, Telangana 16%, Maharashtra 2%, Arunachal Pradesh 0%, Nagaland 0%, Mizoram 18%, Tripura 0%, Lakshadweep 0%, Puducherry 93%, Andaman and Nicobar Island 12%, Daman and Diu 86% and Dadra and Nagar Haveli 54% equipment are approved for operation in AERB. Analysis to identify compliance in each category of medical device (Fixed X-ray, Mobile X-ray, C-arm, CT scan and Mammography) among States/UTs, revealed flat 50% non-compliance in all category of device. The lowest observed was for Fixed X-ray, 31.6% and highest for Mobile X-ray 51.4%.

Discussion: Potential Hazards of Radiation: It is found that most of the states, AERB compliance is very less than satisfactory level. Doses of ionizing radiation in occupation can escalate the risk of longer-term effects such as cancer.

Legal aspects: AERB has powers to take enforcement actions on health facility having radiation-based diagnostic/therapeutic procedures, for ensuring radiological safety as well as environmental safety. Program Under National Health Mission: In 2017, the Government of India launched AERB compliance program for public health facilities, the Ministry of Health and family welfare provides financial and technical resources to the state govt. for acquiring these goals.

Conclusion: Results shows that patient, worker and environment safety associated with radiation-based medical device needs to improve in India

Keywords: Diagnostics radiology, AERB, Public Health, India

09. International standards and regulations

HEALTH TECHNOLOGY IN ALBANIA

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This work presents health technology developments in Albania. Progress of Ministry of Health and Social Protection (MHSP) of Albania to develop a regulatory framework for health technology in line with current European Union (EU) legislation. The regulation framework aim to ensure safety for the patients and users. Market surveillance process, relatively new, aims to control still chaotic Albanian market. Challenges mainly related to strengthen of the capacities to implement the regulations, development of a strategic action plan for implementation of the regulations, etc. The adoption to the Albanian legislation of the upcoming EU Regulations for medical devices is the next challenge for the experts of MHSP.

09. International standards and regulations

DEVELOPMENT OF A PEER REVIEW PROCESS FOR CLINICAL ENGINEERING SERVICES

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In 1994, the Canadian Medical & Biological Engineering Society (CMBES) passed a motion to develop the “Clinical Engineering Standards of Practice for Canada (CESOP)”. From the outset, these standards were designed to be measurable in a Peer Review process. Any standard that is developed will tend to sit on the shelf unless it is designed to be put in to use. Our strategy was to establish in parallel with the standard, a peer review process, whereby peers from across the country would volunteer to act as surveyors of a service that had requested a peer review.

The first edition of CESOP was published in 1998. It was recognized that for this Standards of Practice document to remain relevant to Canadian Clinical Engineers, it must undergo periodic reviews and updating. The second edition was published in 2007. The third edition, published in 2014 was developed over a period of a year, with contributions from a committee of 13 Engineers and Technologists from across the country. We met on a monthly basis by teleconference, and went through 17 drafts of the document before it was ready for approval by the membership of the Society.

The Peer review process is an essential component of our standard. Peer reviews are voluntary, and the team of surveyors (usually 4 or 5 people) are also volunteers. The benefits of undergoing a peer review are that it provides a roadmap for improvement of the service, and raises the profile of the clinical Engineering Service within the organization. The surveyors interview many key stakeholders, including senior administration.

A service which wishes to have a Peer Review submits an application to the Society, along with some detail on the size and organization of the service. They are then asked to perform a self assessment to see how well they think they conform to CESOP. The Peer Review Committee then assembles a team of surveyors with experience that is relevant to the service to be surveyed. A typical survey can last up to a week, depending on the size of the Health facility, or network of health facilities. The final survey report provides a list of prioritized suggestions for improvement, as well as an assessment of how well the service has met the Standards outlined in CESOP. To date nine peer review surveys have been conducted, and the process has been universally well received.

09. International standards and regulations

SERVICE MODELS OF CLINICAL ENGINEERING

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In Brazil, the increase of competition and customer demand has led healthcare delivery institutions to seek out new standards of quality and safety assurance to their patient. With the diversification of the technology applied to healthcare it becomes necessary the presence of specialized professional to manage it in these organizations.

In 2010, the ordinance RDC 02 was published by ANVISA (National Agency of Sanitary Surveillance) establishing minimum criteria to be followed on the management of applied healthcare technology, in order to ensure traceability, quality, effectiveness, safety and performance, including the planning of physical, material and human resources.

The designated mandatory management plan activities may be in charge of internal or outsourced teams, but no minimum team is defined. Brazil still has few undergraduate courses related to that field, which leads many institutions to seek outsourcing or consultancies to implement the Clinical Engineering (CE) Services. The objective of this study was to analyze the different models of implementation of CE services in order to facilitate the access of institutions to standards more appropriate to their needs, since institutions with different sizes, limited resources and different types of administrations must comply with the same legislation.

This work was developed having EBEM-TECSAÚDE, the largest CE Outsourcing Brazilian Group, as framework. With more than 20 years of experience in the Brazilian market, the group has today more than 130 Continuous Clinical Engineering clients, around 550 employees and over 180.000 managed medical equipment. Observing a database of more than 700 (seven hundred) commercial proposals and existing contracts, 6 (six) different models of engineering services have been identified, varying according to who leads (internal or outsourced) and who performs (internal, mixed or outsourced).

The models also varied with respect to whose responsible for the purchase of parts, accessories and supplies. In public hospitals, due to the long acquisition flows, it’s more usual that EC contracts include the supply of parts. The size of the institution, the park of medical equipment, user profile, administrative and financial flows will define the best EC service model option. We found out that philanthropic entities usually choose mixed models, as they benefited with lower social charges on their payroll.

09. International standards and regulations

GLOBAL HEALTH TECHNOLOGY REGULATION PROJECT, 2019-2021, IFMBE CED

By Grainger P., Health Technology Regulation Project Team I.C.

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Society throughout the world, no matter how simple or complex, has a view or impression of the scope and level of performance associated with an occupation - What people do? And, how they may do it? So globally, occupations or Professions typically operate within a set of rules. These rules are more often expressed in regulation. Regulation "liberally" can be law or legal restrictions, directives, general or technical standards, policies, codes of practice, guidelines or simply written memorandum of understandings, etc depending upon where in the world and the complexity of the society a Clinical Engineer is in. Presently, the global voice of the clinical engineer and its Profession cannot comment on its "Body of Regulation" status. A baseline measurement with respect to the body of regulation from around the world that relates to the clinical engineer has not been gathered yet. The Principal Aim of this Global Health Technology Regulation Project is to collate the existing body of regulation from around the Globe pertaining to the 'Clinical Engineer' and the 'Role of the Clinical Engineer'. This Knowledge will then allow for an initial baseline of such Regulation from each area to be known, understood, studied, analysed and shared by the Profession. Other Aims set are to:

- Develop network and linkages with key regulation organisations or bodies and attend meetings with same where possible –IMDRF for example.
- Catalogue regulation organisations and bodies that develop regulation that relate to the clinical engineer.
- Catalogue Clinical Engineer experts who already contribute to regulation development, their areas of expertise, and their membership bodies.
- Conduct an analysis of the questionnaires received and draft a White Paper detailing analysis and recommendations inclusive of strategic ways forward for the CED ...and the Clinical Engineering Profession with regards to HT Regulation.

09. International standards and regulations

MEDICAL DEVICES IN AFRICA: ETHICAL ASPECTS AND UNIVERSALITY OF NORMS

By Pecchia L., Maccaro A.

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The healthcare management in low and middle income countries (LMICs), such as sub-Saharan Africa, is an issue that summons several matters, from the diffusion and fruition of the modern medicine until its compatibility with the traditional forms of care which, inevitably, recalls the First world in which the biomedical progress is decided.

"Most of the world receives health care in low-resource settings, and yet medical technologies are designed to be used mainly in high resource settings, where designers take for granted basic infrastructures" (Science, 342 (6162), 1055-1057) that support medical device safe and effective use. As a matter of fact according to nowadays still ongoing studies, despite the international regulations foresees that medical devices produced in the so-called "First world" must preserve the same safety level and effectiveness in the transfer to any hospital and/or country, it would seem that the run to elevated standard and minimum requirements that comply with certain criteria such as competitiveness inside the global market, makes those criteria impossible to guarantee in the LMICs, which risks to put in discussion the safety of the patients and the effectiveness of the medical devices in those contexts. The allegedly universality of our standards and regulations ignores objective (climatic and hygienic differences) and subjective cultural factors.

This evidently intensifies the disparities and inequalities among populations, injuring the human dignity and rights. Therefore, my studies are aimed at the construction of a new "hermeneutic heuristic framework" aiming to guide medical device designers in interpreting SSA real needs, and policy-makers in improving the universality of international norms. This framework, founding itself on the connection among knowledge due to the selected angle of bioethics, is able to bring to the public attention the necessity to consider the circumstantial conditions of all the countries to determinate criteria that are authentically universal.

The novelty of the study lies in the possibility of offering a multi-disciplinary and inter-disciplinary assessment in which the different knowledge will cross the data collected to offer a comparative and systematic sociological, moral, bioengineering, medical and juridical evaluation of properties, effects and/or impacts of health technology in a developing country.

09. International standards and regulations

RADIATION AND ENGINEERING SERVICES BY CHAK AS A LICENSED QA/QC TSO

By Rugut J.

Nairobi, Kenya

CHAK RADIATION ENGINEERING AND SAFETY ASSESMENT SERVICES- RSA

TSO's are Vetted, selected and licensed under the RPB Kenya act cap 243. Legal notice 160 of 2010. Provides Radiology facilities' designs, Construction Supervision to ensure adequate shielding (business opportunities).

Quality Assurance and control protocols, and Radiation safety assessment (RSA) to local and international standards. Source, install and maintain radiology related equipment in FBO/Non-profit and some public facilities in Kenya. It also facilitates the calibration and certification of the same.

Full refurbishing and bench testing of medical and radiology equipment mostly of donations category before use. Organize CME's and User training for Members and other in the health and radiation industry profession.

This paper is to demonstrate that a service organization can be started and run in affordable and accessible methods in low resource settings to offer health technology standards and regulations interface.

09. International standards and regulations

THE EU GDPR, MEDICAL DEVICES AND THE DPO DATA PROTECTION OFFICER FUNCTION

By Fitton R.

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Since 21st May 2018 onwards, we have been the DPO function for West Pennine Local Medical Committees ("LMCs") and GPs (General Practitioners). The project was designed to implement the GDPR to improve data processing. The project has run successfully for 12 months. The LMC Provides specialist advice and guidance, helping 83 practices in a rapidly evolving health and social care environment. The LMC Liaises with the British Medical Association and other NHS organisations offering support to practices and GPs. Local Medical Committees (LMCs) are the professional voice of General Practice, made up of practising GPs selected by local GPs. LMCs are bodies recognised in statute which are in place to represent the interests of all local GPs and their teams. Much GP is generated by medical devices.

The project wanted to examine the governance implementation of data flow registration, professional information governance competence, Privacy notices and public information sharing. These Governance practices would be suitable for the data flows from medical devices. The project set out to assess data controllers' knowledge, skills and attitudes within the data sharing fields.

The project set out to create a data base of data controllers and data processors and an annual shared visit and education scheme. The patients, doctors, staff and commissioners would benefit.

The Office visited 66 out of 68 practices across East Manchester. It created and shared a GDPR compliance toolkit with all practices. The office mapped (attached) the practices, federations and clusters of practices and maintained a record of the DPOs across the patch. The administrative bodies of the Oldham Clusters and Gotodoc employ their own DPOs. The Office held meetings with the local Hospital, Commissioning Croup and IT leads. The Office signed of Information Sharing Agreements (ISAs).

The Office attended meetings of the Practice Managers meetings of the Greater Manchester Information Governance Group (GMIGG). The Office is auditing the first years' experience of 68 practices and the results so far are very satisfactory.

10. Education, certification, training

COMPLEMENTARY ACTIVITIES FOR AN INTEGRATIVE CLINICAL ENGINEERING EDUCATION

By Martínez--Licona F.M.

Universidad Autonoma Metropolitana -Electrical Engineering Dept. -National Center for Research in Medical Imaging and Instrumentation -Electrical Engineering Depto. -National Center for Research in Medical Imaging and Instrumentation, Mexico City, Mexico

Biomedical engineering students that focus on clinical engineering (CE) at Universidad Autonoma Metropolitana receive a set of theoretical and practical complementary courses that deal with specific aspects of the field like medical technology management and assessment, health economics, entrepreneurship, and quality control. The theoretical part shows them subjects that are not familiar with and makes them develop a more reflexive perspective of the problems healthcare faces. The practical part addresses the realization of activities and projects that solve specific issues within the hospital. This way, they can immerse themselves into the CE area while getting practical knowledge and experience.

Since the academic program at the university orients the students to present scientific reports with an introduction-method-results-conclusion structure, the complementary courses challenge them to be more analytical and to integrate the context in the development of tasks and course projects. A detected problem that influences the performance of the students is the lack of writing and styling skills since they tend to report following the mentioned structure. Also, there don't know how to manage the copyright and don't pay attention to the instructions given at the beginning of the course regarding these issues. This turns into a problem when they report to the hospital in the same way.

The courses include a set of tasks that forces them to improve their analytical and expression skills. The activities are essays about global health problems, short research projects on the topics of the course where they are asked to integrate them into the different contexts, from local to global, and a course project where they are asked to propose and develop a solution to a problem related to the subject of the course. The emphasis relies on critical analysis, the expression of their criteria, and the use of the evidence-based to express conclusions. In the beginning, the students have not developed a writing style yet. Although they apply the given reference rules, they do not resist copying the original text thinking that the reference solves everything. As the courses advance, some of them begin to improve their skills at writing the reports. This situation is evident in the end. Some can express their own opinions based on the evidence they research; others develop a style of writing that will give them their personality. Overall results are satisfactory.

10. Education, certification, training

GLOBAL DEVELOPMENT IN HEALTH CARE TECHNOLOGY MANAGEMENT EDUCATION

By Khalaf A.

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Disruptive and staggering rate of change within healthcare technology (HT) is causing stress to organisations. The integration of information and communication technology (ICT) into health care system is becoming a reality with significant developments in wearable devices, artificial intelligence (AI) and clinical diagnostic support system (CDSS).

Behind HT acquisition and utilisation are people doing their best. However, many of them are not equipped with academic knowledge or professional experience and training needs to navigate through the complexity and effective utilisation of technology.

Embedded technologies and medical internet of things are game changers that will transform the healthcare services and will pose a great challenge to the system. This requires a new approach to the content of our education program for CE/HTM.

As a result of collective and collaborative efforts involving government, industry partners and HTM practitioners; Durham College took the lead and successfully launched the Honours Bachelor of Health Care Technology Management (BHCTM). First degree of its kind in Canada with the first recruit of 22 students in 2018 who have successfully completed the first year of a 4 years program.

The BHCTM degree addresses an identified need in the health care sector for professionals with a hybrid skill set of expertise in medical technology, life sciences and business practices.

10. Education, certification, training

IFMBE-CED 2017 WORLDWIDE CLINICAL ENGINEERING SURVEY

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One of the mission statements of the Clinical Engineering Division of the International Federation for Medical and Biological Engineering (CED/IFMBE), is to “To define and promote an international body of knowledge, skills and competences on which the profession of clinical engineering can be practiced in various clinical settings”. To be able to accomplish such mission, it is necessary to learn what is the present situation of clinical engineers (CEs) worldwide. Based on a previous world survey, carried out in 2007, an extensive follow up survey was conducted in 2017. Of the total of 574 questionnaires that were sent to countries in 5 continents, 199 completed surveys responses from 35 countries were received. The survey tool included questions that were aimed to better understand clinical engineers’ activities, employment relationship, primary position, percentage of time dedicated to specific activities, knowledge needed to develop the activities, and a few more. During the analysis of responses both qualitative and quantitative measures were deployed, with data analysis processing incorporating assignment of weight factors to present the results more clearly. The results show significant differences in the activities developed by CEs, when aggregated according to the analysed world region, but also show striking similarities regarding the needed set of Knowledge expected for development of such activities. Data analysis also made possible to identify a core of Knowledge that could help as a guide for training CEs and for meeting CE certification requirements. An important observation was the resulting comparison between the survey carried out in 2007 and the present one. The number of CEs with activities such as Risk management as well as IT had grown significantly. As conclusion, the results point to a set of core of activities commonly practiced by CEs all over the world. The needed knowledge for better developing their work varies according to the CE model practiced in the country/region, but there is a set of knowledge that is commonly needed worldwide.

10. Education, certification, training

BIOMEDICAL TRAINING PROGRAM: PLANNING, DESIGNING, IMPLEMENTATION AND IMPACT ASSESSMENT

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Developing countries have large number of non-functional medical equipment. Most faults affecting equipment can be avoided if the user is trained on the operation and maintenance of the equipment. The lack of knowledge on operation and maintenance increases the risk of misuse and damage to equipment. Need of training, identified in early 1980, is still a need in 21st century. It's the effective training program which is the current need of developing countries. A well planned and executed training programs on Operation, Maintenance and Calibration of Biomedical Device has potential to strengthen healthcare delivery system by providing theoretical and practical exposure to users. Planning and designing before implementation of training program plays an important role in its final implementation and assessing the impact of the training program. For an effective training program there are four major sections: Planning, Designing, Implementing and Impact assessment. Planning and designing were based on the participants background. Implementation covered topics on basic electronics; repair, maintenance, operation and calibration of biomedical equipment. Effectiveness was assessed using Kirkpatrick Model and control groups. Data on participant's reaction, performance and feedback was collected using questionnaires, assignments before and after sessions and projects.

Planning and Designing of course material, sessions, mode of delivery, hands-on sessions and projects based on background of participants helped in sharing technical knowledge efficiently. Analysis using Kirkpatrick Model and control groups helped in determining the effectiveness of the program. Participants success stories after three and six months of completion helped in determining the efficacy of the program. Some challenges were faced in Impact assessment section.

10. Education, certification, training

A STUDY ON THE EVOLUTION OF BIOMEDICAL ENGINEERING EDUCATION IN EUROPE

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Health care is technology driven today and biomedical engineering is behind the impressive developments that reshaped medicine during the last 50 years. As it has been stated “Biomedical Engineering is not a subset of modern medicine; modern medicine is the outcome of biomedical engineering”. This pivot role of the BME discipline, creates a continuous pressure to biomedical/clinical engineers, as professionals, to keep a high level of knowledge, skills, attitudes and continuous training in order to face recent demands and the forthcoming challenges in the field. In response to this fact BME education experienced an impressive growth during the last 20 years. The aim of this work was to perform a survey of the BME educational programs offered in Europe, compare them with the situation ten and twenty years ago and identify potential trends and approaches. The results demonstrate the exploding growth of the field with the number of graduate and postgraduate study programs offered, to approximately double every 10 years. According to our findings today across Europe 184 Universities offer 343 BME educational programs, of which 115 are Undergraduate offering BSc degrees, and 229 postgraduate programs, 175 of them offering an MSc degree and 54 PhD degrees. In terms of ratios the percentages are: 33 % for BSc, 51 % for MSc, 16% for PhD respectively. The Clinical engineering programs are still less than ten, but their number is increasing. In conclusion BME education is getting a leading role in engineering studies, almost everywhere in Europe. However, harmonisation of studies is necessary for the advancement of the BME/CE profession. This should come out from a wide acceptance, of a consensus-based agreement on a generic core curriculum, that will facilitate a worldwide opening of the BME job market, through mutual recognition of the competencies acquired.

10. Education, certification, training

IMPROVING GOVERNMENT RESPONSE TO TUBERCULOSIS IN PERU: HEALTH TECHNOLOGY PLANNING & MANAGEMENT HYBRID COURSE TO PERUVIAN NIH PUBLIC HEALTH LABORATORIES NETWORK

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In 2018, Instituto Nacional de Salud (National Institute of Health – NIH) requested a strategic training program aimed at: MoH representatives, NIH National Laboratory Chief, and responsible staff of NIH Laboratories. A ten session Health Technology Planning and Management “hybrid” course was planned for October 2019 which promoted knowledge, methods, approaches and good practices for the strengthening of the quality of use and management of technology in laboratories. Participants of the program included: The Department of TB Prevention and Control of the MoH and the National Institute of Health of the Ministry of Health including 13 regional laboratories in Peru. The program was sponsored by MoH, Global Fund-GF and Partners in Health-PARH. The “hybrid” approach combined live classroom instruction, webinars and online platform-based learning. Topics included were: Planning, Evaluation, Standards, Management, Safety, Budgeting, Maintenance, Laboratory operations and Emergency Preparedness. 25 students developed five needed and practical proposals: “Implementation of digital thermometers for Transport of biological samples for diagnosis of tuberculosis-DIRESA Tacna”; “Construction of 1 Modular Laboratory for the Regional Reference Laboratory of Public Health-Piura”; “Implementation of Laboratory Information System-Netlab-version-2 for the Registry of Tuberculosis Diagnosis in Integrated Health Networks in 7 districts of Lima”; “Maintenance of Mycobacteria Laboratory Equipment-Lambayeque”; “Implementation of Transport System of samples to optimize Tuberculosis Diagnosis’s time-Health Network-Region-Satipo, Junín”. The student feedback stated: the objectives of the course and their expectations were achieved; the course is valuable and pertinent to health technology laboratory quality.

10. Education, certification, training

CALIBRATION; THE KEY DETERMINANT TOOL FOR PROVISION OF QUALITY HEALTHCARE IN LMICS

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Little has been known about calibration in low- and middle-income countries yet it yields effectiveness and efficiency in providing quality to both the patients and health workers. According to statistics for medical equipment failures in LMICs, about 80% of all failure cases are caused by preventable factors which include inadequate maintenance that accounts for 60% of the cases and inappropriate handling of the equipment as well as environmental stress and wear-out account for 20% of the cases. Most of these can be prevented by carrying out appropriate measures based on Standards like calibration. However, majority of health workers and biomedical engineers/technicians perceive calibration to be hard, complicated and expensive, therefore ignoring it. This in turn leaves majority of hospital equipment in Uganda uncalibrated, thus subsidizing the quality of results by the machines.

In 2018, the “Knowledge for Change” project at Uganda Blood transfusion services focused at improving management of medical equipment and strengthening biomedical engineering within the organization and had calibration as one of its aims. During this project, one of the most critical equipment in the blood bank that is the fridges had only 11 out of 31 functioning and this was due to a number of factors inclusive of calibration. Calibration has been ignored by 90% of health facilities in Uganda and this is because of reasons like ignorance of the major role it plays in better equipment functionality. Through the project, we discovered that calibration is not complicated, hard and expensive as majority of people in Uganda perceive it to be. A biomedical engineer just needs to be trained and certified in this field and then own the calibration tools which can be bought on the Ugandan market. Therefore, the aim of this paper is to inform biomedical engineers, clinical engineers, health workers and the entire public the gap and impact of calibration and its major need in LMICs. This also comes as a wakeup call to embrace and invest in calibration as part of us, so as to maintain quality services and standards in the developing health-care world.

10. Education, certification, training

COST EFFECTIVE SCHEME TO CREATE CLINICAL ENGINEERING PROFESSIONALS FOR LOWER-MIDDLE INCOME COUNTRIES

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Clinical Engineering professional has increasingly become a global issue with the rapid growth of medical technology and requires at least one skilled clinical engineer is very essential for per 10,000 populations to ensure safety, quality and cost-effective patient care in terms of quality performance outcomes of medical and surgical equipment. Because, unsafe outcomes of medical and surgical equipment are the main cause for adverse events such as patient injuries and even unnatural patients’ deaths. This statement has been established by many countries. In spite of unending demand of this profession, most of the lower middle-income countries like Bangladesh, Bhutan, Maldives, and Indonesia and so forth are yet unknown with this profession. As a result, the patient risk factors associated with medical and surgical equipment have been increased with the rapid introduce of medical devices. Similarly, cancelation of schedule surgical care and interventional care of patient has increased lower middle-income countries like Bangladesh. Investigation reports have been provided the data of clinical one clinical engineer for per 10,000 populations of 125 countries. From the data, it is found that clinical engineering management methodologies in the public and private hospitals in lower middle-income countries are very negligible and the performance of quality of patient care in this region is very much unpleasant. For example, more than 10, 500 clinical engineering professionals were necessary for the patient care system in Bangladesh and whereas, investigations reports have been presented that only 3 biomedical engineers have been working in the healthcare system of Bangladesh. To solve the problem, we submit a cost-effective scheme to produce clinical engineering professionals. Since this proposed study brings benefits regarding quality, safety and cost-effective care in terms of quality performance outcomes of medical and surgical equipment and thus this work will motivate to healthcare stakeholders to implement our proposal in the patient care system that is yet unknown to healthcare system in lower-middle income countries like Bangladesh. It concludes that this study was necessary.

Keywords: Low-middle income countries, Clinical engineering professionals, hospitals, medical equipment management. Conventionally trained engineering professionals.

10. Education, certification, training

IFMBE/CED RECOGNITION OF CERTIFICATION/REGISTRATION PROGRAMS FOR CLINICAL ENGINEERING PRACTITIONERS

By Wear J.

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The IFMBE/Clinical Engineering Division (IFMBE/CED) has established an International Registration Board (IRB) to recognize organizations that certify or register clinical engineering practitioners (CEPs). The IRB has 8 members appointed by the CED Board and the members are experienced Clinical Engineering Practitioners with several certified or registered. The IRB will maintain a list of recognized organizations that certify or register CEPs but will not maintain a list of the individuals certified/registered. The National Examining Authority (NEA) that performs certification/registration can submit information on their program to the IRB for recognition. This will include detail information on the program and how it goes about certifying or registering individuals. Once recognized a program will have a renewal every three years to assure that it is still an operational program.

Since there are no specific guidelines for programs to certify/register CEPs, the IRB will have to evaluate each NEA submission in detail. The IRB will need to determine that the individuals certified/registered are qualified practicing CEPs and the program is well managed. The NEA must have a set of By-Laws and a Code of Ethics. Certification programs may be based on credentials only or programs based on exams and credentials. Registration programs may be based on credentials including experience. The recommendations are that certification/registration programs should meet individual countries needs and how clinical engineering is practiced in a country. It is not recommended that an engineering degree be required since all clinical engineering practitioners do not have engineering degrees. The IRB will also aid professional groups that are trying to establish certification/registration programs for CEPs.

10. Education, certification, training

FLYING OVER THE HUMP PROJECT EDUCATIONAL PROGRAM FOR CHINESE CLINICAL ENGINEER

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As a leading association in the clinical engineering industry, Clinical engineering society of Chinese Medical Association, is the primary driving force for clinical engineer development. By developing Flying over the hump, the educational program, the association aims to introduce advanced international concepts and practices, to broaden the international perspective, to explore the domestic practice, and to enhance the whole life-cycle management of health technology.

The target audiences of the Flying over the hump are clinical engineer. The core and the main line of Flying the Hump is the whole life cycle management of medical devices, from R&D, acquisition, to obsolesce and replacement. The program works closely with international academic institutions, such as AAMI, ACCE, ECRI, IHE, offering cutting-edge HTM knowledge.

For the better implement of the program, it leverages the power of all stakeholders, government, association, hospital and enterprise. They all play great roles in the program. For example, government provide guidance and supervision, association is the sponsor, hospital manager shares the practice, enterprise provides the academic and financial support. They all made a significant contribution to development of clinical engineering in China.

As a multi-level educational system, flying over the hump is consist of train the trainer program, national-level symposium, regional-level workshop and hospital COE (Center of Excellence). Since the program launched in 2015, Flying over the hump has organized almost 40 events, covered 18 provinces, trained more than 3000 trainees. Based on past result, Flying over the hump will continue enhance the HTM localization through national /regional/hospital COE activities, but also speed up the HTM localization through collecting HTM related information and laying a solid foundation for the HTM guideline.

Keywords: FOH(Flying over the hump), HTM, Medical devices management

10. Education, certification, training

CE/HTM PROFESSIONAL ROLES IN HEALTHCARE DELIVERY: IS IT TIME FOR A RESET?

By **Grimes S.**

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The complexity and sophistication associated with the latest generations of healthcare technology (e.g., robotics, 3D imaging & printing, systems-of-systems, AI/AR technologies, telehealth) are evolving at an exponential rate and quickly outpacing the CE/HTM professional's ability to provide effective support. To address these challenges, a dramatic reset is necessary in the current level of knowledge, skills and abilities (KSA) associated with the technology managers, engineers and engineering technicians that are the principal deliverers of healthcare technology support services. Education, training and credentialing programs for these CE/HTM professionals all must step up, understand that many traditional elements of their programs may no longer be relevant and recognize that they must be proactive in adopting new elements to better identify and prepare these professionals for the support needs associated with new and future healthcare technologies.

This paper more fully describes the support challenges associated with today's and future generations of healthcare technology, the need for an appropriate proportion and number of support professionals, and the evolving nature of expertise these professionals must represent. Finally, the paper recommends steps that various industry stakeholders (e.g., healthcare delivery organizations, medical device manufacturers, educators, professional organizations, regulators and current practitioners) should now be undertaking if they are to have any hope of addressing these challenges.

10. Education, certification, training

HOW TO WRITE CLINICAL ENGINEERING MANUSCRIPT

By **David Y.^[1], Schultz J.^[2]**

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Healthcare technology field is large and growing expected to reach market size of \$595 billion within the next 5 years. Yet, the volume of published manuscripts in the clinical engineering (CE) field is extremely low. What is the reason for this phenomenon: (1) insufficient publications with interest to focus and promote advances in CE field, or (2) lack of knowledge within the CE community on how to scientifically write about their work?

If it is about the first, then the recent establishment of the Global Clinical Engineering Journal (www.GlobalCE.org) should help overcome this barrier. However, if it is due to the second there is a need for proper education and training especially aimed at the young entrants to the CE field.

There are many good reasons to write such as reporting new data, challenging existing one, sharing best practice, or teaching new methodology. All are general subjects but applicable to the CE field. There are also excuses for not writing such as language insufficiency, the "mystery" of format or paper structure, or "my work has nothing to report."

This paper will describe what is a manuscript its classification, purpose and structure of writings. Including the title and abstract to introduction, methods, results, discussion and conclusions. What is the process of accomplishing publication of one's work and will be supported with examples of segments of good paper contrasted with examples of similar sections in need of revisions? The goal is to elevate the ability and desire of young CE to publish about their work and to teach them how to express their opinion about published work done by others.

10. Education, certification, training

DIGITAL EXPERT ABSTRACT

By Kothari A.

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Problem statement: There is an apparent skill gap among medical technicians in the field of radiology impacting the ability to take scans for complex cases leading to poor quality to scans. This is due to:

- Skilled manpower gap with increasing scan load
- Ageing patient population
- Inadequate training and infrastructure gaps
- Inability to keep abreast with latest technological advancements

This has led to:

1. Significant diagnostic capacity issues hampering patient care
2. Reporting for investigations having wait time more than 30 days
3. Inadequate diagnosis affecting clinical outcomes

Hence, in addition to the current ways of preparing radiographers for practice, some innovative approaches are required to address this problem.

Solution: To bridge this ever increasing skill gap in the field of radiology, GE has developed first of its kind digital platform DIGITAL EXPERT. This novel solution allows users:

- To get connected to GE experts to resolve issues during a live scan
- Get trained as per their convenience on different types of devices and protocols
- Develop capability to perform advanced and complex scans with ease
- Better image quality of scans thereby leading to improved diagnostic outcomes

Impact:

In a small period of 4 months,

- Installed in 10+ countries covering 35+ cities
- 270+ hours of training delivered to over 100+ technicians
- 150+ cases handled spanning across CT cardiac acquisition, MR spectrography, MR fecography, Fetal MRI, Whole spine imaging, MR post processing
- Streamline protocols leading to reduce scan times
- Ensuring consumer support from start to end: Patient Preparation, acquisition and post processing
- Supported clients on complex cases encountered during emergency

This has led to:

- Improved productivity and effectiveness
- Bridging expertise gap removing geographical barriers
- Improved cost controls due to faster resolution and reduced service costs
- Better image quality scans leading to improved clinical outcomes
- Training and expert guidance accessibility to remote areas

Conclusion: Digital Expert has potential to improve skill gap leveraging technology and expertise in developed and developing countries. This allows younger technologists and clinicians to learn faster in the field of imaging by improving accessibility and diagnostic confidence leading to better clinical outcomes.

10. Education, certification, training

2019 PAHO HTM CONFERENCE FOR THE CARIBBEAN: NEXT GENERATION ACEW

By Lemgruber A.^[1], Clark T.^[2], Wear J.^[3]

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Leaders from fourteen Caribbean nations attended the Healthcare Technology Management Workshop held in Washington, DC, March 27-29, 2019 sponsored by Pan American Health Organization and the Healthcare Technology Foundation (HTF). The workshop faculty included James, Wear, Jennifer Ott, Michael Lane and Tobey Clark with active participation from Alexandre Lemgruber, PAHO Senior Advisor for Health Technologies. Also, Paul Coss, HTF President, was prominent in an opening video welcome. The WHO Collaborating Center for HTM at the Technical Services Partnership, U. of Vermont coordinated the event which featured more than eight hours of active discussion between participants and faculty, and included topics such as project planning/deployment, medical device cybersecurity, and network integration and support in addition to staple HTM content. The Caribbean Working Group on Health Technology Management was established and will be facilitated by the Community of Practice at the Regional Platform on Access and Innovation for Health Technologies (PRAIS) on the PAHO website. Future activities are focused on Caribbean nations leveraging actions through collaboration amongst participants in the areas of procurement, maintenance, project planning/deployment, medical device cybersecurity, and network integration.

10. Education, certification, training

CLINICAL ENGINEERING SKILL & CURRICULUM FOR 21ST CENTURY WORKFORCE

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Around the globe, clinical engineers exist in – and contribute to – the 21st Century’s healthcare technology environment of volatility, uncertainty, complexity, and ambiguity (VUCA). In this complicated system of systems (SoS) world, Ministries of Health (MoH) and health delivery organizations (HDOs) healthcare badly need solutions. Clinical Engineers have a common goal of harnessing clinical technology to safely produce desired health outcomes, and improve the quality, equity, safety, and cost-effectiveness of care for all populations. The question is: Where will skills in medical devices and Health IT come from to meet these challenges?” WHO, PAHO, and US IoM publications indicate that the standard practice for Biomedical and Clinical Engineering roles in healthcare will include managing and dealing with comprehensive interoperability of personal care device (PCD, including medical and personal uses) with Electronic Health/Medical Records. One workforce forecast from the US Department of Labor predicts that the US will have a workforce of 25,000 biomedical engineers by 2022, and another 60,000 technicians, and 100,000 related IT staff. This project addresses the limited amount of appropriate curriculum and hands-on laboratory resources among university-based Biomedical Engineering (BME) programs to prepare the field to manage medical device interoperability and fully engage our current workforce for the transitions occurring today. This project’s goal is to produce best-practice course topics, syllabi, lab curricula, AND a curated, open-source collection of teaching and research materials. These resources will include information- computer, and systems-sciences and –engineering topics. The resources will be selected and targeted to prepare 21st Century Clinical and Biomedical Engineering graduates for future leadership in Clinical Engineering and related Health Information Management (HIM), Health Information Technology (HIT), and Health Informatics (HI). The goal is to begin organizing teams to design, validate, and pilot these resources within 6-12 months, to fund, assemble and provide open source, curated web resource libraries for CE users by 12-18 months, and to simultaneously create an ongoing self-sustaining governance framework and system of qualified volunteers to manage these libraries.

10. Education, certification, training

MYSTERY OF CROATIAN HEALTH WORKERS HISTORY

By Medvedec M.

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Health workers are people whose job it is to protect and improve the health of their communities, whereas health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity, as defined by the World Health Organization. Both daily routine work and emergencies related to health imply multi -, inter- and trans-disciplinary team work belonging to various scientific and professional fields.

This paper deals with the national legislation on health care, related to definitions, duties and rights of health workers (croat. zdravstveni radnici), as opposed to, literally, health co-workers (croat. zdravstveni suradnici). Such a health workforce classification was introduced in 1993 stating that university degree health workers are limited to those who have health-orientated education gained at the School of Medicine, School of Dental Medicine or Faculty of Pharmacy and Biochemistry. This classification has been changed at the end of 2018 by re-classifying some of the clinical scientists (biomedical engineers, biotechnologists, clinical biologists, clinical psychologists, dieticians and nutritionists, medical physicists, language and speech therapists, etc.) again as health workers, if they participate in diagnostic or therapeutic procedures.

National benefits for regulated health profession are professional acts and chambers, internships with exams, licensing, continuing professional development, residency/specialty trainings with exams, fellowship/sub-specialty trainings with exam, postgraduate university specialist study programs, liability insurance, both public and private sector employability, etc. Furthermore, national concept of job complexity coefficients i.e. basic salary coefficients in public services provides currently only three coefficients (range 1.445-1.571) for university degree health co-workers and ‘newly recognized’ health workers, as opposed to more than 30 coefficients (range 1.659-2,361) for ‘old’ university degree health workers.

It is expected that ministries, together with professional societies, institutions and prominent individuals, will be hard working towards full regulation of all health care professions in the forthcoming years, since equal opportunities of professional education and training, as well as adequate career advancement and job evaluation should be facilitated and provided to all health care professionals in the same way and under the same conditions.

10. Education, certification, training

CLINICAL AND BIOMEDICAL ENGINEER-REQUIREMENTS IN EU

By Ceresa F., Piaggio D., Pecchia L.

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In order to ensure an equal level of safety and effectiveness for European patients, the European Parliament has published new regulations (MDR 2017/745, IVDR 2017/746), which will be enforced in all the European Community countries and all the countries that are part of the European Free Trade Association (EFTA) and the European Economic Area (EEA) (i.e., Norway, Liechtenstein, Iceland, Turkey and Switzerland) within 2020-2022. MDR 2017/745 and IVDR 2017/746 aim at regulating MDs and IVDs, promoting their safe and efficient use and circulation throughout Europe.

However, the regulations are far from being comprehensive and will definitely need revisions and amendments. For example, they do not define the common requirements to work as Clinical or Biomedical Engineers in hospitals throughout Europe. This is of particular importance as having specialized staff who can guarantee maintenance, service and safety of MD is necessary for granting a good level of healthcare.

Therefore, this study aims at comparing the different requirements needed to work as a clinical or biomedical engineer in different Healthcare Systems across EU, through an online questionnaire, which has been developed through a series of focus groups, mock interviews and the final administration to clinical and biomedical engineers from around Europe. A map of such requirements will be identified by collecting key information (e.g., education, professional background, work experience, etc.).

Our pilot study drew on the replies from 6 professionals and helped us check the validity of the questionnaire and refine the layout. This talk will present the results of this study.

Keywords: clinical and biomedical engineering, European healthcare systems

10. Education, certification, training

STUDENT POV: HEALTHCARE TECHNOLOGY MANAGEMENT, A LAYMAN'S DEFINITION

By Metcalfe J.

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The title 'Healthcare Technology Manager' [shortened to 'HCTM' or 'HTM' for snappier verbiage] tends to leave those of us not entrenched in clinical engineering knowledge with brows furrowed. Further, the furrowing almost turns to total brow implosion when you, like myself, explain you're at a Canadian College getting a University-level Bachelor's Degree in Healthcare Technology Management.

Simply, Healthcare Technology Management is a new name given to an amalgamation of disciplines that have existed in a clinical environment since the conception of modern medicine: Life Science, Engineering, and Business. Since then, the necessity of interdisciplinary professionals has become dire as the future of patient care and healthcare infrastructure is increasingly shaped by the shock-waves of accommodating rapid tech innovation. Healthcare Technology Managers are the Healthcare equivalent of a Jack- (or Jill-) of-all-trades in the inevitable "techno-care" environment, equipped to take on leadership positions with a holistic view of all sides of the clinical coin and to critically assess issues (front-line inefficiencies, integration of new technologies, adverse events, regulatory/safety requirements, quality assurance, etc.) with consideration of the goals of all stakeholders.

But, most of all, they are healthcare communicators, able to maintain a healthy and mutually beneficial dialogue with Nurses, Doctors, Biomedical Engineers/Technologists, Administration, Marketing, Political or Regulatory Bodies, Legal Representatives, Procurement Agencies, and Tech Industry. Through interdisciplinary education bolstering an ability to communally liaise, HCTMs close information flow gaps that stagnate and segment the branches of technology acquisition, integration, and life-cycle management, as well as achieving quality patient care.

However, expertise in HCTM does not yet explicitly exist in all healthcare settings despite widespread need as, among other reasons, education required to provide such insight was previously convoluted and, mirroring the healthcare industry itself, segmented. Consequently, sufficiently equipped talent remains sparse and interdisciplinary positions may be filled by talent with myopic specializations in one of healthcare, engineering/technology, or business. With strong healthcare-technology business skills, HCTM roles are extremely malleable to fill a wide range of leadership gaps in the learning, modern healthcare organization.

10. Education, certification, training

INTRODUCTION OF A RE-ENGINEERED CERTIFICATION PROGRAMME FOR CLINICAL ENGINEERS IN IRELAND

By **O'Reilly A., Grainger P., Collier R., Kearney B., Certification Team P.D.C.B.**

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The BEAI has previously utilised a Certification/Registration programme that was developed in 2002. Over time, changes in our national health service, advances in professional development, European Professions Registration requirements, national legislation and regulation of registration schemes in Ireland, and recent IFMBE Guidelines for National Certification Schemes have required the BEAI to re-engineer a Certification Programme that meets with present day requirements.

The Certification Programme is specifically tailored to meet with certain needs specific to Irish Legislation, such as the "Health and Social Care Professions Act 2005". The Certification Programme is only for those employed within the Healthcare System who are practicing Clinical Engineering; i.e. those working in hospitals; acute, community and appropriate voluntary Irish agencies. The scope of the programme also has potential to be expanded to include industry and academia.

The re-engineered Certification Programme has been developed in line with International Best Practice and Recommendations. The IFMBE White Paper for Certification Programmes has been strictly adhered to. The type of Certification Scheme developed is based on "Certification by Credentialing" only. A Continuous Professional Development scheme has also been developed in parallel. This presentation aims to overview the Irish BEAI experience in redeveloping a National Certification Programme in line with IFMBE White Paper Requirements in relation to:

- Global Clinical Engineering Certification Requirements – IFMBE Certification White Paper; and European Professions Registration Legislation applied and harmonised in Ireland
- Rationale for Irish Certification
- Irish Certification Programme by Credentialing
- Entry Criteria – Certification Requirements; Education, Experience, Role, Demonstration of Requisite Knowledge, Position, Attainments, References etc.-
- Application Process – Expression of interest, Final submission, Application Handbook
- Role, structure, governance & independence of the Certification Board (CEPCB)
- Ethics and Codes of Conduct
- Continuous Professional Development requirements and Handbook.
- Irish Roll out and Implementation

10. Education, certification, training

CLINICAL BIOMEDICAL ENGINEERING IN HEALTHCARE ACT E-COUNCELLING

By **Medvedec M.**

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One of the fundamental pillars of modern democracies is a developed civil society that is, inter alia, realized in open dialogue, cooperation and partnership of citizens, civil society organizations, i.e. generally interested public with public and state institutions. Few years ago the Republic of Croatia joined a group of developed European democracies that established clear standards and measures for e-counselling state bodies with the interested public in the procedures of drafting laws, other regulations and acts by using dedicated web-portal.

The aim of this work is to present e-counselling of the most recent Healthcare Act in Croatia. Namely, at the end of October 2018, the Croatian Parliament adopted a new Healthcare Act in which logopedists, medical technologists, biotechnologists and biomedical engineers, biologists in health, clinical psychologists, medical physicists, phoneticians and nutritionists are considered as health workers, if they participate in the diagnostic and therapeutic procedures.

New Healthcare Act consists of 281 articles in total with more than 5000 comments added during the e-counselling. Furthermore, there are about 700 comments in regard to the article 155 alone. A keyword Biomedical Engineer* appears in comments about 400 times, and this profession is the most frequently commented professions. Interestingly, the majority of individuals and organizations were against considering biomedical engineers as health workers, in particular those subjects representing pharmacy and laboratory medicine.

Despite particular and weird interests of various professions in healthcare, clinical biomedical engineering practitioners are finally considered to be health workers by law, after a quarter of century of struggling for recognition, and are expected to experience a new positive momentum towards the full recognition and regulation of the profession within the health system and for the benefit of patients.

10. Education, certification, training

NATIONAL BENCHMARKING OF THE CLINICAL ENGINEER COMPLEMENTING NATIONAL WORKFORCE PLANNING

By **Mcgrath C., O'Reilly A., Grainger P., Collier R., Kearney B.**

BEAI Benchmarking and Workforce Planning Group, Dublin, Ireland

A National Benchmarking and Self Audit of Clinical Engineering practice in Ireland conducted over a two decades period is outlined in this presentation. Benchmarking is a process whereby like groups who carry out similar roles and have similar responsibilities are compared, and an optimum level is agreed. The Clinical Engineers in Ireland have held one National Benchmarking forum over 10 years ago with the second being conducted this year. The survey methodology used over two decades has changed from hosting a Workshop day, conducting many parallel breakout sessions and using paperwork questionnaires to remote online survey distribution and computerised analysis. Twenty years ago, with all questionnaires being in paperwork format only a crude analysis on 3,800 answered questions was undertaken at that time. In the 2000's there were approximately 40 hospitals in Ireland with in-house Clinical Engineering services. 36 Hospitals were represented from both the public and private sectors. Approximately 80 to 90% participation level was achieved. This year a repeat survey has been conducted, using the same questionnaire title subject matter. In preparation over the past 6 months two education forums on the content and understanding of the Questionnaire has been conducted to provide commonality of understanding in order to allow effective completion of the Questionnaire. Now, with 47 hospitals in the public system a 90% + has been achieved. This presentation highlights the results received in both Surveys, develops trends, and provides for a modern day snapshot of Clinical Engineering Workforce information in Ireland. Some of Questionnaire Subject Titles are listed below:

- Name
- Job Title
- Job Purpose
- Education & Training
- Roles and Responsibilities
- Asset Database
- Recruitment, Training, Education & Research
- Safety, Test & Calibration
- Documentation
- Equipment Commissioning and Decommissioning
- Equipment Management
- Knowledge and Skills
- Judgement
- Leadership/Teamwork
- Accountability and Responsibility

Recently analysed trends then allow for the BEAI to discuss National Clinical Engineering Profession Workforce Planning needs, demands, deficits etc with the Irish National Health Service Planning Department in an informed way, and for the benefit of Clinical Engineer Nationally.

10. Education, certification, training

AUSTRALIA'S CLINICAL ENGINEERING DEVELOPMENT WORKSHOP

By **Richards A.**

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Opportunities for people newly entering the field of Clinical Engineering within Australia had traditionally been limited with few employers offering internships for new graduates and much of the specific CE training being provided on the job in the workplace. The National Committee on Clinical Engineering (NCCE) within Engineers Australia (the country's peak professional body for engineering) formed the view over a period of time that a means of not only engaging with but educating and inspiring the next generation of Clinical Engineers was an unmet need. Following a model known to be used by a medical college the NCCE decided to convene a national Clinical Engineering development workshop. This was to be aimed at practitioners at any level of academic qualification who has been in the field nominally for less than 5 years. This workshop has now been convened by Engineers Australia, successfully for over 20 years with it always being fully subscribed. It is now the most sought-after CE training, networking and development opportunity within Australia with a substantial number of attendees subsequently working their way into leadership positions within the profession. It is often described by them as a transformational experience that not only opens their eyes to the depth and breadth of their newly adopted career but also introduces them to both their peers and leaders in the profession that is of great value in their on-going development. Plans are now underway to build on the success of this concept by expanding it internationally.

10. Education, certification, training

THE BIOMEDICAL ENGINEERING INDUSTRY IN ANDALUSIA: A 10-YEAR REVIEW

By Elena M.^[1], Barriga--Rivera A.^[2]

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Andalusia is the most southern region in Spain, well communicated and it is strategically located at the entrance of the Mediterranean Sea. At the same time, it sustains the 3rd regional economy in the country, has one of the lowest wages in Spain, and its unemployment rate exceeds 20%. In this context, the efforts developed to increase the penetration of the biomedical engineering industry, both, in education and employment, is not yet producing a relevant outcome. The incorporation of new degrees such as Health Engineering to the portfolio of some Andalusian universities, has a brief history. In 2008, the Andalusia International Campus of Excellence (Andalucia-Tech) was created with the aim of joining the strengths of two major universities, in the development of new degrees that targeted the growing health technology market.

Although Andalucia-Tech has promoted the attraction of talent and the creation of new technology-based companies, this has not yet enabled the establishment of a factual network of experts in the field of Biomedical Engineering. The analysis of the authors points at several possible factors: financial difficulties to stabilize new hires, the re-use of the existing human resources lacking the required expertise along with a notorious academic inbreeding, and the absence of an established Biomedical Engineering industry able to absorb new graduates. In parallel, other academic initiatives that promote Biomedical Engineering have been carried out at different institutions, including the agglutination of multidisciplinary research groups and the offer of complementary subjects to other undergraduate students. It has to be noted that some tertiary health centres such as the University Hospital Virgen del Rocio can act as research hubs for engineers and physicians.

In the authors' point of view, Biomedical Engineering industry could be better promoted by (1) facilitating world-class academics to be hired and retained, (2) discarding inherited administrative structures that impede the incorporation of emerging technologies, and (3) supporting and endorsing a business fabric able to attract local graduates. In turns, biomedical engineers should become more actively engaged with the community in order to raise social concerns that could eventually persuade policy-makers to contribute to transforming the health technology industry in the region.

10. Education, certification, training

BIOMEDICAL ENGINEERS ROLE AND IMPACT IN THE AMERICAS REGION: MEXICO AND PERU CASES

By Rivas R.^[1], Ayala R.^[2]

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Biomedical Engineering-BE profession's context in Mexico and Peru is presented and analyzed, the contents include the identification of opportunity areas for strengthening the intervention of BE professional in both countries, it also includes approaches aimed to develop improvement actions. The purpose is to contribute to strengthening of the Biomedical Engineering professionals in Mexico and Peru, by proposing the: a) promotion of the knowledge about what Biomedical Engineering is and its value for health, and: b) determination of an annual day to celebrate the career in the country level. The objective is to contribute to the strengthening of opportunities for the development and sustainability of the profession of Biomedical Engineering. How to strengthen the role and impact of Biomedical Engineering? the paper presents areas of opportunity for the Biomedical Engineering professional which are shared by both countries. As surely happens with any profession, the perception of the Biomedical Engineer on what is the main problem for the development of the career in the country is the lack of opportunities and the absence of an adequate remuneration. The authors consider part of the solution is based on building a substantiated and sustained sense of identity that, motivates the professional's self-worth to leave the comfort zone.

10. Education, certification, training

USING A HACKATHON FOR EXPERIENTIAL LEARNING IN EHEALTH/MHEALTH/ TELEHEALTH SYSTEMS DESIGN, SOFTWARE ENGINEERING, & BUSINESS

By Silva R.^[1], Sloane E.^[2]

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Although 'Hackathons' have been used widely to engage students in coding and security challenges, few have focused on the exciting needs and opportunities in healthcare. Typically all digital natives (i.e., they are very comfortable with web, cloud, app, and other tools) few, however, have sufficiently broad education or experience to begin to understand the eHealth/mHealth needs of the growing community of seniors who struggle to live independently with one or more chronic diseases. This project describes an experiential learning approach to eHealth/mHealth concepts for university curriculums. It uses the popular Hackathon method of engaging "digital native" students to enthusiastically immerse themselves in the challenge of designing and developing app-based tools to improve the safety and efficiency of patient care for senior citizens living independently with chronic diseases. This project introduces several novel approaches that engage students, including use of low/no-code app prototyping tools, agile system/software development, and business planning. It is suitable for clinical engineers, systems/software engineers, MIS, health administration, and nursing students.

In conclusion, when students are given easy-to-use app-development tools and simple, valid patient care use cases, they can, in a 1-2 day proctored Hackathon, rapidly and enthusiastically learn how to work together to create workable prototypes that are worthy of business case development and presentation.

10. Education, certification, training

MASTER IN CLINICAL ENGINEERING

By Lago P.

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Is an innovative course, aiming at the formation of professional specialists and managers in the field of Clinical Engineering, able to supervise the Clinical Engineering Departments, organizing and coordinating operational units of clinical engineers and technical staff. The clinical engineer is a professional who supports and promotes the patients' care through the application of technological and management know-how to health care. The innovative side of this emerging professional profile is in the ability to conjugate high level technical-specialist know-how with healthcare know-how, so obtaining a highly necessary contribute to current needs for collaboration with health operators to find solution to clinical and management problems in social and health services (both within hospital services and within distributed home-care structures)

The Master course originates from a close collaboration between the Faculty of Engineering, the Faculty of Medicine of the University of Pavia and Clinical Engineering Department of San Matteo Hospital in Pavia. The goal educates professional and manager specialists in the field of Clinical Engineering that will supervise the Clinical Engineering Services, organizing and coordinating operational units of clinical engineers and technical staff. The main aim is the safe and efficient management of technologies and applications of medical and biological engineering in the clinical environment, to promote and develop healthcare.

The courses are about Hospital and Clinical Information Systems, Medical Instrumentation for Functional Explorations, Bioimaging Instrumentation, Clinical Chemistry Laboratory, Hospital Safety and Prevention, Health Planning, Health Organization; Health Management; Teachers come from the University of Pavia (Faculty of Engineering, Faculty of Medicine, Faculty of Mathematics and Science, Faculty of Economics) but are also Clinical Engineers, Physicians, Health Manager from Industry. The Master goes on Academic Year accounting for 60 ECTS (European credits - Italian CFU) with lessons during week-end, practical training, thesis and auxiliary activities. It prepares clinical engineering specialists able to implement and work on integrated health systems. The recognition process of Clinical Engineer as a Health Professional will stimulate the transformation of Master in Specialization School of Clinical Engineering.

10. Education, certification, training

LOW COST PHYSIOLOGICAL MONITOR WITH WIFI COMMUNICATION

By **Shaikh F., Dave O.**

Student, Biomedical Engineering Technology, Oshawa, Canada

In the era of expanding technology and innovative solutions, research and enthusiasm should be encouraged at the college and university level. A project-based curriculum is the best practice in encouraging young minds to create new technology or upgrade current technologies. As a student for Biomedical Engineering Technology at Durham College, for our capstone project, our team channelled creativity, innovation, and managed time limitations, component restrictions, and financial constraints to build an inexpensive contemporary medical technology. The idea of designing a physiological monitor was to manufacture a valuable tool used by clinical staff on a daily basis for continuous monitoring of the patient. In this project, we focused on creating a low-cost monitor with parameters for measuring ECG and Invasive Arterial Blood Pressure. The viewpoint of the project was to help students understand the importance of standards such as AAMI EC11 and IEC 60601 and to develop a device that follows the best standards of practice. The device was created in stages, the team first designed various circuits and then developed a PCB design which was sent out to create PCB boards. Working from the basics helped us to improve our troubleshooting skills and financial constraints helped us to comprise the project using mostly off the shelf components and find inexpensive alternatives. The later stage was to concentrate on the usability of the device and writing manuals.

With the help of curious and innovative minds we were able to create a device that was inexpensive, easy to use and had numerous features as follows:

- Digital Gain and Zero Calibration
- Ability to capture screenshots
- Ability to change the colour scheme of the display
- Accurate count for Beats per Minute, Systolic, Diastolic and Mean Arterial Pressure
- Internal calibration signal for both ECG and IABP
- Fault indicator and other alarm conditions for bradycardia, tachycardia, and hypertension
- Remote access via the website for a clinical review
- A dedicated test point LED indicator section for an authorized technologist or engineer to troubleshoot other than the individual test points
- Comprehensive Service and Operator manuals

In the future, the device can be further upgraded to include other physiological parameters such as SpO₂, temperature and NIBP.

10. Education, certification, training

SPANISH ELECTROMEDICAL AND CLINIC ENGINEERING IN SPAIN, SEEIC

By **Sanmartín J.D.**

SEEIC, Sevilla, Spain

Undoubtedly, the relevance acquired in the Spanish Health System of concepts and techniques associated with Electromedical Equipment. In our Hospitals, the importance of concepts such as “Comprehensive Patient Safety”, “Quality”, “Protocolization”, “Outsourcing”, etc., has been shown with some delay compared to the rest of the countries of the European Community. Together with the increase of its social importance, it has created a need for Regulation, Training, and Interlocution before the Administration (Health and Judicial in many cases) that the newly created Spanish Society of Electromedicine and Clinical Engineering intends to fill.

The crystallization of this Society of Scientific and Technical nature, is produced as an element of cohesion, communication, representation and training of those people who, from different areas, are dedicated to the management, Security, Development, Manufacture and maintenance of the Electromedical equipment in our state. Whether from Public or Private Healthcare, Manufacturer, Distributor or users, there are elements in common that are necessary to enhance, and in some cases claim, as a highly qualified group, with an increasingly relevant role in Health.

Our objective. To be interlocutors before the public organisms and private entities of the professionals of the sector. Promote the organization and professional standardization of the standards and requirements necessary for the correct application of electromedical equipment. Preparation of protocols, standardization documents and procedures, base of specifications, contracts, etc. Collaborating body for the accreditation of the professionals of the Electromedicine and Clinical Engineering. Promote the promotion and / or collaboration in scientific and technical events and publications. Promote and collaborate in the training of professionals in all fields related to Electromedicine and Clinical Engineering, with the participation and / or organization of accredited courses, conferences, congresses, etc. To become a forum of experts for the requirements made by public bodies or private entities (expert reports, reports, etc.)

10. Education, certification, training

USE OF PLATFORM IN THE TRAINING OF MEDICAL STUDENTS

By **Abreu F.D.L., Silva S.M., Silva A.P., Bissaco M.A., Boschi S.R.M.S., Scardovelli T.A., Martini S.C.**

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INTRODUCTION: The medical error resulting from the evaluation of clinical exams is a delicate and more common problem than one might imagine. Especially when these tests require the interpretation of images because these can arise false positive and negative diagnoses. Several factors influence the diagnosis failure, among them the professional experience, which suggests the importance of training as students and residents. Using technological resources such as computers, projectors, and even the cell phone in the air of didactics in the classroom has become more and more common. The aim of this work is the application of an online platform developed for the training of medical students.

MATERIAL AND METHOD: The platform is available online with tools for uploading images the .PNG, .JPG, .TIF and DICOM formats of various types of images, such as mammography, radi-ography, resonance, and others. After uploading the image, carried out by the teacher/maintainer, it is possible to a) select the area of interest in the image, and then request some information from the student; b) elaborate questionnaires, clinical cases, among other elements of the test. Besides entering the score of each question and the number of questions required and the correct alternative; c) Make the access of the platform to the student through a login and password; d) Accompany student results through reports and graphs. The work presented here consisted of elaborating a questionnaire (test) to apply to students of the medical course on knowledge in chest images. The Ethics Committee approved the research under the number CAAE 74069517.2.0000.5497. Data on the questionnaire and student responses are stored in a database man-agement system.

RESULTS: Thirty-eight students of the imaging discipline took part in the study in the course of medicine at the University of Mogi das Cruzes. They were divided into two groups: experimental and control (GE and GC), 16 students in the GC group and 22 in the GE. Each group answered 10 tests. The competency test was answered by the two groups and their points were analyzed. The GC Group got an average of 7.3 hits while the GE group 8.4. Both groups had difficulties in responding to the tests, being that question 7 was the greatest difficulty of the experimental group and questions 4 and 5 in the control group. No relationship was found between these questions and the applied test.

10. Education, certification, training

LESSONS FROM TEACHING CE IN EGYPT FOR 30 YEARS

By **Tawfik B.**

Department of Biomedical Engineering, Cairo University, Egypt

As I considered my teaching CE in Egypt, I retrieved my exams through the years! I authored every question that reflected course content. I used to change the course annually by 10-30% keeping a fixed core of 20% so in 7 years, the course would be fully renewed. I kept a book of funny answers by students that would serve later to educate future generations and stir strong laughs by mood changing and breaking monotonicity.

I finished both my MSc and PhD in Biomedical Engineering in California in 1984 and 1988. As I returned home, I felt that pure academic work would not serve my country very well because how would Egypt gain from knowing that nonlinearities in mechanics of breathing can be a sign of early onset of emphysema? That led me to CE. Upon my return to the US in 1991 as a Fulbright Fellow, I attended an AAMI conference and it started from there. Back in Egypt, I accepted a part-time job as a chief CE in a private hospital in Cairo, a two-year experience that enriched my teaching greatly.

As I look at the first exam, back in 1991, it was short with the picture of the inside of a cautery. I was testing the ability to recognize circuit components. Later versions would test basic troubleshooting skills. In 1993, I asked about the X-ray calibration. In 1995, teaching Management Information Systems triggering a discussion of CMMS. As the electronics industry leapfrogged, it appeared that a hospital CE would not have the tools to test, troubleshoot, and repair most devices, with the alternative to focus more on lifecycle. So I engaged the students in infection control and the role of sterilization. 1999 was the year of batteries, 2000 beginning to use the term "Healthcare Technology Management". I focused on what constituted a "Core" versus "support" technology, what is "state of the art" versus emerging and visionary technology.

As I was a short-term consultant with WHO-EMRO, I was interested in "Appropriate Technology". I also started talking about "Quality Management Systems" and ISO certification. I touched upon productivity for BMETs and CEs. In the new Millennium, I discussed role of FDA, CE mark, IEC standards, and how to evaluate safety and adequacy of the hospital's electric grid. This led me to the new scope of medical equipment planning and the construction process. Nowadays, I discuss Infection Control Risk Assessment, FMEA, Risk Assessment, and the role of Accreditation in enhancing CE services around hospitals.

11. Artificial Intelligence, Big Data

IMPROVING TB/LYMPHOMA DIFFERENTIATION USING NATURAL LANGUAGE PROCESSING AND ENSEMBLE METHODS

By Pholo M.D., Hamam Y., Khalaf A., Du C.

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Despite global efforts to end tuberculosis (TB), the disease remains the infectious disease with the highest mortality, killing 1.3 million people in 2017. In countries with a high TB burden, the disease is therefore considered as the most probable diagnosis when a patient presents with symptoms such as lymphadenopathy. The patients are therefore given empiric TB treatment even though in 50% of the cases, patients with lymphadenopathy do not have TB. One disease that can be misdiagnosed as TB is lymphoma, since it also share symptoms such as fatigue, fever and night sweats with TB. Additionally, lymphoma and TB can present the same way on radiological images.

This study therefore assessed the performance of a machine learning screening tool in differentiating between the two diseases.

In order to achieve our goal, TB and lymphoma case reports were collected from ScienDirect using web scraping. Each case was converted from free text into a feature vector using Natural Language Processing tools. Various algorithms were then trained and tuned on the created dataset. The best models in terms of accuracy, recall and precision were combined into an ensemble classifier, which was evaluated using test case reports.

A total of 512 lymphoma and 223 TB case reports were retrieved from ScienceDirect. After pre-processing, the entire set contained 13400 features. During the training phase, Logistic Regression performed best in terms of precision (97.6%) and recall (96.7 %) while Support Vector Machines achieved the best accuracy (97.4 %).

Combining these models using majority voting ensemble, we achieved an accuracy of 98.6 % on the test set, with 99 % recall and 99 % precision. This study therefore showed a significantly high performance of the ensemble classifier in terms of classifying TB and lymphoma case reports correctly. Additionally, the high precision and recall indicated that both the number false positives and false negatives were highly minimised. Since proper and timely diagnosis is of the utmost importance, especially in low-income, endemic TB regions, this ensemble classifier can serve as an effective screening support tool.

11. Artificial Intelligence, Big Data

PPADS: PHYSICIAN-PARENT DECISION SUPPORT FOR THE NEONATAL INTENSIVE CARE UNIT (NICU)

By Frize M.^[1], Gilchrist J.^[1], Bariciak E.^[2]

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The development of this artificial intelligence tool is unique as it provides decision support not only for physicians but also for parents of the ill infants. The design includes a Clinical Data Repository (CDR) which collects physiological data from infants in the NICU. PPADS was designed using the International Patient Decision Aids Standards (IPDAS) Collaboration recommendations. It contains a physician module and a parent module, the latter being activated by the infant's physician when requested by a parent. The physicians see a summary of all patients; data can be retrieved for any of the infants. There is also a trending tool enabling physicians to track patients' vital signs and generate alerts for deviations from a defined baseline. Visual tools are more intuitive and user-friendly for physicians. The aim is to identify trends which may precede clinical deterioration in patients.

Parents can submit questions or write notes to their physician about their values, level of understanding, or need for a meeting. The material is presented at a grade eight level to facilitate understanding by parents of various educational backgrounds. Parents can select an option such as "Read more" to understand better the clinical terminology. The parent homepage contains a welcome statement and instructions for easy navigation to five sections: current condition, current treatment, outcome prediction, decision support, and the glossary. The condition module displays the neonate's gestational age, a list of the neonate's current conditions, and any notes from the doctor. Each of the neonate's current conditions is an active link to a glossary definition explaining the condition.

The treatment module displays the neonate's current therapies which are linked to a glossary definition. The outcome prediction module, if activated by the physician, provides parents with real time, machine learning-based risk predictions for mortality displayed in a graphical "speedometer" format and written out in sentence form to help facilitate parent understanding. Alerts are sent to the physician for significant deviations in this risk prediction. An earlier version of the prototype was subjected to usability testing with parents and physicians. The results were very encouraging. The new usability study will be using real time information with both physicians and parents. The system will then be deployed at two hospitals in the Ottawa area.

11. Artificial Intelligence, Big Data

IMAGE ENHANCEMENT AND ARTIFICIAL INTELLIGENCE IN DIGITAL CYTOLOGY: A CHANCE TO INCREASE THE DIAGNOSTIC CONTENT

By Giansanti D.

ISS, ROMA, Italy

Introduction: Digital cytology plays an important role in the e-cytology laboratory and has great potential to modify workflows and optimize workloads. However, digital cytology shows some limitations in healthcare applications: The e-slide still takes up too much memory [1] and some details such as the chromatin needed in oncology for cancer assessment do not yet have adequate resolution. The high memory occupation is due to the need to save different layers for the focus function in the e-slide.

Objective of the study: The study explored the following achievable improvements in this area:

1. "The focus emulation". It might be useful; it could also minimize memory occupation. In fact, the methodology currently used in digital cytology for emulation of fire considers the use of the so-called Z-stack a very expensive solution in terms of memory as it leads to the generation of very large e-slides during digitization. The focus function of a zoom currently requires the creation of 100 layers!
2. "The dynamic 3D simulation" of the nucleus useful to provide increased diagnostic content.
3. "The application of feature recognition methodologies" that could accelerate and improve the cellular classification in the diagnosis of cancer, for example to quickly group nuclei together.

Results: Technological actions were therefore developed to achieve the objectives divided into three distinct phases: (1) improvement of the diagnostic content (for example the 3D simulation) (2) emulation of the focusing function and (3) feature recognition. A procedure based on algorithms developed by means of the Mathematica software has been configured. This procedure was successfully tested on some the snap-shots extracted from the cervico-vaginal e-slides. The evaluation was carried out involving biomedical laboratory technologists and engineers and also using mobile technology.

Conclusions: The methodology could be useful:

1. In the teleconsultation and in the cooperative diagnosis because it could simultaneously allow the improvement of the diagnostic power combined with a decrease in the occupation of the snap-shots memory.
2. In training by lightening the loads of traditional laboratories.

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11. Artificial Intelligence, Big Data

PLATFORM FOR DECISIONS SUPPORT IN THE GENERATION THE INFORMATION FOR THE MANAGEMENT OF MEDICAL DEVICES

By Hernandez B.

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Introduction: Fortunately, in the world each day there are more technology, clinical procedures and new professional profiles that provide solutions in diagnostic, treatment and rehabilitation for a better quality life of the populations. Nevertheless, the medical devices managers need obtain more information and new knowledge for the development of their functions. If we want that they take the best decision and do the best performance in their management it is necessary to provide information reliable, timely and easy to understand. For the Organizations that have the objective of providing information is necessary generated efficient and effective information because they spend time, money and human resources. Fortunately, now we have new technology tools how big data, machine learning, deep learning and artificial intelligence giving us opportunities to identify trends, needs, and statistics that help us to obtain a greater impact in the generation of information.

Objective: Develop a platform for management of information related with the medical devices management that allows takes decisions in the production of the information inside of organizations that help to medical devices managers.

Material and methods: Based on the theoretical methods how inductive-deductive, synthetic analytical, hypothetical-deductive, systemic, dialectical-materialist and empirical methods how observation, measure and computational experimentation. We consider how observation unit the variables of the lifecycle of the management of medical devices and as sample the information generated by the search engines. Also we identify automation algorithms for the acquisition, analysis and visualization of data as well as the identification of relevant data that that provide opportunities to increase benefits to users.

Result: Design of the methodology for the integration of information related with the medical devices management and design and creation of the platform of decisions support in the generation of relevant information.

Conclusions: If a platform can identify the priority information that the medical device managers need, the quality of the information produced for the organizations will be better and they could predict trends as well as find new opportunities for improve the use of the technology.

11. Artificial Intelligence, Big Data

A BIG DATA APPROACH AND DATABASE FOR MANAGING HOSPITAL ASSETS TO PREVENT MEDICAL DESERTS: A CASE STUDY IN MEXICO

By Rivera Leyva J.E., Ochoa Ruiz G., Cruz Ham J., Lopez Juarez C.E., Moreno Alanis C.

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The concentration of highly specialized hospitals and technology in Mexico is due to a reference system provided by the public sector organized into levels of attention where the patient is referenced by a general practitioner to a second level with a specialist. This can lead to the travel of a patient to another city to receive the proper healthcare in a hospital that is often in the capital or the largest cities in Mexico. In consequence there is a high economic burden for the healthcare provider in the public sector and in some cases also for the patient in the private sector and their quality of life due to the missed opportunity of treatment in their vicinity. Highly specialized medical devices are associated to higher levels of care and highly trained technical staff that is found in larger cities in the country where patients are referred often for care in the private or public sector from other regions. Due to the lack of access to some technologies in smaller clinics those regions are left without important diagnostic devices that can contribute to improve the opportunity of treatment and finally on a healthier outcome. The analysis of concentration of medical device technologies in the different regions of the country and larger cities through big data analysis can provide with a comparison between the levels of care offered to a population and the investment opportunities for healthcare improvement and economic growth.

METHODOLOGY: The regions with a lack of medical technology devices can be benefited from the investment from the private or public sector and increase the quality of life of a population and the renewal of technologies to provide safer care and more accurate treatment and diagnosis. The results can benefit the decision-making process and provide with a better scope of the technology access. In this sense, our proposal makes use of a large dataset containing information of various medical assets and equipment in different medical institutions in Mexico. This database is currently under-utilized as contains a great deal of information that could be used for gaining insights and knowledge about the status of the infrastructure and promote prognosis approaches within the governmental bodies, using data science and big data methodologies. The main rationale of this work is to exploit this dataset to train a predictive model, which can help special agencies to carry out investment decisions in a more informed manner.

11. Artificial Intelligence, Big Data

ML & AI, IMAGE CLASSIFICATION AND RECOGNITION FOR THE REMOTE TAKE CHARGE OF PATIENTS AND THE IMPROVING OF MELANOMA EARLY DIAGNOSIS

By Naccari Carlizzi D.^[1], D'Errigo F.^[1], Falcomatà V.^[1], Parlagreco M.^[1], Quattrone A.^[2], Vannuzzi P.^[3], Hassan G.^[3], Marchese M.^[3], Alessandra A.^[3]

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Artificial Intelligence and Big Data change the patient management model to which a path of prevention and early diagnosis of Melanoma is applied. The goal is to focus on the patient, improve the accuracy in the prevention and diagnosis of the territorial hospitals, break down the waiting lists, up to "socialize" and make efficient the services of taking charge by modifying the interaction between Hospital-Territory-Patient. The focus is on "precision" prevention campaigns with the Real World Evidence of Big Data for Preventive, Predictive, Personalized and Participatory digital healthcare. Trained deep neural networks and Deep Learning techniques obtain more accurate precision than dermatologists on Melanoma with the analysis of dermoscopic images and patient's information (age, sex, phototype, residence, familiarity, lifestyles). Trained algorithms improve the diagnostic accuracy and support the doctors. The project therefore aims the creation of a Digital Platform for the remote take charge of patients, the collection of data and images from heterogeneous sources (BD), their processing using AI/DL algorithms to support non-expert doctors and the Hub center. The patient can be taken in charge and enrolled in different innovative ways through: -sending images from a smartphone with a mobile App (which sets the standard criteria for image acquisition and collects information for anamnesis); -acquisition of images with automatic videodermatoscopy (self-service) systems by expanding the Dermatoscopy, a Melanoma diagnostic tool, from the Hub to territory. The data collected on the Platform feed the databases to train the algorithms used to select the patients to be visited and to define the target of the prevention campaign. The patient's report of a suspect neo, validated by algorithm, leads to taking charge directly in the Hub, determining timely treatment and care. The first results of the Project consist in the realization of a proof of concept and its experimentation in the Calabria Region, because the less advanced systems as in Southern Italy have a negative spread of 43.5%, compared to those of the North in the incidence of Melanoma (Airtum 2018). This difference is determined by a greater capacity to prevent the health systems of the Center-North. The proposed system costs much less than the recruitment and training of specialists not present on the market today and allows to reduce the incidence of the disease, treatment costs, mortality and social costs.

11. Artificial Intelligence, Big Data

A SYSTEM FOR HYPOGLYCAEMIA DETECTION USING NON-INVASIVE WEARABLE SENSORS

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Tracking the fluctuations in blood glucose levels is crucial for the health of both healthy individuals and diabetic patients. Tight glucose monitoring reduces the risk of hypoglycaemia or low blood glucose levels, which can result in a series of complications especially in diabetic patients, such as confusion, irritability, seizure and can even be fatal in specific conditions. Over time, repeated episodes of hypoglycaemia can lead to hypoglycaemia unawareness, meaning that the body and brain no longer indicate signs and symptoms that warn of low blood glucose, such as shakiness or irregular heartbeats. Therefore, the development of non-invasive methods that can warn of hypoglycaemia events is highly desirable. Current methods for detecting hypoglycaemia are either invasive tests performed by analysing a drop of blood resulted from a finger prick using a glucometer or minimally-invasive but expensive devices such as continuous glucose monitors. The aim of the project was to develop a prototype of a non-invasive hypoglycaemia alarming system using physiological signals recorded with wearable devices. The proposed system uses a body-worn sensor that records electrocardiography (ECG) and chest actigraphy (3D accelerations). Hypoglycaemia is known to affect the repolarization characteristics of the heart. Therefore, this study presents an efficient, personalized approach that enables nocturnal hypoglycaemia detection using the raw electrocardiogram (ECG) signals recorded with non-invasive, wearable devices. The proposed system was piloted on a cohort of healthy individuals that underwent an experiment in free-living conditions during a period of 14 consecutive days. In this study deep learning (DL) methods were employed for the automatic ECG features learning, that were used for nocturnal hypoglycaemia detection. DL methods facilitate the implementation of the proposed system in real-life as it heavily reduces the need for ECG processing and feature selection. The results of the study showed that nocturnal hypoglycaemia can be detected with an average accuracy of 82%, which showed a great improvement over the results presented in previous studies that were based on the extraction of different ECG parameters. These results show that non-invasive wearable devices used in free-living conditions can be used for hypoglycaemia detection. The work presented here is subject to a **UK Patent Application No. 1912487.4**, Title 'Low glucose level detection', Authors: M. Porumb, L. Pecchia.

Keywords: hypoglycaemia, electrocardiogram, non-invasive wearable sensors, deep learning

11. Artificial Intelligence, Big Data

BONE COMPUTED TOMOGRAPHY IMAGE SEGMENTATION USING BALLON ACTIVE CONTOUR TECHNIQUES

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In today's era, Machine Learning became one of the significant tool for analysis of medical images. Machine learning is a technique which utilized pattern recognition that can be applied to medical images for disease diagnosis. Machine learning algorithm comprise with multiple algorithms in which the system will be able compute the various features of medical image that can have great importance in making the disease diagnosis and prediction of abnormality. Bone medical images like computed tomography (CT), Magnetic resonance imaging (MRI) and positron emission tomography (PET) scan plays crucial role in determination of bone abnormalities like deformation of bone, osteoporosis, bone cancer, bone tumor, bone tuberculosis etc. It is of great significance to medical computer aided diagnosis and treatment. In this work we had done segmentation of pelvic bone CT image. We used Ballon active contour model for segmentation of pelvic bone (CT) images. We had taken bone CT images in DICOM (Digital Imaging and Communications in Medicine) format from online data source Radiology Assistant.nl. Ballon model is very effective in terms of segmenting closed object in closed image. With help of ballon model we can find out the lesion area and lesion volume for our input bone CT image. In this model active contour are in better position to be converge down to its boundary. As bone images have the high contrast value so Ballon method proved to be more accurate in terms of calculating the region of interest. Through Ballon model we got the exact region of interest segmentation of pelvic bone CT image. After segmentation we calculated the Peak Signal to Noise Ratio (PSNR) and Mean Square Error (MSE) values which shows the promising results. The region of interest obtained by this, will allow the medical practitioner for detecting abnormalities of bone at early stage and finding the shortest path to apply invasive procedure from the outer surface of the patient. This will also helpful for doctor to set protocol before they performed surgical intervention.

Keywords: Machine Learning, Computed Tomography, Ballon Model, DICOM

11. Artificial Intelligence, Big Data

MODELING AN AUTOMATIC DIAGNOSIS OF MALARIA BASED ON DIGITAL HOLOGRAPHIC MICROSCOPY

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The objective of this work is to exhibit the strength of object-oriented and agent technologies in handling the automated diagnosis of malaria based on digital holography microscopy. We consider that a web-based medical decision support system requires an ideal intelligent software system that senses a particular situation, analyze it and make a search for the desired goals. Concerning by providing a most accurate and practical malaria diagnostics, and to ensure its effectivity and sustainability, we proposed an approach of problem resolution. We assume that our contributions are mainly a methodology of specifying automation of malaria laboratory diagnosis based virtual slide, and specifically a framework of Semi-Supervised Machine Learning. The framework proposed provides abstraction of activities that allows easy implementation of SSML system.

11. Artificial Intelligence, Big Data

PHCHAT: A CHATBOT MOBILE APPLICATION TO ASSIST PROFESSIONALS IN PRIMARY HEALTH CARE

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Introduction: Primary health care (PHC) is an associated strategy in preventive and curative actions of family and community orientation, composed of doctors, nurses, and community health agents. However, many difficulties with these professionals arose, mainly the difficulty in attendance or the excessive number of attendances, besides insufficient training and lack of integration with the teams. In this context, computational solutions arise with the purpose of assisting or training them before or after a visit to the family. This work deals with the development of a mobile application in a chatbot, called PHChat, for health professionals and a module for analysis of questions, divided into three parts: identification of descriptions or health symptoms, causes generator and solutions on the identified doubt and an issue to generate more knowledge. This tool will aim to assist professionals with low experience or those who have doubts about any subject in the activities carried out in PHC.

Methods: First, it began by the bibliographical survey of correlated works in natural language, decision-making tree, the decision by heuristics and systems based on knowledge. After the results, we explored a development platform for chatbots and the representation of a knowledge base and an application of a real study in PHC for the validation of the results. Finally, interface prototypes will be built according to good programming practices and the use of design patterns.

Results: The literature review on artificial intelligence techniques already mentioned and the similar works on the subject in question was obtained through indexed digital databases. Implementing the chatbot and the analysis module within the IBM Watson platform is underway, as is the search for reports from professionals familiar with PHC focused family services to expand the database. Finally, the interface prototypes developed in Android Studio follow the MVC (Model-View-Control) design pattern.

Conclusions: At the end of the development, it is expected to get a robust chatbot, of natural and simple language through an intelligent interaction for the professional. However, PHChat was not designed as a clinical diagnostic or decision-making tool, but an assistant to assist these health professionals in PHC.

11. Artificial Intelligence, Big Data

RESEARCH ON THE PREDICTION OF THE WHOLE LIFE CYCLE OF HOSPITAL EQUIPMENT UNDER THE BACKGROUND OF BIG DATA OF HEALTH CARE

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The hospital has a lot of medical equipment, such as CT in the radiology department and ventilator in the ICU. There are more than 28,000 professional hospitals and nearly 1 million medical institutions in China, with trillion-level equipment assets. However, there are some pain points in the discrete distribution of equipment in hospitals, such as the lack of efficient management in the maintenance process. All kinds of problems cannot be cured by traditional equipment management software alone. The formal implementation of the measures for the quality supervision and management of the use of medical devices puts forward higher requirements for the management of medical devices. With the increase of medical needs, epidemics and mutation, the innovation of medical technology, the implementation of humanized design of medical equipment, hospital of variability and adaptability in the growing health medical equipment, can provide more health good medical environment for patients, advanced medical technology and medical equipment, increases to a certain extent to meet the growing health consciousness and medical environment demand, but at the same time led to the whole life cycle of hospital equipment efficiency decrease year by year. Medical equipment can be used in a complex and diverse manner, involving a wide range of departments, and operating methods are different. Therefore, it is necessary to study and master the electronic file of equipment in the business department, and the equipment maintenance process can be traced. As for equipment medical workers, they can receive abundant information of equipment repair report in the first time, standardize professional services of equipment, and achieve "high efficiency". For hospital managers, the equipment status of the whole hospital can be known at anytime and anywhere, and the equipment benefits are presented intuitively, which is "easy to manage". It is the foundation of the management of the hospital equipment cloud platform to perfect the analysis of the whole life cycle monitoring data and the mining of association rules. In this regard, based on the big data of health care, this paper carries out the prediction research of the whole life cycle through the hospital equipment management system, and puts forward the corresponding countermeasures, so as to provide inspiration and reference for various hospitals in the equipment management reform stage.

11. Artificial Intelligence, Big Data

BIG DATA ANALYTICS IN PRACTICE - A STRATEGIC APPROACH TO MANAGE THE REGIONAL HEALTHCARE SYSTEM

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The Friuli Venezia Giulia Region has a Health Bigdata with a high historical depth (e.g. patient registry and pathological anatomy since 80's). Thanks to the completeness and quality of the data, and the availability of a dedicated "advance analytics" competence center, have been developed two use cases: (i) location intelligence for predicting the impact of organizational changes on citizens and structures (ii) intelligence analysis and investigation management for the analysis of interregional and international mobility flows.

The scope of the first one is to simulate new organization scenario and predict the impact on citizens and healthcare departments. The location intelligent tool applies advance analytics model to analyses real scenarios considering all the healthcare regional structures and the population using their healthcare services passive in a three-year period. Impact predictions are easily understandable thanks to interactive heat map visualization. The results confirmed knowledge of the territory and hypotheses formulated a priori by sector experts.

The scope of the second one is to identify area of improvement and centres of excellence of the regional health systems analysing and active citizen's mobility in a three-year period. The investigation management tool allows to navigate in visual and interactive mode the mobility phenomena and to detect anomalous situations. The result of the investigation confirmed the presence of some well-known center of excellence and, as well as, the discovering of unknown phenomena.

Both uses cases demonstrated that a huge amount of data with high historical depth can be driver of innovation services and support to new model of governance only if supported by; (i) right tools, (ii) ability to apply advanced analytics models to analyze phenomena and (iii) new specific skills such as big data manger, big data scientist, etc. The intelligent use of BigData provides to policy maker the opportunity to improve the decision making process thanks to innovative tools able to describe and predict social and organization phenomena.

11. Artificial Intelligence, Big Data

AN ADVANCED HYBRID GRAVITATIONAL SEARCH PARTICLE SWARM OPTIMIZATION ALGORITHM FOR SOLVING DNA PROBLEM

By **Khan T.A.**

University of Technology Sydney, Sydney, Australia

In this paper, an amalgam of Advanced Gravitational Search Algorithm (AGSA) and Advanced Particle Swarm Optimization Algorithm (APSO) that is Advanced Hybrid Gravitational Search and Particle Swarm Optimization Algorithm (AHGSPSO) is proposed. The hybrid version contains exploitation abilities of the GSA and social abilities of the PSO. This advanced hybrid version is used on the five benchmark functions to test the effectiveness of the presented method. The results empirically validated that the presented algorithm has extraordinarily resulted in accordance with solution stability and convergence when compared to the advanced versions of the GSA and PSO. In addition, AHGSPSO is used to solve a DNA objective functions that are continuity, similarity, hairpin, and H-measure which are used to evaluate this objective problem. Average and Standard deviation values of the objective functions are used to calculate the efficiency of the presented method. The results obtained are compared with the other approaches and it showed that AHGSPSO gives better performance.

12. Global challenges, sustainable development

GLOBAL CLINICAL ENGINEERING CENTER FOR EXCELLENCE (CFE) PART II: PROCESS AND WORKFLOW

By **Clark D.^[1], Calil S.^[2]**

^[1] Nottingham University Hospitals NUH Trust, NOTTINGHAM, United Kingdom, ^[2] Universidade Estadual de Campinas, Brazil

Situation: There is no platform for connecting top professionals within and across countries for addressing global health technology (HT) challenges. The Global Clinical Engineering (CE) Center for Excellence (CFE) will bring together leading cross-discipline experts to provide healthcare decision-makers with insights to create better, more informed business and clinical outcomes.

Background: In the twelve years since the 2007 WHO HT resolution, there has been progress by Member States. However, these stories could typically be better implemented through engagement with WHO CE-focused collaborating centres, national Ministry of Health HT units and health institutes. With evidence-based knowledge, the response to HT challenges by resource-limited international organizations (public and private), and regional and national agencies, will be positioned more effectively. These entities are not finding timely insights and solutions for global HT questions. This new CFE entity will have the platform to bring together the experts and institutions to address these issues, identified and potentially paid for by Foundations, the World Health Organization (WHO), the World Bank, and/or similar global and regional entities.

Assessment: Sample of current WHO HT outstanding challenges in 2018:

- Access to medical devices for Universal Health Coverage
- Essential Diagnostics List
- Medical devices nomenclature
- Biomedical engineering global resources
- Technical specifications

Recommendations: Recommendations to address this challenge include:

1. Explore concept and feasibility of establishing a Centre for Excellence to address these challenges
2. Establishing a structure and system for managing projects and workflows
3. Initiating pilot projects to test the systems

One of 3 linked papers, we explore here the second recommendation and will illustrate the initial process for the CFE and suggestions for the workflow management.

12. Global challenges, sustainable development

IFMBE CED STUDY ADDRESSING WHO 2019 CHALLENGE #1 IN GLOBAL CE-HTM

By Judd T.

IFMBE CED, Marietta, Georgia

The World Health Organization (WHO) has been facilitating global Health Technology (HT) management improvement initiatives since its 2007 World Health Assembly Resolution². IFMBE³ CED⁴ – in official relationship with WHO – has notably been partnering with WHO's Medical Device Unit since 2009 to address various HT management challenges. This Study will describe CED's 2018-2021 projects that address WHO's 2019 Challenge #1 – issued by Adriana Velazquez, Senior Advisor, WHO Medical Device Unit, in 2019, as follows:

“Present HTM messages to non-HTM community to benefit patients and the general population”

1. Share expertise from CE-HTM in government positions in LMIC
2. Prepare documents and evidence to request funds to Parliamentarians
3. Set the research agenda, based on needs and engage with academics
4. Inform on: Prices, Total Cost of Ownership, investment, Certificate of need
5. Engage Doctors, nurses, quality improvement people to recognize CE-HTM
6. Inform managers: admin financing officers at hospital / state / national level
7. Develop Standards that can be accessible for all
8. Work with industry to provide health impact.
9. Prepare date for international development agencies
10. Collaborate/ engage with national regulatory agencies

CED's 2019 updated website - <https://ced.ifmbe.org/> - has three main target 'customers' or 'stakeholders': (1) the global CE-HTM community; (2) other healthcare leaders and allied professionals, eg, Ministries of Health of LMICs, administrators, managers, etc. and (3) the wider public – who are becoming increasingly interested in how HT are managed.

The Study will demonstrate that CED's current 2018-2021 projects –<https://ced.ifmbe.org/projects.html>– address all aspects of WHO CE-HTM 2019 Challenge #1, benefitting all three Stakeholder groups noted above.

12. Global challenges, sustainable development

THE WEEE EUROPEAN DIRECTIVE 2012/19/UE : WHY IS IT RELEVANT TO MEDICAL EQUIPMENT DONATIONS TO LMIC?

By Blanc Gonnet C., Amrouche M.

HUMATEM (NGO), Les Houches, France

The European directive 2012/19/EU on Waste Electrical and Electronic Equipment (WEEE) aimed at advancing EU's environmental and sustainability agenda. It sets up a regulatory framework to fight against the growing waste stream. This includes provisions to promote the re-use of Electrical and Electronic Equipment (EEE) and to prevent shipment of WEEE particularly to developing countries. Medical devices are one of the ten product categories of EEE covered by the directive. This means that the directive has direct consequences on the re-use and transfer of medical devices and this is the reason why it evidently concerns the aid organizations involved in the distribution of second-hand medical devices to developing countries. However, this regulation is still relatively unknown by cooperation stakeholders. The Annex VI entitled Minimal requirements for shipment is particularly relevant for those stakeholders. It imposes significant obligations such as providing written evidence of the equipment evaluation and testing which has to be securely fixed either on the equipment itself or on the load. Appropriate packaging and stacking is also mandatory to protect the equipment against damage during transportation. Equipment that would not meet these requirements could be re-characterized as waste. Non-compliance with the regulation will lead to sanctions (i.e. enforced return). Those obligations and constraints are expected to prevent the shipment of faulty second-hand medical equipment. Transposed into national law of UE Member States, these regulations can be a powerful tool to foster good practices in the field of medical equipment donations. This is why the members of the European Network Medical Equipment in Low-Income Countries have analyzed the directive and have produced a resource document dedicated to international aid organizations and to the cooperation sector in order to raise awareness and to help them comply with the regulation. This collective publication has been coordinated by the French NGO Humatem and is available online.

12. Global challenges, sustainable development

GLOBAL CFE PART III: PAHO PILOT PROJECT

By Judd T.^[1], Calil S.^[2]

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Situation: There is no platform for connecting top professionals within and across countries for addressing global health technology (HT) challenges. The IFMBE CED Global Clinical Engineering (CE) Center for Excellence (CFE) will bring together leading cross-discipline experts to provide healthcare decision-makers with insights to create better, more informed business and clinical outcomes. In the twelve years since the 2007 World Health Organization (WHO) HT resolution, there has been progress by Member States. However, this could typically be better implemented through engagement with WHO CE-focused collaborating centres, national Ministry of Health (MOH) HT units, and health institutes. With evidence-based knowledge, the response to HT challenges by resource-limited international organizations, and regional and national agencies, will be positioned more effectively. This new CFE entity will have the platform to bring together experts and institutions to address these issues, identified and potentially paid for by Foundations, the World Health Organization (WHO), the World Bank, and/or similar global and regional entities.

Assessment: WHO's Regional Office for the Americas is particularly strong in Health Technologies' work. That said, PAHO has a history of partnering with other regional and global networks to enhance their capacities. A meeting in the 2nd quarter of 2019 with PAHO and CED HT leaders developed the following joint-partnership plan in 2019:

1. Joint Webinars in Summer of 2019 and ongoing through PAHO Health Technology networks
 - Healthcare Transformation through CE-IT
 - Healthcare Management: Communicating Global CE Success Stories to MOH
2. Assessment – CED join RedESTA in Colombia, September
3. III ICEHTMC – Rome PAHO presentation Integration of HTA & HTM initiatives, October
4. Regulation – CED join Regulation Regional Working Group in Cuba, November
5. Management – PAHO-CED conduct Caribbean countries' Training, December
6. Pricing - PAHO developing Communities of Practice this year; CED to help

The CED CFE will facilitate this project; funding for the various efforts to come from PAHO and its various funding sources, as well as CED and potentially the Healthcare Technology Foundation, eg, for faculty costs for on-site HT Management training. The work will also be supported by Latin America & the Caribbean (LA&C) WHO Collaborating Centers, such as University of Vermont, and perhaps others in the Region of the Americas.

12. Global challenges, sustainable development

GLOBAL CLINICAL ENGINEERING CENTER FOR EXCELLENCE (CFE): PART I

By Calil S.^[1], Clark D.^[2], Judd T.^[3]

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^[3] Clinical Engineering Division/IFMBE, Atlanta, United States of America

Situation: There is no platform for connecting top professionals within and across countries for addressing global health technology (HT) challenges. The Global Clinical Engineering (CE) Center for Excellence (CFE) will bring together leading cross-discipline experts to provide healthcare decision-makers with insights to create better, more informed business and clinical outcomes.

Background: In the twelve years since the 2007 WHO HT resolution, there has been progress by Member States. However, these stories could typically be better implemented through engagement with WHO CE-focused collaborating centres, national Ministry of Health HT units and health institutes. With evidence-based knowledge, the response to HT challenges by resource-limited international organizations (public and private), and regional and national agencies, will be positioned more effectively. These entities are not finding timely insights and solutions for global HT questions. This new CFE entity will have the platform to bring together the experts and institutions to address these issues, identified and potentially paid for by Foundations, the World Health Organization (WHO), the World Bank, and/or similar global and regional entities.

Assessment: Sample of current WHO HT outstanding challenges in 2018:

- Access to medical devices for Universal Health Coverage
- Essential Diagnostics List
- Medical devices nomenclature
- Biomedical engineering global resources
- Technical specifications

Recommendations: Recommendations to address this challenge include:

Explore concept and feasibility of establishing a Centre for Excellence to address these challenges

One of 3 linked papers, we explore here the second recommendation and will illustrate the initial process for the CFE and suggestions for the workflow management.

12. Global challenges, sustainable development

IMPLEMENTING SAFER BIRTHS BUNDLE TO IMPROVE INTRAPARTUM CARE

By Linde K., Girnary S., Liland F.

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Background: Births are still not safe. Consequences of labor complications and sub-optimal newborn care are the major reasons that each year, 3 million newborns die and another 2.6 million are stillborn. 99% of these deaths happen in low-middle-income-countries.

Objective: Primary objective was to Improve perinatal outcomes by supporting the prevention, detection and management of birth asphyxia through sustainable, feasible and adaptable training and therapy solutions coupled with Helping Babies Breathe (HBB) training program.

Methods: A research device was developed and introduced at Haydom, a rural, referral hospital in Tanzania. The device collected 1,600 cases of objective data on newborn heartrate and health worker's performance during resuscitation. This information was coupled with data collected by trained observers and video recordings. To address the gaps found in clinical care, innovative training and therapy innovations were developed to support improved care in newborn resuscitation and fetal heart rate monitoring. These innovations included:

- Upright with PEEP: an ergonomic and reusable bag-mask for babies who require respiratory support with positive end-expiratory pressure

- NeoNatalie Live: a smart training manikin that provides feedback on key elements that providers have difficulties with during newborn resuscitation

- NeoBeat: An easy-to-use heart rate meter that provides accurate and continuous display of heart rate and can help guide neonatal resuscitation

- Moyo: A fetal heart rate (FHR) monitor designed for intermittent and prolonged monitoring. It detects abnormal FHR more quickly and easily, enabling appropriate and timely decision-making.

Results: A CUSUM Analysis showed that HBB and Safer Births tools led to 250 extra newborn lives saved over a five-year implementation period in Tanzania. Individual studies showed that Moyo detected abnormal FHR at a much better rate than existing FHRM devices and improved quality of care during labour management. Upright and NeoNatalie Live supported improved care during newborn ventilation. Upright was found to deliver higher tidal volumes which is better for outcomes and was preferred by health care providers over standard resuscitator, and the training manikin increased the competence and confidence of providers during newborn ventilation. **Conclusions:** The HBB and Safer Births bundle of solutions can be used to improve quality of care during FHR monitoring and newborn resuscitation.

12. Global challenges, sustainable development

IFMBE CED STUDY ADDRESSING WHO 2019 CHALLENGE #5: GLOBAL CE-HTM INDICATORS

By Judd T.^[1], Clark T.^[2], Hernandez A.^[1], Painter F.^[3], Velazquez A.^[4]

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The World Health Organization (WHO) has been facilitating global Health Technology Management (HTM) improvement initiatives since its 2007 World Health Assembly Resolution2. IFMBE3 CED4 – in official relationship with WHO – has notably been partnering with WHO's Medical Device Unit since 2009 to address various HT management challenges. This Study will describe CED's efforts to address WHO's 2019 Challenge #5 – issued by Adriana Velazquez, Senior Advisor, WHO Medical Device Unit, in 2019, as follows: WHO HTM Challenge 5: Determine WHO recommendations for biomedical engineering and technician personnel / number of equipment/ type of hospital / beds? Searching evidence from HIC and LMIC, CED will make a recommendation to WHO to consider: <http://apps.who.int/gho/data/view.main.BIOENGHWF8v>

Prior Studies and Definitions: There have been several prior studies regarding CE-HTM indicators, two are captured in References 5-6 below, eg, one from a WHO study in 2009, and another from Tobey Clark in 2015. Rationale of Indicators1 includes the following considerations: (1) relationship between the indicator and process or outcome; (2) benchmark or comparison; (3) definition of each indicator; and (4) results of empirical testing. The Group of indicators5 includes Impact of CE-HTM on: (1) Infrastructure; (2) Service quality; (3) Investment / use of resources; and (4) Clinical outcomes, or quality of care and patient safety – at National, Central and Local Levels. Issues to be defined for WHO recommendations include:

1. Qualifications
2. Activities
3. Profile
4. Functions
5. Indicators
6. Evidence

Results: CED and WHO will work together to gather this information available from several existing sources.

12. Global challenges, sustainable development

BANGLADESH GOVERNMENT ACTION PLAN FOR CERTIFIED CLINICAL ENGINEERS TO ACHIEVE HEALTHCARE SDG BY 2030

By Ashrafuzzaman M.^[1], Zarin F.^[1], Foysal Rabbi M.^[1], Sanjana Binte Hoque P.^[1], Sultana Laboni F.^[1], Monjurul Ahsan S.^[1], Zakir Hossain Patwari M.^[2]

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Bangladesh has recently introduced biomedical engineering in education system. Compared to even neighbour countries, implementation of biomedical engineering in this country is a later one. This leads wide gap in healthcare workforce which supposed to be occupied by CE/CETs. Maintenance and operation of medical devices is heavily reliant on different company's personnel and their technicians, takes a toll on finances allocated for equipping healthcare sector. Absence of the country's own certified CE/CET and solutions related to problems involving medical equipment is a serious challenge. The overall HTM relies on the availability of technicians specific to the equipment from the supplier companies which affects quality control of equipment. With government's recent initiative, only 5790 CET and a mere 203 BME/CE exist in country for a population of 167 million. Further, these CE/CET professionals are yet to certify. Since the population is projected to be 194 million by the year 2030, more than 62,000 BME/CE/CET shall be required to meet the growing demand of healthcare sector. This number will not be achieved if the current rate of BME graduates per year is maintained. In this paper, we propose ways to rapidly overcome the lack of BME/CE/BMET/CETs in the nation. It is evident that drastic measures are required in order for Bangladesh to develop its own self-sufficient workforce consisting of clinical engineers and the equivalent. A dedicated biomedical engineering and technology institute for developing biomedical engineers can fill these gaps immediately. The development of new training module and CE certification system to ensure number of certified BME/CE/CET required by government in its creation of CE/CET posts in the hospitals can only be the potential for achieving the global sustainable development goal in healthcare sector by 2030. We shall achieve the certification of CE/CET professionals with the establishment of an association that is recognized by the IFMBE. The process shall be overseen by trained and senior BME/CE and shall follow the standards provided by IFMBE from the get go. This shall promote regular maintenance cycle for medical equipment, which will implement timely quality control and upgrade the overall HTM. The availability of these services at all 64 districts of the country will enable all regions to gain access to quality healthcare irrespective of the state of the regions development, allowing no compromise with healthcare.

12. Global challenges, sustainable development

AVOIDABLE CHALLENGES FOR MAINTENANCE OF MEDICAL ELECTRON LINEAR ACCELERATORS IN LOW AND MIDDLE INCOME COUNTRIES

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Radiation therapy is an important component for curative and palliative treatment of most cancer. Radiation therapy facilities relies mostly worldwide on electron linear accelerators (linacs) worldwide due to many reasons. However, as cancer incidence increases in many low- and middle-income countries (LMICs), there is a severe shortage in the availability of radiotherapy based on electron linear accelerators, leaving most cancer patients in these countries without any access to potentially life-saving radiotherapy treatment. The main reasons of this situation are inter alia: the initial cost of medical electron linear accelerator, the cost of services on machines and a shortage of trained personnel. The maintenance problems of linear accelerators are the focus of this work. The purpose of this work was to examine the factors that contribute to overcome the challenges relate to maintenance of medical electron accelerators in developing countries especially in many Countries of Africa like Benin. The study was conducted taking into account two aspects. The first concerns the generic model of possible interactions with the accelerator such as linac-patient, linac-environment and linac operating staff. The second aspect concerns the different phases involved in the establishment of radiotherapy facilities including mainly site evaluation, building and linacs design, acceptance test and exploitation. The factors proposed to address the maintenance problem in developing countries are essentially technical factors. The important challenge is to manufacture linacs capable of operating in severe environmental conditions of developing countries. If the proposed factors in this study are addressed, electron linear accelerators can successfully be operated in low- and middle-income countries.

Keywords: Radiation therapy, linac, cancer, maintenance, developing countries.

12. Global challenges, sustainable development

CHALLENGES FACED WITH MEDICAL EQUIPMENT DONATIONS: THE CHILDREN'S HOSPITAL OF EASTERN ONTARIO STORY WITH THE HAITI DIALYSIS PROJECT

By Riggs--Willey A., Heathcote M., Janvier M.A., Asbil M., Greenwood K.

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In 2016, the Children's Hospital of Eastern Ontario (CHEO) replaced their dialysis machines. This equipment was in good condition and had not seen heavy use. Kim Greenwood, Director of Clinical Engineering at CHEO wanted to find a good home for this equipment in another country capable of supporting this technology. He reached out to Marie-Ange Janvier, a clinical engineer in his team who has several contacts with non-profit organizations in Haiti. We were able to identify a government run hospital with OFATMA (Office d'Assurance Accidents du Travail Maladie et Maternité) that could make use of the equipment. This entire process took almost 2 years to complete because of the communication issues with OFATMA and liability concerns at CHEO.

From the start, our team at CHEO realized that training and support would be key to a successful equipment donation. Before the machines were shipped a lot of time was spent preparing the units, completing the PM's and investigating the correct procedures for preserving the machines during the shipping process to keep them sanitized. Our project team met regularly to plan the trip and compile an inventory required items including supplies, spare parts, manuals and test equipment. A large crate full of items required by CHEO's team to operationalize the dialysis machines was prepared in advance of shipment. The team planned for a one week trip to Haiti. One to two days of preparing/rinsing/testing the machines and four to five days of training the staff. Given the political tensions in Haiti it was confirmed that our technologists (Aimee Riggs-Willey and Mark Heathcote) would travel during the first week of January after the holiday season.

Once the team arrived in Haiti, they encountered many challenges. The correct water connections were not available. Not to waste time, our team started with the technical training instead. Once the connectors arrived the team proceeded to rinse the machines and get them ready for use. They were other challenges such as the language barrier. All teaching was done through interpreters. Our team was sent back earlier to their hotel on one occasion after warnings of rioting which delayed work. By the end of the week the staff was able to successfully complete the mission.

This experience taught us that it is just not enough to ship used, complex medical equipment to the developing world. If you are going to donate equipment you must be willing to invest time, money and knowledge as well.

12. Global challenges, sustainable development

WHY I HAVE ALWAYS WANTED TO BE A CLINICAL ENGINEER

By David Y.

Global Clinical Engineering Journal, Houston, United States of America

People dream of becoming best version of themselves and as far as I can remember I too wanted to make the world a better place. Generality turned specific after I walked hospital's corridors and saw patients in needs & medical equipment in disrepair. Many professions can be practiced, and many more paths will lead there. But knowledge of which profession matches where you can make good, have an impact and satisfaction will make the decision obvious. It was always clear to me.

Person may spend career in field of practice because of choices made, aspiration followed, chance or failing in another. Clinical Engineering (CE) is not ubiquitous nor known field, thus chances are lower that choice or aspiration will be infatuated causes. I have been working in variety of jobs ranging from design of space orbiters to development of smart projectiles, even served in armed forces. Before attending college, I worked as electronic technician and audio players repairman. All the jobs fitted into the stage of life I was in at the time. But I never anticipated the rewards experienced from life-long engagement in the CE practice. Practice that turns work into mission that diligently seeks fulfilment of obligations to support better patients' outcomes, safer more affordable & appropriate solutions. Offer opportunities to become member of team of care providers where dependence on technology to collect, treat and make critical decisions is growing. Dependence that your family's health outcomes may someday be impacted by. Knowledge of making a difference especially for patients not able to fend for themselves and finding solutions to technical problems by applying expertise and leadership are unique to CE as is the satisfaction from achieving that. We need to identify gaps and grow professional capacity to address them, reaching affordable and effective technological solutions to clinical challenges. It is our obligation as CE community to raise awareness of this field and of its rewards. Obligation to volunteer, serve on committees/task forces in multidisciplinary fields. When we subscribe to this mission we will educate effectively, practice ethically, lead successfully, pursue life-long training, interact smartly, focus on health/wellness outcomes, and do no harm. Finally, achieving consensus on the common traits and credentials that best contribute to successful CE career will magnify the echo I have always wanted to be a Clinical Engineer and I know why.

12. Global challenges, sustainable development

IMPROVING SYSTEMS FOR SAFE OXYGEN DELIVERY AND OTHER MNCH DEVICES

By Gupta K.

PATH, New Delhi, India

Oxygen therapy is one of the 30 most effective interventions for preventing deaths from a broad range of health complications that disproportionately affect vulnerable populations, in particular, newborns, pregnant women, and children (WHO, 2012). Hypoxemia affects millions of people each year suffering from a range of common conditions—including newborn conditions, obstetric emergencies, and childhood pneumonia. At least 13 percent of children admitted to a hospital with severe pneumonia have hypoxemia, corresponding to approximately 1.5 to 2.7 million children requiring oxygen therapy for hypoxemic pneumonia each year (Subhi et. al., 2009). Furthermore, global estimates suggest that one in five sick newborns has hypoxemia upon admission to a hospital (Graham et. al., 2017), and 15 percent of all pregnant women develop a potentially life-threatening complication, many of whom may require treatment with oxygen therapy (Holmer et. al., 2015).

The current scope of the project focuses on three complementary objectives:

1. demonstrate approaches and provide a toolkit of resources built alongside stakeholders in each focus country (India, Indonesia, Kenya, Malawi, Senegal and Ethiopia)
2. contribute technical expertise and a toolkit of resources to build engagement and capacity in oxygen work with global partners (WHO, UNICEF, USAID, GFF)
3. create an analytical framework to prioritize opportunities for scaling reliable access to safe oxygen to maximize health impact and determine how a similar analytical approach can be leveraged for other MNCH medical devices.

The primary dissemination piece will be a toolkit of generalizable resources from across the six focus countries. All resources proposed in the project will be shared with UNICEF and WHO for inclusion in their decision-support tool. The long-term vision of this work is to contribute to a sustainable market and best practices for oxygen delivery technologies and pulse oximeters in LMIC. This scope will focus on improving the supporting systems—budgeting, procurement, contracting, supply chain, maintenance, and asset management—surrounding medical devices to increase the reliability of access to safe oxygen delivery. Introduction of the toolkit resources to improve these systems will be shared with country stakeholders as well as global partners for broader dissemination and use. These system changes may also inform broader health system improvements to expand access to essential medical devices.

12. Global challenges, sustainable development

EFFECTIVE CE HEALTH POLICY INNOVATION, LEADERSHIP, STRATEGY, AND ACTION PLAN TO OVERCOME GLOBAL HEALTHCARE DISPARITIES

By Sloane E.

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Clinical Engineers have designed many innovations, such as mobile and remote patient monitoring (mHealth, telehealth), but the deployment of technologies have stalled around the globe.

The underlying issue is no longer technology; eg, USA FDA-approved smartphone apps and adapters exist for PO₂, BP, ECG, Weight, Respiration, etc, but they are not being deployed beyond pilot project. The elephant in the room: diffusion of remote monitoring will illuminate the disparities of care for low-income, low educated, marginalized populations, and costs could skyrocket.

Virtually every Ministry of Health around the globe has initiated telehealth pilot projects, but hardly any have scaled into sustainable components of everyday health and wellness management. Clinical Engineers have an urgent opportunity, need, and responsibility to access and influence local, regional, and national policies that are blocking effective adoption of telehealth technologies. The Plenary discussion will focus on development of one or more high-priority Action Plans to analyse and overcome the barriers which are preventing or delaying technologies that can reduce inequities of access to appropriate care. Tentative proposed work plan:

- identification of leadership, working groups, and committees, as appropriate, to develop and publish an Action Plan within the coming 12 months.
- Agile Methodology Workplan: 1-month sprints
 - Initial report: immediate distribution of Plenary notes
 - Monthly teleconference meetings by subcommittees with immediate publication of meeting notes and action items
 - Interim Progress Report to CED and committee members at month 6.
 - Monthly teleconference meetings
 - Final Report and Recommendations at month 12.

12. Global challenges, sustainable development

IMPROVING THE MANAGEMENT OF MEDICAL EQUIPMENT IN HEALTH CARE FACILITIES

By **Abazi N.**

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Based on the statistics, the majority of cases of failures of medical equipment in developing countries are a consequence of poor maintenance. Public hospitals in Kosovo are faced with challenges in the prevention of failures of medical equipment and the proper maintenance. 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 influence directly the availability and the access of health care services which involve the availability of medical equipment. Solution to the aforementioned issues. In order to implement a system of effective health care management, their management should be integrated in a system of monitoring from the distance, in real time, from the specific 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 to have real time alarms of failures, maintenance schedules and the due dates for preventive measures.

This monitoring system will enable the following:

- Reduction of downtime.
- Reduction of Costs.
- Monitoring active alarm.
- Alarms identification and control.
- Controlling the contractor's work.
- Preserving through logs the access and work history.
- Automatic generation of reports.
- Online schedule of maintenance and preventive measures.

The specific designated Department of the Ministry of Health will have in its monitoring system all the medical equipment in health care facilities. New procedures will be put in place for regular preventive measures in all public hospitals of the country. The procedures and protocols for intervention will be created for urgent situation, when an alarm has been receiving regarding a medical equipment. The specific department for monitoring will be responsible for every alarm and to fix the failures of medical equipment. The system will create a work order, with an accurate description of the defect for clinical engineers or the contracted company, which will be responsible to fix the functioning of the medical equipment in a timely manner. These measures will increase the clinical effectiveness, the clinical utility and will improve the quality and access of health care services, which are depended on health care technology.

12. Global challenges, sustainable development

CLINICAL ENGINEERING IN MOZAMBIQUE

By **Forjaz Secca M.^[1], Sumalgy A.^[2]**

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After independence Mozambique was faced with a difficult situation concerning its health services, because a lot of qualified people left the country. Therefore, there was a need to restart the whole medical equipment strategy in the health services and consequently its clinical engineering support.

In this project we aim to give a picture of the present status of Clinical Engineering in Mozambique, including the current situation of clinical engineers working in health facilities and how they were trained, and a description of the processes of acquisition, management and maintenance of medical equipment in the health services. We also present a short history of the development of Clinical Engineering in the country.

Clinical engineering still has a long way to go in terms of implantation and impact in Mozambique, and based on the results of this project we propose directions for the future development of the field in Mozambique and we believe this study will be very useful to all the present clinical engineers in the country and hopefully will help policy makers to shape a better futures for us.

12. Global challenges, sustainable development

A DEVICE FOR TRACKING THE PHOTOPUPILLARY REFLEX VIA SMARTPHONE IN LMICS

By **Piaggio D., Pecchia L.**

University of Warwick, Coventry, United Kingdom

The United Nations defined 17 Sustainable Development Goals (SDGs) in the 2030 Agenda for Sustainable Development. The Goal number 3, Good health and well-being, has 13 specific targets, one of which is target SDG3.6, i.e., “halve the number of global deaths and injuries from road traffic accidents by 2020”. In fact, Africa accounts for 10% of global deaths caused by vehicular injuries, though it owns less than 5% of the motor vehicles in the world. A timely diagnosis of brain trauma, crucial to avoid vehicular accident severe injuries, can be done by testing the photopupillary reflex, i.e., the reaction of the pupil to a flash of light. As of now, the main device for the assessment of this reflex is the penlight, which requires specialised doctors and extensive training to be used reliably. Alternatively, digital pupilometers have been developed to help users assess this reflex. Unfortunately, Africa lacks specialized personnel and digital pupilometers are rather expensive.

Our study aimed at designing a digital pupilometer using only Android smartphones and little or no accessories, which could be used by lay-users for detecting brain trauma, utilizing image processing and artificial intelligence. Moreover, we aimed at validating the algorithms with manual annotated video frames recording the pupil while shrinking in reaction to the light (i.e., benchmark) and validating the performance of our system against a commercial infrared (IR) pupilometer.

The design was informed by the results of a SWOT analysis run during 5 field studies in Sub-Saharan Africa (SSA). Such results are also presented, as can be informative for other works in LMICs. In fact, there is a gap in the literature regarding the criteria to be followed during the design of medical devices resilient to low-resource settings. While most literature focused on the lack of resources, our SWOT highlighted that there are other factors hindering the efficacy and the safety of medical devices in LMICs: the harsh African conditions; absence or poor supply chain; no minimum requirements for hospitals; lack of clinical engineering and specialized doctors. As a consequence, a huge part of donated medical devices is not working or have a limited lifespan. This talk will present the application of our findings to the design of the proposed pupilometer, fostering the adoption of a consistent framework for a resilient design (or reconditioning) for Africa, beyond the mere economic considerations.

12. Global challenges, sustainable development

HYPERTENSION DIAGNOSIS AND MANAGEMENT IN AFRICA USING MOBILE PHONES: A SCOPING REVIEW

By **Oronti I.B., Pecchia L.**

The University of Warwick, Coventry, United Kingdom

The United Nations (UN) and World Health Organization (WHO) identified 17 Sustainable Development Goals. Goal number 3 aims at safeguarding healthy lives and promoting wellbeing in all populations. This goal is further articulated into 13 specific targets. Target 3.4 aims to reduce premature mortality from non-communicable diseases (NCDs) by one third. Epidemiological data presented by the WHO show that in 2016, out of a total 57 million deaths worldwide, approximately 41 million (71%) deaths occurred due to NCDs, with 78% of such deaths occurring in low- and middle-income countries (LMICs). Unfortunately, Africa now faces an impending NCD epidemic because most countries fall within the low to lower-middle income groups.

An emerging trend in the management of NCDs is the use of mobile technologies and tools (mHealth). One of the more popular devices employed for mHealth strategies is the mobile phone. Over 75% of the world’s mobile phone subscriptions reside in LMICs, hence making the mobile phone particularly relevant to mHealth deployment in Africa. Majority of investigations on NCDs agree that the leading risk factor worldwide attributable to death is hypertension. This study is thus aimed at determining the scope of the bulk of literature available on hypertension diagnosis and management in Africa, with particular emphasis on interventions based on the use of smartphones.

A systematic search was performed returning 30 relevant publications. Studies were included if: they were carried out in African countries, or a pool of LMICs including at least one African country; focused on hypertension, or comorbidities that included hypertension; and using smartphones. Only 18 paper describing 13 different health interventions met the inclusion criteria. Interventions report the feasibility and potential of carrying out mHealth interventions in Africa in terms of acceptability and effectiveness. The bulk of the evidence considered overwhelmingly show that SMS technology is yet the most used medium for executing interventions in Africa. Applicability in all of African is however doubtful due to low levels of literacy. Consequently, the need to define novel ways of providing effective and low-cost monitoring, diagnosis and management of NCDs which can yet deliver superior results is clear. Results from this study will inform my project design criteria and also serve as information to policy designers and other researchers involved in designing interventions.

12. Global challenges, sustainable development

UPCOMING CE/HTM CHALLENGES ON SMART AND INTERNET OF MEDICAL THINGS (IOMT) DEVICES

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Trends indicate a US\$ 130 Billion market for Global Telemedicine and about US\$ 77.5 Billion on Internet of Medical Things (IoT) devices connected for 2025. Those devices, which represent new technologies often used in non-clinical environments by non-clinicians, will require a different type of technical support. Due to such big number of devices in use, all stakeholders (e.g., medical device manufacturers, owner-operators, clinicians, CE/HTM/IT professionals and their associations, regulators, ministries of health) are challenged to develop strategies and tools to ensure the appropriate:

- selection and acquisition
- use
- technical support (monitoring, maintenance)
- data security
- asset management
- best practices, standards, regulations
- disposal of devices

Clinical Engineers and Healthcare Technology Managers and other stakeholders have a great opportunity to shape new approaches to keeping devices working safely and effectively.

Compared with traditional medical equipment, the growing number of increasingly complex and integrated devices and systems will require major changes to existing clinical engineering, healthcare technologies management (CE/HTM) and their educational and training programs. New support paradigms will be required.

This intent of this paper is to stimulating new thinking and discussions about how industry can successfully face these challenges.

12. Global challenges, sustainable development

HEALTH TECHNOLOGY MAINTENANCE IN COMPLEX SETTINGS: LESSONS LEARNT FROM THREE HOSPITALS IN HAITI

By Kouemo Tchokodjeu E.

Unops, Port au Prince, Haiti

Haiti is a developing country where the local context is characterized by gaps of capacity in terms of logistics, security, technical services, Technical skills, funds availability; governance structure all aspects that deeply affect the introduction of new maintenance methodologies in the public system. This project outlines the lessons learnt from implementing maintenance and technical sustainability program in complex settings. Financed by the Brazilian Ministry of Health, UNOPS Haiti was appointed by UNDP Brazil in 2011 to build and equip 3 community hospitals (HCR) in the capital city. In collaboration with the Haitian Ministry of Health (MSPP), a second phase project Jun 2015 – Dec 2020 was financed with the scope to set up a roadmap for the introduction and implementation of proper health facility management policies and practices, which are essential to guarantee appropriate operations and maintenance of installations and equipment and their sustainability.

Goals of the project and final users that will benefit:

- Objective 1 Operations: To support the hospitals in terms of technology maintenance, healthcare offer upgrading (set up of new medical units)
- Objective 2 Capacity Building : To Train the Hospitals staff to the proper use and maintenance of Health technologies,
- Objectives 3 HTM: To Train the Hospital staff in activities related to the procurement of consumables, goods and services
- Objectifs 4 Phase Out: Operations Cost Reduction strategies, Ministry and Hospital Staff Empowerment Strategy, Project's activities progressive transfer to the Hospital/Ministry. Definition and Implementation of activities insuring the sustainability of the 3 hospitals after the project end.

LESSONS LEARNT

1. Deepen the Knowledge of the local Context (Market, Education, Social...) and the Needs:
 - Adaptation of standards and procedures to the local context.
 - Appropriateness of Medical Technologies, Infrastructures, electro mechanic plants
2. Collaboration & Reinforcement of governance structure (Organigram, Job Description, RACI chart)
3. Capacity Building plan for Hospital /Ministry Staff (Empowerment of Users and Future Trainers)
4. Motivation of the Hospital Staff (Staff Retention Strategy)
5. Reduction of Operation and Maintenance Cost (Renewable energy, Simplification of plants, Use of local materials)
6. Phase Out Strategy: Define a clear progressive project Phase Out Strategy involving the ALL stakeholders

12. Global challenges, sustainable development

THE PROMISING AND POTENTIAL ROLE OF BIOMEDICAL ENGINEERING : THE WEWOMENGINEERS COMMUNITY EXPERIENCE FOR RAISING AWARENESS IN THE BIOMEDICAL FIELD

By Appendino M.

WWE, Torino, Italy

The BioMedical Engineering (BME) is a worldwide interesting field finding applications in many environments, from research to the direct clinical interaction with patients. Gender segregation in engineering fields, traditionally regarded as masculine, is much more pronounced in advanced industrialized countries. Currently we are moving from the concept of gender equity to gender equality. Gender Equity is distinct and different from Gender Equality, referring that different gender, behaviour, aspirations and needs of women and men are indifferently considered, valued, and equally favoured (ILO, 2000). In the world, many programs operate for improving careers and reducing diversity in engineering fields. WeWomEngineers (WWE) born to have a direct association with women, especially by social media to reduce distances, and works across 4 focuses: capacity building, mentoring, awareness of talent, inclusiveness. It is a real community, searching a balance between equity and equality. WWE is the first European Community that intercepted 70 stories from girls, being still far from the perspective of equal opportunities and still often containing specific dynamics, called invisible barriers. WWE is changing the focus by main requests of those who needed explanations on future opportunities and risks, involving 20 biomedical engineers (internal team), mostly women, both students and workers, PhD Students, researchers and professionals in the field of medical devices to take part in events, communications and writing from biomedical areas. WWE took part in 4 international conferences, 23 events in Italy inspiring dozens of young biomedical engineers (extra-WWE), and in a career day (MEDTECHDAY), promoted by Jobadvisor, which involved almost 400 others. WWE is also actively working in an international program to motivate girls and male by WWE's biomedical stories, and in the National Movement InclusionDonna, concerning priority issues to increase female employment and representation. WWE dreams to develop a network including the Women Committee IFMBE, increasing the presence of biomedical women in the workplaces, in according to the fifth ONU Global Goals (Gender Equality) and supporting in the recognition not only legal but real of the role of biomedical engineers. Thus, we recognize the need to sensitize the biomedical relationships, reducing any type of invisible barrier by mentoring young people for identification of a specific biomedical role for both genders.

12. Global challenges, sustainable development

POLICY ON TECHNOLOGICAL INNOVATION AND SUSTAINABLE DEVELOPMENT

By Toscas F.

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The construction of a universal health system, which meets the population's health demand, presupposes the growth of the country's health production base, which includes the creation of an endogenous dynamics of health innovation. In this perspective, the Ministry of Health has made efforts to consolidate public policy instruments capable of creating a favorable environment for productive, technological and innovation development. These instruments include the launch of the National Policy on Technological Innovation in Health (PNITS) which aims to promote the SUS's technological and economic sustainability, with the definition of structural conditions to increase the productive capacity and innovation of the country, with a view to contributing to the expansion of access to health; to encourage innovation and scientific and technological research in the productive environment, with a view to technological training, to reach the technological autonomy and to the development of the national and regional productive system in the health area; reduce the country's external dependence and productive and technological vulnerability in relation to strategic products and services for the SUS; and establish the criteria for the use of state purchasing power in order to rationalize health spending and induce scientific, technological and industrial development. PNITS has crucial elements for sustainable development aligned with Agenda 2030, Goal 3: Health and Welfare (ensure a healthy life and promote well-being for all, at all ages); and goal 9: Industry, Innovation and Infrastructure (build resilient infrastructures, promote inclusive and sustainable industrialization and foster innovation). It should be noted that in 2018, WHO member countries approved the World Health Assembly Resolution WHA 71.7, which deals with Digital Health considering its potential for achieving the Sustainable Development Goals. The resolution highlights the potential of these technologies as instruments to support the integrality and broadening of access to health services. The objectives of PNITS can contribute to the expansion of productive capacity and new solutions to global health problems, with the health sector being one of the structuring vectors in the global mobilization of development for social welfare and wealth generation, combining the social and citizenship dimension with the economic dimension and innovation.

12. Global challenges, sustainable development

UBORA: EURO-AFRICAN OPEN BIOMEDICAL ENGINEERING E-INFRASTRUCTURE

By Di Pietro L.^[1], Ravizza A.^[2], Diaz Lanta A.^[3], De Maria C.^[1], Ahluwalia A.^[1]

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Medical technology is one of the pillars of an effective healthcare system, as recognized by the United Nations (UN) in the 2030 Agenda for Sustainable Development Goals (SDGs). The overall high costs of medical devices (MDs) can be linked to their long life-cycle (design, prototyping, manufacturing, labelling and packaging, provision, installation, operation, maintenance, repair and disposal), during which each step is strictly normed, to guarantee their efficacy and the safety of patients, healthcare providers and bystanders. These costs create a barrier for the accessibility of medical technologies in particular for developing countries where more than 80% of medical equipment is donated, but only 10-30% of these become operational, given the high operating cost, the lack of personnel and the frequent failures due to harsh environment, extreme climate conditions, humidity, dust and power instability.

Developing sustainable medical technologies to make healthcare affordable to a larger population, and thus reducing global inequalities, can only be performed taking into account the cultural and socio-economic context in which these will be applied. Compared to the traditional methods of design, the open-source (OS) and collaborative approach to design MDs can be a possible alternative offering a unique combination of advantages, such as increasing safety, security, reliability and reducing costs.

To this end, a new e-infrastructure, UBORA ("excellence" in Swahili), available at <https://platform.ubora-biomedical.org/>, which fuses the OS concepts with the European safety and efficacy requirements, has recently been established.

UBORA (H2020 GA731053) provides a structured framework, inspired by the ISO 13485:2016 and MDR 2017/745, for the identification of needs, risk class, relevant standards, management of computer aided modelling files and preparation of the pre-production device dossier. The entire process is supervised by expert mentors to ensure that safety criteria are met during the design process. The e-infrastructure is organized in 3 main sections devoted to the development of OSMDs (Clinical needs, Project management, Resource section), a part for the creation and strengthening of a Community of developers, mentors and stakeholders, and a series of tools for the management of the e-infrastructure. In a nutshell, the final aim is to promote well-being for all, increasing access to MDs and moving towards health equity in accordance with the SDGs.

12. Global challenges, sustainable development

MULTIDISCIPLINARY TELECONSULTATION IN DEVELOPING COUNTRIES

By Ferrari F.

GLOBAL HEALTH TELEMEDICINE, ROME, Italy

Global Health Telemedicine (GHT) is a non-profit organisation that was set up in 2013 to provide telemedicine services in developing countries, mainly in sub-Saharan Africa. The GHT telemedicine centre collaborates with the traditional healthcare centres and hospitals that are already present in the country. GHT's offer of diagnosis and therapy consists of providing remote teleconsultation by medical specialists working in Europe, to the physicians working in the country requesting the service, who are often general practitioners.

Our purpose is to provide a free second expert opinion by the web to local doctors, with a widespread diffusion of the centres to reach also the population in the most remote and rural areas in sub-Saharan Africa. The platform for sending and replying to teleconsultations, called "TeleConsulto 2", was developed by the Italian ICT company Ttreinformatica active in the development of health information systems. TeleConsulto 2 is a software integrated system based on the interaction between a web and a desktop application that aims to solve the data connection lack in consistency of many developing countries.

The chosen technologies are completely open source (LAMP platform for web application and ELECTRON for the desktop one). The data transmissions are based on standard encrypted protocols. The system is able to work online, sending requests and receiving answers real time, but also offline, storing teleconsultations and sending them automatically as soon as the connection is re-established. Since GHT was set up in March 2013 8388 multi-disciplinary teleconsultations, 4354 of which during the last 38 months, which is 51.2% of the total, which shows the programme's growing success (2).

The data regarding the urgency of the teleconsultations indicate that our local staff use the telemedicine service above all for outpatients consultations that are not urgent (62.3% of the total, white + green), and that the chronic-degenerative cardiovascular diseases (arterial hypertension, heart failure on ischemic and hypertensive cardiopathy, diabetes mellitus) are the most frequent clinical problems for which teleconsultation is requested. We also observed an increase in the request for radiological consultations, which now represent the third most requested specialist branch, to refer to the increase in the spread of radiological machinery in local hospitals.

12. Global challenges, sustainable development

HEALTH TECHNOLOGY AND PUBLIC POLICY

By Hernandez A.

Global Health International Advisors

Clinical Engineers (CE) play a leading role in the Health Technology (HT) Management field, this participation has grown dramatically since the days that the scope of work was limited to medical equipment maintenance activities and testing in hospital environment. Recognition of the outstanding work, commitment, and responsibility have not followed the same fast-growing trend and have been confined mostly to the hospital setting. With the fast development of HT and convergence with information and communication technologies (ICT), the contribution of CEs has started to make pathways as the leaders in handling this challenging scenario.

In spite of these advances, much of the health sector groups outside healthcare facilities are not fully aware of the contribution of the CEs to the safety and quality of health services. If we move out of the health sector and academia, there is a total lack of knowledge and information concerning the operation of health care facilities and the quality of services received via CEs. Based on the lack of knowledge and information that the groups directly involved in outcomes could potentially experience, it is necessary to get them involved in supporting professionals working in the HTM field. The strategy for building this support would be to have the CEs actively participating in Public Policy making at the national level to help influence regulations and judicial interpretations authorized by national legislations.

The evolution of the HT field has many examples where the relevance of engineers in the biomedical device field has impacted and mobilized organization and the population to respond to safety threats and transforming these responses into Public Policies.

For example, the report "To Err is Human" from Institute of Medicine (IOM) released in 1999 triggered a global response led by the World Health Organization in support of policies to guarantee the safety of patients in the healthcare environment. The convergence of the HT with ICT is the opportunity for CEs to actively get involved in Public Policy. The CEs are the most qualified professionals to lead this process and advocate for the need of safety environments for the deployment of these new technologies.

12. Global challenges, sustainable development

INTERNATIONAL BIOMEDICAL SERVICES FOUNDATION (IBSF)

By Sharma J.

CEO, AMTZ, India

AMTZ, is a large medical technology infrastructural eco-system and a government funded enterprise, and is intending to create an International Foundation for Biomedical Engineering Services in 2019 with an intent to link volunteers who wish to serve in low resource settings (15-90 days) and the LMICs (low and middle income countries) who seek their support. While the entire operations shall be financed by donations (including flight costs for volunteers), AMTZ is willing to put in a modest seed capital.

As was demonstrated by the recent AAMI Conference Global Track session on "Contributing to HTM around the world: making a difference from the equipment to the patient; a bottoms-up approach to improving access and quality of care", led by Ray Dalton and highlighting the efforts of many individuals, companies, foundations, and NGOs (non-governmental organizations) over the years, there is a clear demand for volunteer CE-HTM in LMIC around the world.

IBSF is intended to work with other stakeholders, eg, IFMBE CED, AAMI, ACCE, and the Ray Dalton Foundation among others, to systematically address all aspects of this need. Examples are help in all aspects of equipment lifecycle, from equipment selection, dealing with donations, on-boarding, inventory capture and ongoing analysis, maintenance and troubleshooting (on-site or remotely), acquisition of repair parts and spare parts, etc.

Some excerpts from the IBSF founding document include the following:

- To focus in Biomedical Technology, with the aim of improving and maintaining health care sector in resource-limited countries.
- To develop practical troubleshooting and repair skills in settings those have been traditionally strong on theory and weak on practical experience.
- To enhance health care technology in countries with a view to improve functionality of medical devices by:
 - Improving the availability of functioning medical equipment through repair and maintenance services;
 - Facilitating local training programs that are self-sustaining and adaptive to medical technologies;
 - Train local biomedical technologists and medical staff on proper care and use of medical devices;
 - Partner with other organizations providing technical training and repair services for Biomedical equipment.
- Other such tasks for promotion of Biomedical/ Clinical Engineering services.

12. Global challenges, sustainable development

CLINICAL ENGINEERING – HEALTH TECHNOLOGY (HT) MANAGEMENT IN THE MIDDLE EAST AND NORTH AFRICA (MENA) REGION

By Farah R.

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Background: In the 20+ countries of the MENA Region, there are six known active CE Societies, in Tunisia, Egypt, Lebanon, Kingdom of Saudi Arabia (KSA), UAE and Jordan. Demand on healthcare in MENA is expected to rise due to: (1) high population growth; (2) increased life expectancy and lower mortality rates; (3) higher literacy; and (4) awareness of health insurance. The private sector healthcare market in most MENA countries remains underdeveloped, a major portion of the healthcare spending is done by the government, where nearly two-thirds of all hospitals in MENA are government-owned. A key trend - western healthcare companies like Johns Hopkins, Mayo Clinic, Cleveland Clinic are present, eg, Johns Hopkins is currently associated with six hospitals in the MENA, 3 in UAE, 2 in KSA, and 1 in Lebanon - leading to an expectation for high demand for CE certification, mainly in KSA, UAE, Egypt, Kuwait, Lebanon and Jordan. The majority of medical devices come from USA and EU, with demand across MENA continuing to rise.

Recommendations:

- Promote awareness of global CE-HTM's important role in HT management (HTM)
- CE-HTM education and training should encompass more IT and Cybersecurity in the curriculum, and development of standards that define each role and responsibilities to support new systems
- Unify CE-HTM professionals' definitions for National and International Certifications and Education
- Need to expand CE-HTM fields and opportunities; more Strategic Planning, and Technology Assessment
- Need to unify Medical Devices Nomenclature
- Need to develop more Benchmarking Indicators valid in most Countries

Health Technology Management & Advancement (HTMA) - a Regional CE multidisciplinary society - was created in 2015. Its vision is to (1) lead innovative HTM, (2) HT assessment (HTA) and (3) advancement of solutions and initiatives for safe quality healthcare, education and research through the development of professionals, standards, systems and technologies in the region. There were two regional events in 2017, focused on medical device innovation, regulation, and lifecycle management, and several other related events since, eg, with Bio-Clinic, Arab Health Federation, etc. This session is intended to discuss how HTMA can best move forward within the Region and to connect with global health leaders and encourage CE-HTM best practices.

12. Global challenges, sustainable development

FILLING THE GAPS, CONNECTING THE DOTS AND ESTABLISHING THE LINKS

By Macalinao B.

BMET Trainer & Facilitator at Blended Learning & Mentoring

As health technologies and innovations emerging swiftly, Standards and Regulations requirements have to be addressed to cope up with growing demand of the Health Care Sectors for performance for diagnostic and therapeutic equipment in accordance with manufacturer's and health industry standards. Skilled professionals responsible in the management of these devices are needed, developing their skills and knowledge to cater to the demand of the pressing market. In the Philippines, I have a dream of deploying at least 1 in-house BMET for every healthcare provider that also includes stand-alone diagnostic centers and dialysis centers. I started a project in La Union Province north of Manila in August 2017 conducting training on basic equipment to all district hospitals targeting BMETs with basic background. The basic Medical Equipment Technology, MET, is a training module covering equipment of at least 12 units in 12 days including assessment with the TVET competency-based learning programs integrating the basic, common and core competencies. Wherefore the basic MET training program I have started in 2017 up to 2019 was able to produce at least 50+ Biomed technicians (BMETs) and got their certification as NC II from Technical Education and Skills Development Authority, TESDA. All of the 5 district hospitals in La Union province now have certified BMETs. I am currently developing the MET 2 module that covers the equipment for ICU. This would be a continuing knowledge from basic MET 1 with additional BMET role and responsibilities including documentation and participation on the management and procurement of medical equipment. The challenges would be financial support from the organization and schedule of training after work hours. The training programs were designed per module with maximum 15 learners and at least 80 hours. Another challenge is potential candidates taking the career path into Biomedical Equipment Technology. Strategies to move ahead: I) WHO regulations, policies, standards and compliance policies must be strengthened and enforced through stakeholder awareness. Conduct training on BMETs and Hospital Administrators about HTM. II) Link various Government and Private Agencies & Stakeholders.

I would strongly recommend WHO as the prime mover to communicate with the national partners installed in all countries in Asia Pacific Region. WHO can work with global CE-HTM organizations to ensure CE-HTM best practice.

12. Global challenges, sustainable development

NOMENCLATURE OF ESSENTIAL MEDICAL DEVICES IN BENIN (REDUCED)

By Soroheye P.

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Introduction: Medical devices are important elements in the capital asset inventory of health care facilities. Given the plurality of nomenclatures at the international level, each country must have its own nomenclature. Benin Ministry of Health wants to have a sole nomenclature of medical devices starting with the mother and child care.

Objectives: have a sole nomenclature of medical devices,

Methodologies: The settling of the list of essential medical devices in Benin has taken several steps. The establishment of a work team was the starting point. The work team conducted a census of all the documentation related to care activities for the management of maternal and child illnesses in Benin. The different nomenclature lists of international and national medical devices were read. From the read documents, the team highlighted all the interventions about the mother and the child. Then, the list of all the mandatory medical devices by intervention and level of care at the for the mother and the child are taken into account. To have an integrated and participative list of the document, it was decided to make an assessment of the availability of these devices in health facilities in Benin at all levels of the health pyramid. At each structure, the collection permitted to take the stock of what exists in relation to the cards and to complete the list of equipment developed by other medical devices not previously chosen and which exist in these health facilities.

The evaluation permitted to take the stock of interventions by level of care, to highlight the equipment needed for these interventions and sometimes even a bad distribution of MD. The classification of MDs into families was made using two documents: the CNEH nomenclature and the inter-institutional DM list. Results: 18 centers available in the country were evaluated. From this assessment, the availability rate of DM is 66.5%. 93.5% DM from the list are recognized as essential. 0.65% DM was completed to the initial list developed. On the list of DM originally developed 0.5% are recognized as essential by users. 0.2% of MDs are not used in health facilities because their usage is higher. The list of essential DMs was re-read by the committee and validated by the Minister's office. A grouping by DM 17 family has been made.

Conclusion: The country's challenge is to have a single list of all medical devices required for all interventions at the level of health facilities in Benin.

12. Global challenges, sustainable development

WORKING GROUP ON AFRICA ACTIVITY (WGAA) OF IFMBE

By Hussein A.

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The creation and existence of professional societies is vital for professional development, for international collaboration. Collaboration and integration being the key elements for effective, efficient and valuable results. The field of clinical/ Biomedical Engineering is multidisciplinary in its nature. The level of development in the field differs from country to country. Especially in Africa, it is new to the society even though the demand is high. The graduate clinical /biomedical professionals have tied most of the time to maintenance of medical equipment. The other areas of the field are not developed and no focus is given. It is important to develop the profession both nationally and internationally by enhancing collaboration, togetherness for effective implementation of activities related to the field. Professional societies are established in most countries with the mission to enhance the field of study, though the number, strength differs from countries to countries. Some of the area of focus in the Working group are Networking (creating a platform), increasing the number of members joining IFMBE – (The number of official members has increased from Two to seven after the formation of the working group). Working on Topic specific real problem related to HTM, Education, Research and Innovation, awareness creation etc...

So far charter of the working group is created, different meeting are done based on the platform agreed, three year plan was approved, representation of the working group as collaborator in Clinical Engineering division of IFMBE, attending and promoting WGAA in different meeting such as EPIG, AAMI, East African Conference, Health Conference in South Africa, Closely working with AU, promoting other African countries to join IFMBE and the working group. Different clusters were proposed and piloted to make the working group more reachable. The French speaking cluster, the Portuguese speaking cluster, the Arabic speaking clusters, the East cluster and the west cluster. Challenges on finance, commitment are already there but the creation of the working group has create awareness and encouragement to the clinical/biomedical engineering field and give confidence to those that are working in this field.

Key Words: Clinical/biomedical engineering, HTM, WGAA, IFMBE



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