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Welcome to ICEHTMC 2025

Dear Colleagues and Friends,

It is our great pleasure to welcome you to the 6th International Clinical Engineering & Health Technology Management Congress (ICEHTMC 2025)!

Excitement is building across the global Clinical Engineering community as we gather once again to share knowledge, address critical challenges, and strengthen our international network. This year's host city, Shenzhen, China—widely known as China's Silicon Valley—provides the perfect backdrop. Just north of Hong Kong, Shenzhen is a modern, innovative metropolis renowned for its vibrant culture, dynamic industry, and world-class hospitality. We are confident that your time here will be both professionally enriching and personally memorable. ICEHTMC stands apart as the only global forum specifically focused on the essential intersection between engineering, technology, and patient care. This Congress will energize and equip stakeholders from every corner of the world to improve healthcare outcomes and elevate patient experiences.

Ten years ago, nearly 200 globally renowned experts from over 30 countries gathered in Hangzhou, China, for the first ICEHTMC, where we explored common challenges and opportunities, achieving impactful outcomes. The event was designated as the Global CE Day celebration. Following the ICEHTMC Congress has been bi-annually hosted in countries around the world. Including China, Brazil, Italy, USA, and India. Thanks to many volunteers and growing global collaboration, we overcame challenges and accomplished impactful results for both our discipline and patients, including the creation of GCEA and Global CE Journal. Today, a decade later, our Chinese CE colleagues warmly invite CE colleagues from around the world to return to China to explore a decade of development and innovations. It is the foundation upon which we build our future - through shared knowledge, cooperation, and a stronger, more connected CE community. Together, We Are making it Better.

Our venue, a magnificent and fully equipped conference hotel, sets the stage for meaningful learning, professional development, and international collaboration. Attendees include students, early-career professionals, leading practitioners, industry members, researchers, academicians, and policymakers, all coming together to engage and inspire.

The scientific program is the most comprehensive in ICEHTMC history, offering the best selection from over 440 abstracts submitted from over 60 countries on topics such as cutting-edge innovations, digital health, robotics, and A.I., in addition to workshops on a wide range of topics, including:

· Digital Health, Artificial Intelligence, and Robotics
· Cybersecurity, Risk Management, and Disaster Preparedness
· Best practices and Smart Hospitals

· Health Technology Assessment and Management Strategies
· Innovation, Regulation, and Sustainable Development
· Writing and publishing engineering papers

Sessions will be presented in English and Chinese, with simultaneous interpretation available for all. This multilingual approach ensures greater access, inclusion, and global reach.

Program Highlights Include:

· Opening Ceremony and Plenary Session with world-renowned speakers
· 10th Anniversary Celebration of Global Clinical Engineering Week
· National Chinese Clinical Engineering Tracks
· Global Clinical Engineering Summit
· Global CE Journal Editorial Board Meeting
· GCEA members Annual Meeting and Officer Elections
· Inaugural innovative "Meet & Greet", a commercial Networking Program
· Health and Wellness Technology Exhibition
· Closing Ceremony

Social Program

ICEHTMC 2025 is not only a platform for learning about the latest global health technologies and Clinical Engineering professional exchange but also a celebration of our community's culture and passion. This year's social program offers a delightful blend of experiences, such as:

· Traditional Chinese cultural performances
· Guided city tours exploring Shenzhen's heritage and innovation
· A refined culinary journey highlighting local cuisines
· A leisurely stroll through one of Shenzhen's beautiful parks, offering time for informal networking and relaxation
· China's highlights tour following the Congress

These special moments will enrich your Congress experience and foster lasting personal and professional relationships.

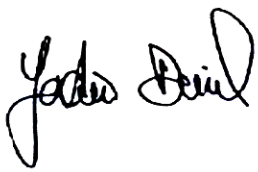
We are proud to present the ICEHTMC 2025 Proceedings, a peer-reviewed collection of abstracts from the oral and poster sessions. Supported by more than 100 expert reviewers coordinated by the Scientific Program Committee and the Global Clinical Engineering Journal, this publication upholds our tradition of academic rigor and excellence. It also marks the fourth ICEHTMC proceedings are published online at GlobalCE.org, further strengthening the global knowledge base of our field.

This Congress is made possible through the dedicated collaboration of the Global Clinical Engineering Alliance (GCEA) and its over 50,000 members – along with 30 Member Associations, the Association for the Advancement of Medical Instrumentation (AAMI), China Medical Devices Journal Press (CMD), the *Global Clinical Engineering Journal (GCEJ)*, AMTZ, Mindray, and our local hosts. Their combined commitment ensures ICEHTMC continues to serve as the cornerstone of our professional community.

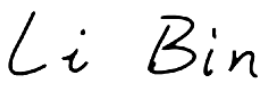
ICEHTMC 2025 is a hybrid Congress, designed to maximize engagement of both in-person and virtual participants, utilizing live streaming technology and Zoom webinars. Whether joining in Shenzhen or virtually, we invite all attendees to actively engage, exchange insights, and build meaningful connections.

On behalf of the organizers, sponsors, volunteers, and host organizations, we thank you for your presence and participation. We wish you a productive and inspiring experience and look forward to continuing this shared journey at future Congresses. Together, let us envision and build a common future for our profession and global health.

Warm regards,



Dr. Yadin David
Chair, ICEHTMC 2025
Organizing Committee
Global Clinical Engineering Alliance



Li Bin
Co-Chair, ICEHTMC 2025
Organizing Committee
China Society of Clinical Engineering

Dong Jin
Local Host, ICEHTMC 2025
Organizing Committee
China Medical Devices Journal Press

Program at a Glance

Friday, 17 October 2025

Time	Entry Lounge	Jing Room	Song 1 Room	Exhibition Centre
9:00 am - 13:00 am	Registration			
13:00 pm - 15:00 pm	Registration	**Welcome event**		
15:00 pm - 15:30 pm		Workshop 1: **Global Clinical Engineering Accreditation Program**	Workshop 2: **Bridging Complementary Medicine, Personalized Care & Clinical Engineering**	**Exhibition Hall Open**
15:30 pm - 15:45pm	Coffee Break			Exhibition
15:45 pm - 16:30 pm	Registration	Short Course: **How to write a research paper**	Workshop 3: **CE/HTM Bodies of Knowledge and Practice**	**Set up Posters**
16:30 pm - 17:00 pm		**Global CE Summit**		
17:00 pm - 18:30 pm				
9 am — 5 pm	**Committee meetings, Panel discussions and Vendor presentations (MEET & GREET)**			

Saturday, 18 October 2025

Time	Entry Lounge	Ballroom	Chinese CE Program	Yuan 1 room	Yuan 2 room	Yuan 3 room	Yuan 4 room	Tang 2+3 room	Exhibition Center
8:30 am - 12:00 am	Registration	**Joint Opening Ceremony for ICEHTMC 2025 and 10th Global CE Week celebration**							**Exhibition Hall Open**
									Exhibition Hall Open
12:00 pm - 13:00 pm	Lunch Break & Posters								Lunch Break & Posters
13:00 pm - 15:00 pm				**A1. CE Service Delivery I**	**B1. HT Innovation & Impact**	**C1. Health Facility Planning & Design I**	**D1. System Interventions**	**E1. Preparedness Challenges**	**Exhibition Hall Open**
15:00 pm - 15:15 pm	Coffee break and Posters								Coffee break and Posters
15:15 pm– 17:15 pm				**A2. CE Information Systems I**	**B2. HT Assessment & Evaluation**	**C2. Health Facility Planning & Design II**	**D2. Policy, Discipline & Inclusion**	**E2. Medical Oxygen Challenges**	**Exhibition Hall Open**
9 am — 5 pm	**Committee meetings, Panel discussions and Vendor presentations (MEET & GREET)**								
18:30 pm— Midnight	**Gala Dinner & Awards (Tickets required)**								

Program at a Glance

Sunday, 19 October 2025

Time	Ballroom	Chinese CE Program	Yuan 1 room	Yuan 2 room	Yuan 3 room	Yuan 4 room	Tang 2+3 room	Room Wu 1+2	Song 2 room	Exhibition Centre
8:30 am - 10:30 am	9:00 am **Sharing the World of Clinical Engineering Forum 1**		A3. CE General Management I	B3. HT Innovation - AI, Digital Twins & Machine Learning	C3. Quality of Care & Patient Safety	D3. Training & Education for Next-Gen CE	E3. CE/HTM LMIC Innovations	F1. Digital Health & Connected Devices	9:30 am **Global CE Journal Editorial Board meeting**	**Exhibition Hall Open**
10:30 am - 10:45 am										Coffee Break & Posters
10:45 am - 12:45 pm	**Sharing the World of Clinical Engineering Forum 2**		A4. CE Information Systems II	B4. HT Innovation - AI, Machine Learning & VR	C4. Medical Imaging	D4. Quality Assurance & Patient Safety	E4. CE/HTM Challenges in LMICs	F2. AI, IoT & Future of HTM		**Exhibition Hall Open**
12:45 pm - 13:30 pm									Lunch & Posters	Lunch & Posters
13:30 pm - 15:00 pm	**Sharing the World of Clinical Engineering Forum 3**		A5. CE Service Delivery II	B5. HT Innovation - Device Development I	C5. Facility-related Interventions	D5. Women in CE/HTM: Inclusion & Impact	E5. HTM Lifecycle Challenges	F3. AI for Improved & Safer Patient Care	Panel Discussion: **Harmonisation of Medical Device Regulations**	**Exhibition Hall Open**
15:00 pm - 15:15 pm	Coffee Break & Posters								Coffee Break & Posters	Coffee Break & Posters
15:15pm– 17:30 pm	**GCEA Annual Meeting** (Auditorium Room)									
9 am — 5 pm	Committee meetings, Panel discussions and Vendor presentations (MEET & GREET)									

Monday, 20 October 2025

Time	Entry Lounge	Wen 1+2	Yuan 1 room	Yuan 2 room	Yuan 3 room	Yuan 4 room	Exhibition Centre
8:30 am - 10:30 am			A6. CE Data & AI	B6. HT Innovation - Device Development II	D6. CE Societies, Alliances & Strategy	E6. HTA Challenges IN LMICs	**Exhibition Hall Open**
10:30 am - 12:30 pm			A7. CE General Management II	B7. HT Innovation - Clinical Studies	D7. Credentialing & Accreditation for Global CE	E7. Quality of Care Strategies	**Exhibition Hall Open**
12:30 pm - 13:30 pm	Lunch Break & Posters						Lunch & Posters
13:30 pm - 15:00 pm		**Congress Closing Ceremony**					
10am—1pm	Committee meetings, Panel discussions and Vendor presentations (MEET & GREET)						

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E: CE/HTM Challenges & Solutions in LMICs

F: Digital Health, Connected Devices & AI/IoT

A1: CE Service Delivery I

Design and Development of a Regional Medical Imaging Equipment Quality Control Sharing Platform Under the Mutual Recognition of Diagnostic Imaging Results Policy

By Qin Zhang[1,*], Ruiqiang Zheng[2], Xianli Ma[1], Tan Xue[1], Zhengda Lu[1], Ju Tang[1], Dingsheng Cheng[1], Jian Zhang[3]

[1] Department of Medical Engineering, Northern Jiangsu People's Hospital, Yangzhou 225001, Jiangsu Province, China.
[2] Hospital Administration Office, Northern Jiangsu People's Hospital, Yangzhou 225001, Jiangsu Province, China.
[3] Information Center, Northern Jiangsu People's Hospital, Yangzhou 225001, Jiangsu Province, China.

To address challenges such as significant variations in quality control standards for medical imaging equipment across regional healthcare institutions, data siloing, and difficulties in cross-institutional collaboration, this study integrates regional medical resources through the convergence of Internet of Things (IoT), 5G, blockchain, and digital twin technologies. We established a regional medical imaging equipment quality control sharing platform that enables real-time dynamic monitoring of operational parameters for core components of large-scale imaging devices. The platform achieves standardized data acquisition, intelligent analysis, and cross-institutional sharing mechanisms for quality control results across multiple device types in different hospital campuses, establishing a novel quality control management model and training framework for imaging equipment. Implementation outcomes demonstrate that since its launch in November 2024, the platform has connected 20 CT/MRI devices from closely-affiliated medical consortium units in Yangzhou. It has guided routine quality control for primary-level hospital imaging equipment, generated 372 equipment anomaly alerts, identified and resolved over 10 potential safety hazards, and increased daily average examination capacity by 10% in primary-level hospital facilities. The platform provides robust technical support for regional mutual recognition of imaging results. This research represents the first realization of homogeneous quality control management for regional medical imaging equipment, offering a replicable model for implementing cross-institutional medical resource coordination and regional mutual recognition policies for imaging examinations.

A1: CE Service Delivery I

Quality and Risk Management System for Medical Equipment in Hospitals

By Shengjun Wang[*]

Medical Engineering Department, Nanfang Hospital, Southern Medical University, Guangzhou, Guangdong Province, China.

Description: The establishment of a comprehensive quality and risk management system for medical equipment is critical to ensuring patient safety, operational efficiency, and regulatory compliance in healthcare settings. Quality management encompasses the entire lifecycle of medical devices, including procurement, installation and acceptance, maintenance, routine inspection, operational management, and decommissioning. During procurement, rigorous technical evaluations and compliance checks are conducted to align with clinical needs and safety standards. Post-procurement, installation, and acceptance protocols verify equipment functionality and safety. Maintenance and routine inspections ensure continuous operational reliability, while standardized operational management guidelines and user training optimize equipment utilization. Decommissioning procedures address environmental and regulatory requirements to mitigate residual risks. Risk management integrates theoretical frameworks and methodologies to foster collaborative risk mitigation across clinical departments. By prioritizing adverse event monitoring as a core strategy, the system facilitates proactive risk identification, assessment, and control. Multidisciplinary teams, including clinical users and engineers, undergo specialized training to enhance risk awareness and response capabilities. Risk identification involves analyzing historical adverse events, equipment failure patterns, and workflow vulnerabilities. Risk assessment employs quantitative and qualitative tools to prioritize hazards based on severity and likelihood. Mitigation measures include technical modifications, process optimization, and targeted training. A feedback loop, supported by digital platforms for real-time

data collection and analysis, ensures dynamic system refinement. **Conclusion:** The integration of quality and risk management systems establishes a robust framework for medical equipment governance. By harmonizing lifecycle quality control with proactive risk strategies, hospitals can significantly reduce equipment-related adverse events, enhance clinical outcomes, and ensure regulatory adherence. Key success factors include interdisciplinary collaboration, continuous training, and data-driven decision-making. Future efforts should focus on adopting advanced technologies, such as predictive maintenance and AI-enabled risk analytics, to further strengthen system resilience. This holistic approach not only safeguards patient safety but also promotes sustainable healthcare resource management, aligning with global standards such as ISO 14971 and Joint Commission on Accreditation of Healthcare Organizations (JCAHO) requirements.

A1: CE Service Delivery I

Research on Continuous Quality Improvement Project for Reducing Downtime of Linacs

By Qipeng Lu[1,2], Hangguan Shan[*,1], Jian Shao[2], Yu Luo[2], Qikai Yu[2], Wei Zhang[2], Longjie Zhong[2], Ciyong Wang[2]

[1] Zhejiang University, Hangzhou, Zhejiang Province, China.
[2] Zhejiang Cancer Hospital, Hangzhou, Zhejiang Province, China.

This study deeply explored and analyzed the quality control management strategies of Linacs, as well as the development trend of their downtime. The research time span was as long as five years. The basic data and materials of the project mainly come from 1,685 maintenance reports generated by a total of seven Linacs from three manufacturers within Zhejiang Cancer Hospital from January 2021 to December 2024. Meanwhile, these data are compared and analyzed with the project data from January 2019 to December 2020. The research results are mainly presented from four dimensions: the number of radiotherapy patients, the number of downtime events, the downtime time, and the reliability parameters of the equipment. During the four years from 2021 to 2024, the four core indicators of the seven Linacs showed differentiated fluctuations. The overall number of downtime events has shown a continuous downward trend, which indirectly confirms that the effectiveness of quality control management measures is gradually emerging. The changing trends of downtime indicators are complex and diverse. Among them, the downtime durations of Linacs No.2 and No.7 experience fluctuation curves that first increase and then decrease. Linacs No.9 shows a special change of a significant reduction first, and then a recovery. In 2022, most devices were in a state of frequent downtime, but in 2024, the downtime of some devices was significantly reduced. This shift may indicate a substantial improvement in equipment reliability. From the perspective of radiotherapy services, the overall number of radiotherapy patients has shown a stable growth trend, and the equipment load began to decline after reaching its peak in 2022. Focusing on equipment reliability parameters, the Mean Time to Repair (MTTR) from 2019 to 2024 reflects fluctuations in equipment maintenance efficiency, while the Mean Time between Failures (MTBF) indicates instability in the duration of equipment failure intervals.

A1: CE Service Delivery I

Big Data-Driven Optimization of End-to-End Reagents Supply Chains: A Healthcare Practice Study

By Yan Dan[1,*], Zha Haitao[2], Cheng Chong[2], Lu Ping[3]

[1] Department of Medical Engineering, China-Japan Friendship Hospital, Beijing, China.
[2] Beijing Sinopharm New Creation Technology Development Co., Ltd., Beijing, China.
[3] Sinopharm (Beijing) Medical Devices Co., Ltd., Beijing, China.

This study investigates the reagents supply chain within healthcare ecosystems and systematically optimizes the entire supply chain process from manufacturers to smart cabinets through the construction of big data analysis models. The

results demonstrate that big data-driven demand forecasting and time-sensitive replenishment protocols significantly enhanced supply chain operational efficiency while reducing inventory carrying costs across tiered suppliers. This study provides an innovative path and practical reference for reagents supply management in the context of intelligent logistics and digital healthcare.

A1: CE Service Delivery I

Closed-Loop Management of the Full Cycle of Medical Equipment Asset Renewal

By Ruoyao Pan, Xiaoxiao Luan*, Sujuan Yu, Yun Tian

Department of Medical Engineering, Peking University Third Hospital, Beijing, China.

Renewal of medical equipment is a key aspect of hospital operation and management, which requires the establishment of a standardized and traceable closed-loop management system. As the core management department, the Medical Engineering Department is responsible for coordinating the whole process from demand collection to disposal of old assets to ensure that equipment renewal is scientific, efficient, and compliant. The main processes include:

Demand Declaration and Reserve Bank Establishment: the clinical department applies to equipment renewal through the equipment management system, indicating the intention to purchase new equipment, the reason and the basis for renewal of the old equipment (the asset number of the equipment to be eliminated, etc.), and the Medical Engineering Department audits and incorporates it into the reserve bank for equipment renewal, forming a dynamic management pool.

Coordinated planning and decision-making and approval: the Medical Engineering Department, combined with clinical needs, budget allocation, and equipment benefit assessment, develops updated priority schemes, after the approval of the hospital leadership, to form the final implementation plan.

Procurement implementation and introduction of new equipment: based on the approved plan, the procurement team organizes bidding and procurement, strictly controls technical parameters, contract payment terms, etc., and supervises the arrival and acceptance of the equipment.

Disposal of old assets and closed-loop management: after the clinical departments submit the application for disposal of old equipment, the medical engineering department will work with the relevant departments to complete the scrapping process, ensure the recovery of residual value, and pay the final payment for the new equipment after the arrival of the equipment, to realize the binding mechanism of "trading in the old for the new".

Conclusion: Through full-cycle closed-loop management, the medical engineering department can optimize the process of medical equipment renewal, improve the efficiency of resource utilization, and reduce the financial and compliance risks. The core advantages of this model include:

Standardized management: reduce arbitrary declarations and ensure scientific and orderly equipment renewal;

Controllable risk: disposal of old equipment is linked to the acquisition of new equipment, avoiding loss of assets;

Data-supported decision-making: the reserve bank provides the basis for long-term equipment planning and helps the hospital's high-quality development.

A1: CE Service Delivery I

Enhancing Medical Equipment Management Through the Implementation of China's International Hospital Accreditation (CIHA) Standards in Hong Kong

By Tony Chi Wah Tai[1,*], Cheuk Him Pang[2], Lok Him Tse[2], Julie Shuk Nei Li[3]

[1] Hospital Authority, Hong Kong SAR, China.
[2] Electrical & Mechanical Services Department, Hong Kong SAR, China.

[3] Pamela Youde Nethersole Eastern Hospital, Hong Kong SAR, China.

Objective: With the increasing complexity of medical technologies, hospitals face significant challenges in optimizing equipment management to ensure reliability, availability, and patient safety. This study explores the adoption of China's International Hospital Accreditation (CIHA) Standards in Hong Kong to enhance medical equipment management. By leveraging CIHA, hospital leaders, clinical engineers (CE), and health technology managers (HTM) can establish a safer, more sustainable management system with continuous improvement.

Method: A regional acute care hospital in Hong Kong SAR piloted CIHA standards in 2024. Mock accreditation and consultancy sessions were conducted by surveyors from the Shenzhen Hospital Accreditation Research Center (SHARC). A new management platform for critical medical equipment was introduced to improve condition monitoring, particularly for resuscitation equipment. The governance structure for health technology management was redefined under the CIHA framework to clarify roles and responsibilities.

Results: Developed by SHARC based on hospital accreditation experience in China, CIHA differs from domestic China Hospital Accreditation standards by aligning with global best practices to facilitate international recognition. The CIHA standards were accredited by the International Society for Quality in Health Care External Evaluation Association (ISQua EEA) in February 2022. The CIHA does not just impose requirements, but it elevates the role of Clinical Engineering (CE) departments through:

Formalized Governance:

- CIHA mandates a "Three Major and One Large" policy, requiring top management involvement in major decisions, personnel appointments, project investments, and large fund allocations.
- CE representation in governing committees ensures oversight during equipment acquisition.
- CE leadership reports directly to hospital executives for equipment-related incidents, reinforcing accountability.

Standardized Data-Driven Processes:

- Hospitals must implement a computerized inventory and maintenance management system to digitize workflows.
- CE departments are required to analyze data regularly and propose actionable improvements.

Risk-Based Prioritization:

CIHA emphasizes stringent management of Resuscitation and Life Support (R&LS) equipment, requiring:

- A comprehensive inventory of R&LS equipment.
- Redundancy protocols and preventive maintenance (PM) aligned with manufacturer recommendations.
- Co-management with user departments, where clinical staff conduct pre-use checks and training, while CE ensures PM and quality assurance.

Incident Management and Risk Mitigation:

- CIHA mandates strict protocols for managing medical equipment incidents and contractor accountability. The CE/HTM team, clinical staff, and contractors must jointly investigate major incidents and conduct Root Cause Analysis (RCA).
- Contractor service logs, RCA findings, and corrective actions must be recorded and retained for reference.
- RCA outcomes must be reported to and reviewed by a cross-functional committee involving the Quality and Safety Department to ensure accountability and systemic improvements.

Conclusion: CIHA adoption not only demonstrates a hospital's attainment of international healthcare service quality but also provides CE/HTM leaders a strategic framework to strengthen lifecycle management, improve patient outcomes, and ensure sustainability. Crucially, CIHA transforms CE/HTM departments from support functions into strategic assets, elevating their impact on healthcare service development.

A2: CE Information Systems I

Application Exploration of Medical Equipment Management Scenarios in the Metaverse

By Xiaochao Liu*, Li Jia, Jinrui Bai

Department of Medical Engineering, Honghui Hospital, Xi'an Jiaotong University, Xi'an, Shaanxi Province, China.

Objective: This study aims to apply the interactive scene technology of the metaverse to innovate the whole life cycle

management of medical equipment, improve the efficiency and quality of management, ensure the stable operation of equipment, reduce the operating cost, and then improve the level of medical service. **Method:** Using the open-source software XREngine as the platform, combined with tools such as panoramic cameras, 3D imaging scanners, and ZEGO Avatar SDK, a digital twin framework for medical equipment management is constructed. Data collection and modeling of various medical devices and their physical spaces within hospitals are carried out to generate virtual scenes. Multiple roles and their task processes are created and defined, integrating equipment management procedures and standards. VR virtual images are generated to simulate the entire interaction scenario of medical equipment management, covering collaborative management tasks involving equipment engineers, clinical staff, personnel from equipment management departments, supplier technical support personnel, and hospital management. **Results:** The results show that this technology has significantly improved the efficiency of equipment management training, with engineers' fault diagnosis efficiency increasing by 42%, and clinical staff's adherence to equipment operation standards improving by 38%. The average time for equipment fault repair has been reduced by 32%, and the first-time repair success rate has increased to 82%. Asset inventory efficiency has improved by 65%, with information accuracy exceeding 99%. Multi-role collaboration effectiveness has been enhanced, reducing equipment procurement cycles by 25%, and the first-time installation and commissioning success rate has increased by 36%. **Conclusion:** The application of metaverse interactive scenes in medical equipment management can optimize the management process, reduce the cost, ensure the operation of equipment, improve the quality of medical services, and provide strong support for the digital transformation of the medical industry and the construction of smart hospitals.

A2: CE Information Systems I

Design and Development of a Comprehensive Medical Device Lifecycle Management System Utilizing Multi-Platform Real-Time Information

By Xinxin Wang[†], Shuo Wang[†], Weizhe Luo[†], Ai He, Chao Ma, Debiao Yao, Jiawen Zhang, Wenbin Wu, Fengqin Zhang[*]

Fuwai Hospital, Chinese Academy of Medical Sciences, Beijing, China.
[†] Co-first Author: Xinxin Wang, Shuo Wang, Weizhe Luo

Objective: The management of medical devices throughout their lifecycle is confronted with significant challenges, including fragmented processes, insufficient interoperability among information systems, and delays in data updates, primarily due to the extensive array of medical devices present in hospitals and the complexity of data sources. This paper presents a multi-platform real-time data integration approach aimed at enhancing data integration and device sharing within the medical device lifecycle management system, to improve operational efficiency, management safety, and economic benefits. **Methods:** This study developed a comprehensive lifecycle management system for medical devices, informed by data research and workflow modeling. The system comprises four essential modules: Procurement management, asset management, operations and maintenance management, and benefit analysis management. The procurement management module functions as the initial data entry point for devices, seamlessly integrated with the hospital's Office Automation (OA) approval system, facilitating budget preparation, task execution, contract management, and goods receipt and storage. The asset management module enables the querying and generation of statistical reports concerning various aspects of device procurement, maintenance, repair, usage, and inspection. The operations and maintenance management module captures data related to repairs, routine inspections, and tests, while the benefit analysis management module consolidates data from Picture Archiving and Communication System (PACS) and Laboratory Information System (LIS) to facilitate cost-benefit analysis at both the device and departmental levels. **Results:** Implementation of this device management system resulted in a reduction of the average query time for individual device files from 10 min to 2 min, and a decrease in the preparation time for administrative inspections from approximately 3 h to 1 h. Furthermore, the incidence of missed inspections post-warranty expiration was

eliminated. Correlation analysis between ultrasound charges and examination volumes revealed disparities in ultrasound workload across various locations, providing valuable insights for negotiating maintenance costs, which yielded savings of approximately 2.4 million RMB. The system generates an average of 2,100 reminders annually, including 87 notifications for device warranty expirations and around 2,000 reminders for measurement expirations. **Conclusions:** This system has revolutionized the comprehensive management of devices throughout their lifecycle, transitioning from "dispersed recording" to "digital closed-loop control". It has significantly enhanced the completeness rate of device files and reduced the preparation time for administrative inspections, while achieving a zero rate of missed inspections post-warranty expiration. These improvements have resulted in substantial time savings and increased operational efficiency. The visualization of ultrasound benefits introduces a novel framework for the integration of devices and clinical systems. This system serves as a critical tool for hospitals to implement "refined management" practices and can provide a model for other hospitals seeking to establish their own device management systems and integrate operational management data. Future developments will include the creation of a device benefit warning module in conjunction with Diagnosis-Related Group (DRG) cost data to further support the high-quality advancement of hospitals.

A2: CE Information Systems I

Comparative Analysis of the Functionalities of Clinical Engineering Management Software in Brazil

By Marcella Darold*, Mariana Brandão

Institute of Biomedical Engineering at Federal University Santa Catarina (IEB-UFSC), Florianópolis 88040-970, Santa Carina, Brazil.

Background/Objectives: The rapid evolution of medical technologies has made the efficient management of medical equipment a critical component of healthcare delivery. Clinical engineering (CE) management software plays a central role in ensuring the safety, reliability, and availability of these assets. In Brazil, various software solutions are adopted across healthcare institutions, each offering different functionalities and degrees of integration. This study aimed to conduct a comparative analysis of the main CE management software used in Brazil, mapping their functionalities, integration capabilities, and user interface characteristics. **Methods:** The study was structured in three phases. Phase 1 involved a literature search in scientific databases (Google Scholar, ScienceDirect, and PubMed) and market mapping of CE management software. Phase 2 consisted of developing a questionnaire based on Brazilian standards and regulations (ABNT-NBR-15943 and RDC 509/2021), followed by meetings with software company representatives to clarify technical and operational features. The information gathered was compiled into a comparative spreadsheet. Phase 3 involved completing the spreadsheet, developing a second questionnaire, and distributing it to CE professionals to capture practical insights regarding usability, satisfaction, and feature relevance. **Results:** Among the six identified CE software solutions, four agreed to participate in the study. All shared core functionalities, including lifecycle management of medical equipment, preventive maintenance scheduling, service call and work order tracking, and report generation. Despite this similarity, important differences emerged. Some systems featured artificial intelligence (AI) tools for performance analysis and technovigilance integration, while others offered mobile applications to facilitate remote access and real-time updates. Integration with calibration devices and hospital systems also varied, as did the availability of digital and electronic signature support. Interviews with fourteen CE professionals from different healthcare institutions revealed high satisfaction levels, particularly regarding interface usability, traceability, and automation capabilities. Users emphasized the importance of features such as asset history, performance indicators, and maintenance planning. However, some also identified areas for improvement, including enhanced contract management modules, more flexible report generation, improved system stability, and better customization without compromising interoperability. **Conclusion:** The analyzed CE management software solutions share similar essential functionalities but differ in their technological advancements and customization options. These differences reflect efforts to meet the diverse operational needs of healthcare institutions. This study offers relevant insights to guide software selection in the healthcare context. Future research should include in-practice usability evaluations, broader analysis of integration capabilities, and feedback from various professional profiles to provide a comprehensive understanding of these systems' performance in daily clinical engineering operations.

A2: CE Information Systems I

Construction and Practical Analysis of an Information Management System for the Full Lifecycle of Medical Equipment

By Sujuan Yu, Zhenlin Liu, Xiaoxiao Luan*, Yun Tian, Dongxu Wang, Ying Xiao, Ruoyao Pan

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Purpose: To explore an efficient management model for medical equipment throughout the entire process, including the generation of demand, evaluation and demonstration, budget establishment, procurement implementation, in-hospital operation and maintenance, and disposal and scrapping. Additionally, to establish an information management system for medical equipment across its full lifecycle, with the goal of achieving scientific and intelligent management and maximizing efficiency. **Methods:** Based on health technology management and health technology assessment, during the budget formulation stage, a multi-dimensional evaluation system was established according to the characteristics of the disease spectrum in medical institutions and the needs of disciplinary development. This system covers equipment purchase conditions, purchase expectations, performance evaluation, and other aspects to identify equipment configurations and models that are suitable for diagnostic and therapeutic needs, which are listed as priority support projects. In the procurement implementation stage, configuration models for specialized and general equipment were established in the knowledge base of medical equipment products and technical parameters. According to the development characteristics of specialized disciplines, advanced equipment was recommended to enhance diagnostic and therapeutic capabilities and scientific research support. For general equipment with similar demand characteristics, clustered procurement and base stockpiling in warehouses were adopted to achieve one-stop service of "demand submission—warehouse requisition" in clinical departments, shortening the procurement cycle. **Results:** The equipment configuration was scientific and reasonable. On the basis of meeting clinical diagnostic and therapeutic needs, strategies such as comprehensive monitoring of the usage of operating equipment through a cockpit, overall hospital planning, shared allocation, etc., were adopted to maximize the efficiency of equipment use, ensuring the safety, accessibility, economy, and social adaptability of medical services. **Conclusion:** The information management system for medical equipment across the full lifecycle has changed the traditional management model, realizing the interconnection of data throughout the entire process of budget management and procurement implementation, performance analysis, operation and maintenance support, shared allocation, asset revitalization, and disposal and scrapping. It drives decision-making through data, optimizes resource allocation, improves management quality and efficiency, and reduces medical costs. This is a breakthrough practice in management innovation and system innovation, which can provide a replicable management paradigm for medical equipment management in other medical institutions and promote the transformation of medical equipment management towards "refinement and intelligence".

A2: CE Information Systems I

Digital Management of Maintenance Work Orders for a Health Center in Peru

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Efficient management of Maintenance Work Orders (MWO) ensures the availability and functionality of biomedical equipment in hospitals. This paper addresses the significant challenges faced by a public hospital in Peru stemming from the manual handling of MWO through comprehensive qualitative and quantitative analyses. The need for a digital, cloud-based maintenance management system was identified. The proposed solution involves developing and implementing a standardized MWO digitalization and storage application, utilizing cloud technologies and Google Sheets integration. This

system aims to streamline maintenance processes, reduce manual workloads, and enhance data accessibility and accuracy. The paper details the problem identification and analysis methodology, explores solution alternatives, and presents a detailed implementation plan. Key benefits include time and cost savings, improved data management, and increased operational efficiency. The system aims to impact maintenance efficiency and resource optimization, which are evaluated using key performance indicators (KPIs), with recommendations for training and iterative updates to ensure long-term success and adaptability.

A3: CE General Management I

Deepseek Clinical Application Analysis of Orthopedic Diagnostic and Treatment Equipment

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Objective: This study aims to deeply explore the application effect of DeepSeek in the whole life cycle management of orthopedic diagnosis and treatment equipment, analyze its advantages and effectiveness in key links such as equipment procurement, use, maintenance, and scrapping through actual cases, and provide new ideas and methods for the field of medical equipment management.

Method: This study employs case analysis, using the orthopedic treatment equipment management of a large tertiary hospital as an example, and combines actual application data from the DeepSeek platform to analyze its effectiveness in the full lifecycle management of equipment. The research subjects include the intelligent navigation robot system for orthopedics, imaging equipment for orthopedics, surgical instruments, etc.

Results: Equipment Procurement Phase: By analyzing the hospital's historical data and business processes, accurately predict equipment needs, assist hospitals in planning procurement plans reasonably, avoiding over-procurement or under-supply of equipment. At the same time, leverage its data processing capabilities to select the most suitable suppliers for the hospital, optimize procurement contract terms, and reduce procurement costs.

Equipment Usage Phase: DeepSeek provides diagnostic recommendations and treatment plans to doctors, significantly enhancing the success rate and safety of surgeries. Through virtual simulation technology, it offers guidance and training for medical staff on equipment operation, improving their skills and proficiency. Additionally, real-time analysis of patient treatment data supports clinical decision-making, optimizing treatment outcomes.

Equipment Maintenance Phase: DeepSeek real-time monitoring of equipment status, early detection of potential faults and hidden dangers, timely warning, and effectively reducing the failure rate of equipment. According to the operation status of equipment and fault prediction results, formulate reasonable maintenance plans to improve maintenance efficiency and equipment reliability.

Equipment Scrapping Phase: DeepSeek Scientifically evaluate whether the equipment meets the scrapping standard by analyzing data such as service life, operating status, and maintenance cost, so as to avoid premature or excessive scrapping of equipment. At the same time, provide support for hospital asset disposal, select appropriate asset disposal methods, and realize the maximum utilization of assets.

Conclusion: The application of DeepSeek in the full lifecycle management of orthopedic diagnostic and therapeutic equipment demonstrates its ability to significantly enhance management efficiency, reduce operating costs, and improve medical quality and safety. By optimizing equipment procurement plans, monitoring equipment usage in real time, and scientifically evaluating equipment scrapping standards, DeepSeek provides strong support for hospitals' refined management. In the future, with continuous technological improvements and expanded application scenarios, DeepSeek is expected to play an even more significant role in the management of orthopedic diagnostic and therapeutic equipment.

A3: CE General Management I

Reduction of Non-Quality Costs Associated with Medical Equipment Use Errors at Clínica Imbanaco

By Karent Eliana Muñoz Salazar*, Ivonne Tatiana Morales

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Description: At Clínica Imbanaco, a project was implemented focused on reducing the non-quality costs associated with errors in the use of medical equipment. This initiative aimed to identify the root causes of operational errors, optimize medical technology management processes, and raise awareness among users. As part of the project, the economic impact was measured, which helped to assess the causes of use-related errors and their impact on process quality, patient safety, and the costs associated with repairs needed to restore functionality. The project involved the implementation of a medical equipment use error reporting system and the adoption of a methodology to quantify the non-quality costs linked to such errors. To achieve this, a non-quality cost matrix was developed, in which events related to operational failures in the use of medical equipment were categorized and quantified. This included direct costs such as maintenance, metrological assurance, spare parts, and labor; indirect costs such as additional contract expenses, transportation, training, immediate replacement, and adverse events; external failure costs such as defective equipment repairs, warranty services, legal costs, and external audit expenses; as well as depreciation costs, including acquisition value, useful life, and years of depreciation of the equipment. This approach allowed for the consolidation of economic information regarding the impact of these errors and the determination of total non-quality costs. Additionally, strategies were established, such as the development of risk matrices for medical technology, the creation of specific usage guidelines by technology family, and the strengthening of staff training. These actions not only contributed to reducing the recurrence of errors but also promoted a culture of safety in the use of medical technology. **Conclusions:** Measuring the non-quality costs associated with medical equipment use errors made it possible to visualize both the clinical and economic impact, facilitating informed decision-making to mitigate risk factors in the patient care environment. The implementation of a system for analyzing use errors strengthened medical technology management and fostered an institutional culture focused on continuous improvement through the adoption of effective strategies that reduced recurring errors, improved patient safety, and increased operational efficiency. The development of medical technology risk matrices enabled the identification of clinical processes with a higher likelihood of use-related errors. This project demonstrated that implementing strategies focused on preventing risks associated with medical technology positively impacts not only costs but also patient safety and the overall quality of care.

A3: CE General Management I

Advanced Software for Budget Management and Strategic Analysis in Clinical Engineering

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The management of budget proposals in Clinical Engineering services requires solutions that enable control, traceability, and agility in decision-making. In response to these needs, a modular and dynamic software has been developed, fully implemented from scratch using proprietary code, allowing for continuous evolution and ongoing adaptation to new functionalities, integrations, or changes in hospital operations. This system has been designed to record, edit, and validate budget proposals in a structured way, with real-time monitoring and high traceability. Each proposal is linked to a specific budget batch (bolsa), from which the amount is automatically deducted once validated, enabling centralized management of available funds. Collaborative validation by multiple stakeholders is visually reflected in the interface, supporting more transparent and effective decision-making. Behind the interface lies a robust system of mathematical algorithms that allows users to edit any value and make various types of decisions, automatically correcting all related batch values. Among its most notable features is the ability to attach documents directly to proposals, with visual indicators alerting users to the presence of files pending review, and an automated system that notifies when there are still stakeholders who need to validate the proposal.

In addition, the software integrates a visual analysis tool that displays, for each hospital unit or equipment family, an interactive chart showing the total number of devices categorized by age ranges based on their installation date. This visualization makes it easy to quickly identify areas where reinvestment is most urgent, helping to objectively prioritize

technological renewal according to obsolescence and clinical workload criteria. The solution has been designed with a simple and intuitive interface, accessible to non-technical staff, and can be deployed on hospital intranets or closed environments, ensuring data confidentiality and security. Its flexible architecture makes it easily scalable to other clinical services or healthcare institutions. This software has completely transformed the way we manage budget allocations. It allows us to centralize everything in one place, validate proposals seamlessly, generate reports instantly, and make better-informed decisions thanks to real-time visual charts and data analysis. But above all, it has saved us countless emails, errors due to duplicated versions, and the loss of important documents. Its full in-code development makes it flexible, alive, and constantly improving, and its practical approach turns it into a powerful tool that can be successfully applied in any hospital setting, aiming to work more clearly, quickly, and efficiently.

A3: CE General Management I

Comparative Study of Medical Device Price System and Drug Price System

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Medical devices are important medical resources in modern hospital management and important tools for clinical diagnosis and treatment. They have complex technology, large capital investment, and high operating costs. With the development of medical equipment technology, there are more and more categories of medical devices, and their clinical application scope is becoming wider and wider. They play an increasingly important role in clinical practice and account for a larger proportion of fixed assets in hospitals. Therefore, the reasonable, compliant, and legal configuration of medical devices has become a focus of attention for medical institutions and regulatory departments. However, current research mainly focuses on the reasonable, compliant, and legal configuration process, and there is relatively little research on the medical device pricing system. Medical device prices are an important factor affecting the management of medical device configuration. Compared with the drug pricing system, the medical device pricing system is incomplete, the product price composition is opaque, and there is a phenomenon of "disorderly pricing"; The price difference between medical devices with similar functions and the same quality is significant, and there is a phenomenon of "disorderly pricing"; The phenomenon of significant price differences in the procurement of medical devices by different medical institutions leads to the problem of "arbitrary selling prices".
This study aims to analyze the price system of drugs, summarize the current price system of medical devices, and explain the differences between the medical device price system and the drug price system from the aspects of price composition analysis, price formation methods, price influencing factors, and the relationship with medical fees. It explores solutions to the problems of "disorderly pricing", "disorderly quotation", and "disorderly selling" of clinical medical devices and provides useful suggestions.

A3: CE General Management I

Medical Equipment Management System-Driven Digital-Intelligent Inventory Model: A Data-Centric Framework for Supply Chain Optimization in Healthcare

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Objective: To develop a data-driven precision inventory model based on the Medical Equipment Management system, providing hospitals with a scientific and rational decision-making framework for stock preparation to achieve digital-intelligent management of medical equipment. **Method:** The precision inventory model was constructed through data-driven approaches. Real-time inventory monitoring of over 20 categories of frequently used devices across warehouse zones was implemented using Radio-Frequency Identification positioning technology. By integrating departmental demand data for each equipment type from the budget management module, dynamic inventory warning thresholds were generated. The

warehouse management module performed algorithmic iterations using historical procurement cycles and warning thresholds, computed optimal restocking quantities, and automatically generated purchase requests routed to the budget management module. Simultaneously, the system displayed real-time metrics (demand, inventory, and restocking quantities) for all critical equipment, enabling data-supported procurement scheduling. **Conclusion:** This model effectively integrates the budget, procurement, and warehouse management modules via data collaboration. It addresses deficiencies in traditional medical equipment inventory methods—such as redundant stock, delayed response, and inadequate emergency capacity—and achieves end-to-end digital-intelligent management of the medical equipment supply chain.

A3: CE General Management I

Construction of an Evaluation Index System for Intelligent Quality Control Devices of Multi-Parameter Patient Monitors

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Description: Addressing the industry-wide lack of an effective evaluation framework for intelligent quality control (QC) devices of multiparameter patient monitors, this study constructed a multidimensional evaluation index system. This was achieved through literature analysis, analysis of 374 valid questionnaires from clinical engineering professionals across 23 provinces in China, and a three-round Delphi expert consultation. The final evaluation index system for intelligent QC devices of multiparameter monitors comprises six primary indicators: Effectiveness, Innovativeness, Subjectivity, Economic Efficiency, Safety, and Applicability. These are further detailed by twenty secondary indicators, encompassing aspects such as QC accuracy for ECG, blood pressure, and blood oxygen saturation, failure rate, electrical safety, and others. Key Findings: Effectiveness (e.g., QC accuracy for ECG, BP, SpO□) and Safety (e.g., failure rate, electrical safety) emerged as the most critical indicators (mean scores > 4.6/5). Due to conceptual overlap and resulting low weighting with poor goodness-of-fit, the secondary indicator "Design Innovativeness" was eliminated. "Appearance and Workmanship" was retained. Significant professional differences were observed in indicator weighting: Clinical engineers prioritized Portability (C2) and Consumables Compatibility (F3), whereas corporate engineers assigned lower importance to compatibility-related indicators. **Conclusion:** This study establishes for the first time a systematic evaluation framework for intelligent QC devices of multiparameter patient monitors. It comprehensively addresses critical dimensions, including performance, safety, cost, and clinical compatibility, providing a scientific basis for medical device R&D, clinical QC management, and international standard development. Future research will extend this framework to devices such as ventilators and dialysis machines, promoting the intelligent advancement of medical equipment quality control.

A4: CE Information Systems II

Strategic Management for Decision-Making in Medical Technology Investments: A Model for Evaluating the Renewal of Medical Equipment at Clínica Imbanaco

By Karent Eliana Muñoz Salazar*

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Description: Renewing medical technology is an essential process to ensure safety and efficiency in healthcare services. Clínica Imbanaco has established a set of detailed criteria to define the conditions under which medical technology should be renewed. These criteria include irreparable failures, metrological assurance results, product recalls, repair costs, renewal assessments, changes in clinical needs, and other relevant factors.
At the organizational level, six types of causes have been defined to determine if medical technology requires renewal:

Irreparable failure: Determined through functionality verification tests conducted by the person responsible for maintaining the medical technology.
Metrological assurance result: When the results of qualifications, metrological characterization, performance evaluation, validation, conformity assessment, or legal metrological control do not meet the standards established by the manufacturer's manual or the tolerance defined by the clinic, and do not allow parameter adjustments.
RISARH: Product recalls, safety reports, alerts, and thefts. The Technovigilance Program issues a concept when a national or international regulatory body defines the product withdrawal from the market.
Repair cost: When the repair cost exceeds 50% of its acquisition cost or equals the current value of medical technology with the same technical specifications.
Renewal assessment: The instruction for evaluating the medical technology installed in clinical and/or administrative processes is applied through operational, economic, and clinical criteria.
Change in clinical needs: When the medical equipment is no longer necessary or is infrequently used.
The renewal assessment is carried out either programmatically or upon request whenever it is necessary to define the investment in the repair of medical equipment. This is done using a tool that evaluates the following criteria:
Operational Performance Evaluation (45%): Analyzes the functioning of the technology and its compliance with established technical parameters.
Economic Evaluation (30%): Determines the costs associated with the technology in relation to its acquisition value.
Clinical Evaluation (25%): Assesses the perception and utility of the technology within the organization, as well as its necessity.
With the implementation of the tool in 2024, the following results were obtained:

- Medical technology does not require renewal: 2078 (78.15%)
- Medical technology in renewal alert: 415 (15.61%)
- Medical technology requires replacement: 166 (6.24%)

Conclusions: Clínica Imbanaco's approach to the renewal of medical technology is comprehensive and ensures that decisions are based on technical, economic, and clinical criteria. This approach not only guarantees the efficiency and safety of medical equipment but also optimizes the clinic's financial and operational resources to maintain high standards of quality in healthcare services and adapt to the changing needs of the clinical environment.

A4: CE Information Systems II

Major Medical Equipment Dashboard: An Analytical Model for Technology Governance in Healthcare

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In today's healthcare landscape—marked by increasing pressure on system sustainability and a growing need for advanced decision-support tools—developing analytical solutions capable of integrating and enhancing available information has become essential, particularly in the field of medical technology. In this context, the Major Medical Equipment Dashboard was developed through a collaboration between the Lombardy Region and ARIA S.p.A. Its primary goal is to provide a structured, interactive, and dynamic representation of the distribution, utilization, and associated costs of key healthcare technologies included in the National NSIS (New Health Information System) data flows, across both public and private facilities in the Region. The development of the Dashboard was based on a complex process of integration and reconciliation of multiple regional administrative data sources. Specifically, it draws on outpatient service data (NSIS flow 28SAN), emergency department records, and Scheda di Dimissione Ospedaliera (SDO, hospital discharge data), with a particular focus on robotic surgery procedures. The reconciliation of clinical activities with medical equipment was made possible through a meticulous review and alignment of healthcare facility registries within the NSIS system. The association between recorded healthcare services and inventoried equipment was achieved through an algorithm using key relational variables such as facility code, technology type, and year of service delivery. Where direct matches were not found, a fallback mechanism was implemented to trace the relevant hospital

code, ensuring maximum reliability in data linking. Functionally, the Dashboard offers a multi-level view of technology utilization dynamics. Through georeferenced visualizations and interactive tools, users can explore the geographical distribution of equipment, volumes of associated procedures, incurred expenditures, and patterns of intra- and inter-facility patient mobility. Additionally, the system measures the attractiveness of individual healthcare facilities based on the origin of patients accessing high-tech services, helping to identify areas of polarization and potential imbalance in service provision. Despite its potential, the implementation process revealed some structural limitations—primarily related to the constraints of the NSIS system in capturing information on major medical technologies. Key future challenges will be to include accurate mapping of equipment to its actual place of use, proper management of decommissioned devices within the data stream, and comprehensive representation of private hospital activity. In addition, the lack of systematic tracking of technology use during inpatient stays is a significant analytical gap. The Major Medical Equipment Dashboard represents a meaningful step forward in healthcare technology governance. It serves not only as a monitoring tool for administrative bodies, but also as a strategic decision-support system. By offering a replicable model for leveraging administrative data flows, it supports regional planning, investment prioritization, and the evaluation of equity and efficiency in the allocation of technological resources—ultimately enabling more informed and strategic decision-making.

A4: CE Information Systems II

Implementation of a Unified Medical Equipment Management and Vigilance System in Greece

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During the last decades, medical technology has become a key factor in all modern healthcare delivery systems. However, the WHO 2022 Global Atlas of Medical Devices shows that most countries worldwide do not have a central national medical equipment (ME) inventory and Medical Equipment Management Software (MEMS). The Institute of Biomedical Technology (INBIT) has undertaken a pivotal role in the Unified MEMS section of a broader National Digital Transformation Project in the Greek Healthcare System, supervised by the Social Security e-Governance (IDIKA). The scope of this project includes all 128 Hospitals of Greece's public healthcare sector, intended to be fully functional during 2026. This project's main pillars are a National Medical Equipment inventory, a MEMS, and a Vigilance system. For the Inventorying, three Working Groups of Biomedical Engineers have been assembled and trained, based in different regions for maximum geographic coverage. The inventorying process implemented is an adaptation of other regional projects that have been completed in the past, adapted for a nationwide scale. It includes the creation of an Electronic Record for each individual machine performed on a room-by-room basis, where each machine is labelled with a unique national ID and QR tag that will be used throughout its lifecycle. A photographic record of every device is also created, including the manufacturer's label, UDI, and a full photo. Other data, such as the acquisition method, operating status, department/ area of installation, are registered in collaboration with the hospital staff. As of the time of writing, 65,000 devices have been registered in 52 Hospitals. For the data entry, an AI-assisted method is incorporated for the assignment of model, manufacturer, and Global/ European Medical Device Nomenclature (GMDN/ EMDN) groups, as the data are fed to the web-Praxis MEMS. Web-Praxis is in line with WHO's technical series on medical equipment inventory management and Computerized maintenance management systems, and will be used nationwide to streamline and facilitate Clinical Engineering activities. Each device QR tag can be scanned using a smartphone app to view existing details, register new ME, and report failures by the staff. In the bigger picture, the implementation of a Unified MEMS across Greece's public healthcare sector marks a significant step toward improving national ME practices. Finally, a Vigilance section will be included in the MEMS web-Praxis, notifying its users about recalls and safety notices published in the EUDAMED vigilance module, after its launch. Furthermore, in collaboration with the National Organization of Drugs and Medicine (EOF), Greece's Competent Authority, an electronic ME adverse event report page can be incorporated in web-Praxis. Taking advantage of digital transformation, this initiative enhances ME traceability, lifecycle management, and overall healthcare efficiency and user safety through the creation of various national databases. The outcomes will provide valuable insights into future large-scale healthcare improvements that rely on evidence-based decisions, such as centralized

contracts, homogenized maintenance practices, and equipment redistribution, and are expected to positively impact productivity, financial planning, regulatory compliance, and ultimately patient care.

A4: CE Information Systems II

Digital Transformation of Medical Equipment Budget Management for High-Quality Development in Public Hospitals

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Background: The pursuit of high-quality development in public hospitals necessitates refined and efficient medical equipment budget management, a core material foundation. Traditional extensive management models are inadequate for cost control and performance evaluation. To address this, leveraging information technology to build intelligent management systems is essential. These systems must integrate planning with budgeting, enable full-process monitoring and dynamic analysis, and ultimately enhance operational efficiency and optimize resource allocation. **Problems:** Current IT development for medical equipment budget management faces significant limitations: (1) Imbalances between procurement and maintenance management, combined with inadequate monitoring of budget execution and fragmented operational data, hinder real-time cost-efficiency analysis and multi-dimensional performance evaluation; (2) Lack of standardized, forward-looking budget reserve mechanisms and systematic long-term project planning compromises the continuity and scientific basis of resource allocation; (3) Significant system heterogeneity and data silos exist, with low integration and inconsistent data standards among core systems such as Equipment Management, Procurement, Financial Accounting, Hospital Information System (HIS), and Hospital Resource Planning (HRP), impeding effective data sharing and automated monitoring/analysis. **Solutions:** This study proposes a three-pronged strategy: (1) Enhance lifecycle cost control and collaborative governance by defining departmental responsibilities, integrating heterogeneous data sources, and establishing analytical platforms for real-time monitoring; (2) Establish a standardized, forward-looking budget project reserve pool with dynamic management; (3) Promote deep system integration via unified data standards and interface specifications, establishing a closed-loop management system encompassing "budget formulation–procurement–payment–performance analysis" to enable intelligent decision support. **Conclusion:** Digital transformation of medical equipment budget management is crucial for achieving high-quality development in public hospitals. A system built on "lifecycle management" and "data-driven" principles enhances scientific resource allocation, supports clinical and research innovation, and mitigates operational risks.

A4: CE Information Systems II

Information System for the Evaluation and Prioritization of Biomedical Equipment Renewal

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This study explores the implementation of an information system designed to objectively assess and prioritize the renewal

of biomedical equipment, aiming to strengthen the strategic planning of technical investments in hospitals. To achieve this goal, we adopted a data-oriented and multicriteria approach, comprising the creation of a database gathering technical (age, breakdowns, maintenance, cost), clinical (usage rate, functional criticality), and economic (residual value, replacement cost) information, as well as the definition of a weighted scoring model based on multicriteria analysis. A user interface was developed to visualize renewal priorities. The results demonstrated that this system allowed equipment to be ranked according to its strategic value and technical obsolescence with a higher level of consistency than traditional empirical methods, suggesting that evaluation supported by a decision-making tool enhances transparency and rigor in investment decisions. Moreover, further observations revealed that the system could highlight underutilized or overvalued equipment, thus helping to optimize the reallocation of technical resources within the hospital. These findings have significant implications for biomedical departments, equipment committees, and hospital planners by providing objective, traceable, and justifiable support for budget decisions related to medical equipment renewal. In conclusion, this study presents an effective decision-making tool to guide equipment renewal policies, emphasizing the impact of digitalization on the strategic management of hospital biomedical assets. Future research could integrate data from IoT (device sensors) or combine the model with multi-year budget forecasts for dynamic long-term planning.

A5: CE Service Delivery II

Revolutionizing Healthcare Technology Management by Harnessing 3D Printing Solutions

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The integration of 3D printing technology into healthcare technology management (HTM) has revolutionized medical device maintenance, significantly improving cost efficiency and operational workflows. This paper explores the establishment, implementation, and outcomes of a 3D printing lab within the Healthcare Technology Management Department at the Ministry of National Guard - Health Affairs (MNGHA) in Saudi Arabia. Beginning with the lab's inception in March 2024, the study details the preparatory phases, including 3D printer procurement, staff training, and documentation development. By August 2024, the lab commenced operations, achieving significant milestones in cost and time reduction. Over eight months, the lab completed 33 orders with a 94.75% completion rate, reducing costs by 98.04% (from 400,123.51 SAR to 7,870.14 SAR) relative to traditional manufacturing costs and achieving a 91.12% reduction in medical device downtime compared to traditional vendor methods. The paper further examines the lab's applications in clinical, educational, and engineering domains, its compliance with regulatory standards, and future expansion plans. The findings underscore the transformative potential of 3D printing in healthcare technology management, underscoring its critical role in optimizing patient care, enhancing operational efficiency, and driving innovation within the HTM sector.
Conclusion: The NGHA-HTM 3D Printing Unit has proven that in-house 3D printing is not only viable but strategically advantageous in healthcare settings. It enables personalized, faster, and more affordable solutions while enhancing operational resilience. The unit is now on track to seek formal accreditation and expand services across all clinical and research domains. This model can be adapted by HTM departments globally to bridge procurement gaps and optimize device lifecycle management.

A5: CE Service Delivery II

Spare Part Availability Management Strategy, Healthcare Technology Management (HTM) at King Saud Medical City (KSMC) Experience

By Mohammed Alghannam*

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Background: King Saud Medical City, the first hospital established in the Kingdom of Saudi Arabia in 1956, continues to lead through innovation and operational excellence. The Executive Administration for Healthcare Technology Management at King Saud Medical City has undertaken a groundbreaking initiative to enhance the efficiency and responsiveness of medical device maintenance. **Aim and Objectives:** This strategic project involved the meticulous analysis and classification of spare part consumption trends across a wide range of medical equipment within the hospital, aiming to identify high-usage components and streamline their procurement and availability. Methodology: Analysis of the most frequently consumed spare parts over two years, along with classification of spare parts consumption trends. The classification was followed by establishing a centralized warehouse of pre-stocked inventory for essential spare parts. The average equipment turnaround time prior to and after the intervention, and to measure the difference and the intervention impact. **Result:** As a result of this study, the first dedicated Spare Parts Warehouse in the history of King Saud Medical City was established under the executive administration. This warehouse now serves as a centralized, pre-stocked inventory for essential spare parts, significantly reducing downtime for critical medical devices. Previously, the average turnaround time for equipment repair was approximately 31 days due to delays in sourcing and acquiring spare parts. Following the implementation of the new warehouse model, the response time has drastically improved, with the average repair cycle now reduced to just 6 days. **Conclusion:** This achievement marks a major operational shift and reinforces the hospital's capability to deliver timely and uninterrupted healthcare services. The new system allows for immediate response once a work order is issued by clinical departments, as the required components are readily accessible, eliminating the previous logistical lag. This initiative has contributed to the hospital's successful attainment of multiple international accreditations, including ISO 9001 for Quality Management Systems, ISO 13485 for Medical Devices Quality Management, and the prestigious ECRI accreditation for healthcare technology management and patient safety. This project stands as a model for proactive asset management and operational innovation, setting a new national benchmark in healthcare technology maintenance and readiness.

A5: CE Service Delivery II

Optimizing Radiotherapy Services at CREO Through Internal Staff Engagement in Linear Accelerator Maintenance

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The Centro Renal y Oncológico Docente (CREO), affiliated with Universidad Peruana Cayetano Heredia, plays a vital role in delivering specialized oncological care in northern Lima. However, its radiotherapy unit has experienced significant service interruptions due to limited internal engagement in the technical management of its linear accelerator. This issue stems from an overreliance on a full-service maintenance contract with external providers, leading to reduced internal autonomy, weak incident documentation, and the absence of a structured system for equipment traceability and performance monitoring. This project identifies key gaps in the current maintenance approach: lack of real-time control over spare parts inventory, nonexistence of historical records of technical incidents, and limited familiarity among in-house staff with key maintenance indicators such as MTTR and MTBF. Additionally, the linear accelerator is not integrated with digital monitoring platforms, and the clinic lacks a centralized system for technical information management—forcing reliance on isolated records and delaying decision-making. To address these limitations, we propose a strategic shift toward empowering CREO's biomedical and technical personnel. The initiative includes implementing local logging systems for technical interventions, developing preventive maintenance routines, and training staff in performance monitoring tools. These measures aim to reduce equipment downtime, improve treatment continuity for oncology patients, and enhance the responsiveness of the radiotherapy service. Ultimately, this intervention seeks to strengthen CREO's institutional autonomy and lay the foundation for a Clinical Engineering framework that ensures the sustainability, efficiency, and quality of high-complexity biomedical equipment. By transitioning from reactive to proactive management, CREO can serve as a model for similar health institutions in low-resource settings facing technological and operational constraints in cancer care.

A5: CE Service Delivery II

Issue of Laboratory Equipment Maintenance at the University of Abomey-Calavi

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This study explores the challenges related to laboratory equipment maintenance at the University of Abomey-Calavi, with the aim of identifying factors hindering proper operation and proposing sustainable solutions. To achieve this objective, we adopted a qualitative and descriptive approach, including field surveys, semi-structured interviews with laboratory managers, and a documentary analysis of scientific equipment management policies. The findings revealed that most laboratory equipment suffers from a lack of preventive maintenance, a shortage of qualified maintenance personnel, and insufficient budget allocation. This indicates that the current maintenance strategy is ineffective and compromises the quality of teaching and scientific research. Furthermore, additional observations showed that many faulty pieces of equipment remain unused for extended periods due to the absence of diagnostics or the unavailability of spare parts locally. These findings have significant implications for the university's scientific asset management policy, highlighting the need for a structured institutional framework for equipment maintenance and valorization. In conclusion, this study provides a critical overview of maintenance practices at UAC, underlining the importance of training specialized technicians and developing a sustainable equipment management plan. Future research could explore the feasibility of public-private partnerships for maintenance services.

A6: CE Data & AI

Towards CMMS 4.0: Digital Transformation of Biomedical Services in Hospital Settings

By Houessouvo C. Roland[1,3], Kinnouezan A. Chams Deen[2,3,*], Idrissou A. Y. Moubarack[2,3], Jossou R. Thierry[1,3], Pecchia Leandro[4], Medenou Daton[1,3]

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This study explores the digital transformation of biomedical services in hospital environments, moving towards CMMS 4.0, with the aim of modernizing maintenance practices, improving traceability, automating decision-making processes, and strengthening interoperability with other hospital systems. To achieve this objective, we adopted a systemic and technological approach, including a comparative analysis of existing CMMS systems, interviews with hospital technicians and engineers, mapping of maintenance workflows, identification of unmet digital needs, and the proposal of a target model integrating IoT, AI, cloud computing, and mobility. The results showed that integrating connected devices and predictive analytics algorithms into the CMMS led to an average 25% reduction in unplanned

interventions and a significant improvement in the availability of critical equipment, suggesting that CMMS 4.0 represents a strategic advancement for care continuity. Furthermore, additional observations revealed that the main obstacles to this transformation are organizational (resistance to change, insufficient training) and technical (isolated systems, lack of APIs), requiring adapted change management and the adoption of open, modular technologies. These findings have significant implications for hospital technical management and IT decision-makers, as they lay the foundation for a more agile, connected, and resilient biomedical engineering, aligned with smart hospital standards. In conclusion, this study presents a roadmap towards hospital-level CMMS 4.0, highlighting the importance of strategic alignment between digital tools, technical teams, and clinical requirements in modernizing biomedical maintenance. Future research could pilot the deployment of CMMS 4.0 in one or more institutions, integrate cybersecurity aspects, or develop intelligent dashboards for real-time monitoring of medical equipment status.

A6: CE Data & AI

Intelligent Decision Support Systems for Hospital Technical Management

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This study explores the design and implementation of intelligent decision support systems (IDSS) applied to hospital technical management, particularly in biomedical and maintenance services, with the aim of facilitating strategic and operational decision-making based on data, optimizing resource allocation, and improving the availability of medical equipment. To achieve this objective, we adopted a decision system and algorithmic modeling-oriented approach, including the structuring of a centralized database (sourced from CMMS, IoT sensors, and intervention logs), the development of dynamic dashboards, the integration of rule engines, and the use of multicriteria decision-making algorithms (AHP, decision trees, Bayesian networks). The results demonstrated that the proposed system reduced critical intervention decision times by 30 to 40% and improved the responsiveness of the technical department, suggesting that data-driven intelligent tools provide a measurable strategic advantage in hospital management. Additionally, further observations revealed that combining technical indicators (mean time to repair, failure rate) with clinical priorities (equipment criticality level) enabled more accurate and efficient prioritization of interventions. These findings have significant implications for hospital technical departments and biomedical engineers, by introducing transparent, adaptive, and interoperable digital decision support tools that can integrate with existing hospital information systems (HIS, ERP, CMMS). In conclusion, this study presents a functional prototype of an IDSS for hospital technical services, emphasizing the importance of digitizing decision-making processes to continuously improve maintenance quality and patient care safety. Future research could integrate AI modules for dynamic resource optimization, assess real-world impact on hospital staff satisfaction, or extend the approach to other technical departments (energy, hygiene, logistics).

A6: CE Data & AI

Development of an Intelligent Mobile Application for Visual Inventory of Biomedical Equipment and Hospital Furniture

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This study explores the development of an intelligent mobile application designed to automate the inventory of biomedical equipment and hospital furniture using photographs and visual recognition powered by artificial intelligence, aiming to simplify and accelerate the inventory process in healthcare facilities, which is often carried out manually and laboriously. To achieve this objective, we adopted a computer vision-based approach involving the collection of annotated images of biomedical equipment and furniture, the training of an object recognition and classification model, and the integration of an AI engine into a mobile application. The results demonstrated that the model can recognize, with a high degree of accuracy (> 90%), several types of common equipment (ECG machines, autoclaves, syringe pumps) as well as hospital furniture (tables, chairs, benches), with the ability to distinguish materials (wood, metal, plastic). This suggests that such a tool can significantly reduce the time spent on inventories while improving traceability. Furthermore, additional observations revealed that the system can be progressively enriched, with new object classes added by users, and can function offline in low-connectivity environments. The database of collected information could also be synchronized with a Computerized Maintenance Management System (CMMS). These findings have significant implications for the management of hospital equipment, particularly in developing countries, by facilitating the oversight of technical platforms and budget planning through better knowledge of available assets. In conclusion, this study presents an innovative solution adapted to hospital realities, enhancing operational efficiency while supporting the digital transformation of the biomedical sector. Future research may focus on expanding the image database, adding functionality for detecting the operational status of equipment, and integrating with automated procurement systems.

A6: CE Data & AI

Contribution of Artificial Intelligence to the Maintenance of Laboratory Equipment at the University of Abomey-Calavi

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This study explores the potential contribution of artificial intelligence (AI) to enhancing the maintenance of laboratory equipment at the University of Abomey-Calavi, with the goal of proposing an innovative technological solution to address current deficiencies in the maintenance system. To achieve this goal, an exploratory approach was adopted, combining an analysis of current maintenance practices, a review of applicable AI algorithms, and a feasibility study on the integration of IoT sensors for real-time monitoring. The results showed that the equipment suffers from a lack of systematic monitoring, which leads to costly failures. The introduction of AI systems could enable predictive maintenance by anticipating failures based on collected data and facilitating remote diagnostics. This suggests that AI offers a sustainable and efficient alternative to enhance the availability and longevity of equipment. Furthermore, the study reveals that implementing AI-based solutions requires an initial investment in digital infrastructure and training, but holds strong potential for medium-term return on investment. These findings have significant implications for the modernization of scientific management

practices at UAC and can serve as a model for other African institutions facing similar challenges. In conclusion, this study highlights the opportunities offered by AI to transform laboratory equipment maintenance, emphasizing the importance of strong institutional commitment to the adoption of such technologies. Future research could focus on the development of intelligent assistant prototypes for technical management or on collaborative platforms for automated diagnostics between universities.

A6: CE Data & AI

Development of a Web-Based System for Structuring and Managing

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This research paper addresses the issue of medical technology maintenance management at the Cayetano Heredia Medical Clinic (Clínica Médica Cayetano Heredia, CMCH). It highlights the importance of this management for the overall functionality of hospitals and the problems that can arise due to suboptimal maintenance practices. In this case, the lack of specialized software at CMCH is what motivates the research. In this regard, the main objective of this research is to develop a web-based system that allows for the efficient recording, consultation, and structuring of technical data on medical equipment, including inventory, historical events, and maintenance schedules.
The methodology was structured by combining the Guidance and Impact Tracking System (GAITS) methodology and the VDI 2206 guideline (Design methodology for mechatronic systems) published by the German Association of Engineers (VDI). First, interviews were conducted with technical staff to determine the functional requirements of the system. Subsequently, a user-centered interface was designed, prioritizing ease of use and clarity in data entry. Then, a web application was developed using ReactJS for the frontend, Spring Boot for the backend, and MySQL as the database management system, implementing a distributed architecture between two VPS servers. Finally, the system was validated quantitatively, technically, and functionally.
The results showed that the system obtained an average score of 89.06 points in the Usability Metric for User Experience (UMUX) survey out of a maximum of 100, indicating a high level of perceived usability, with moderate variability among users, having a standard deviation of 10.89 and an estimated 90% probability that new users would also perceive it as usable. On the other hand, technical validation was performed by verifying compliance with the established requirements. Functional validation was completed through analysis of data migrated from spreadsheets
In addition to meeting technical requirements, the research has a real impact by offering a tailor-made solution that improves efficiency in the area, reduces human error, and paves the way for future data-driven decision-making. The developed system represents a useful and viable tool that substantially improves the organization of technical information in the CMCH's medical equipment area. Its modular and adaptable design lays the foundation for future expansions aimed at more comprehensive and digitized clinical management. Its importance lies in addressing a specific need within the local clinic environment. Therefore, it has the potential to be replicated in similar institutions facing similar problems. Finally, this project also represents a tool of practical value that can contribute to the improvement of hospital management.

A6: CE Data & AI

Artificial Intelligence to Support Clinical Engineering CMMS for Automated Programming of Maintenance and Replacement Plans for the Equipment Fleet

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The incessant increase in management costs, the increase in complexity and heterogeneity of equipment, and the growing pressure to increase productivity trigger tangible tensions that also reverberate on CMMS maintenance management systems, for better planning of maintenance and replacement of the company's fleet of machines. AI emerges as a key tool to enhance operational efficiency, automate routine tasks, reduce costs, and assist professionals in their decision-making process. An AI-based pilot system was deployed on machine data collected through two different management software programs for biomedical equipment operating at the Milan facilities of ASST Fatebenefratelli-Sacco and Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico. The AI in question is expected to autonomously generate strategic maintenance plans for Clinical Engineering professionals based on detailed reports on device malfunction. To achieve this, the AI adopts a discerning approach, prioritizing maintenance based on specific information and a set of key performance indicators (KPIs). The use of AI extends to the formulation of plans for the replacement of tools and technological modernization, following the logic of the "Disinvestment for Investment" type. The scalability of the system, thus conceived therefore allows the implementation in a wide spectrum of healthcare contexts.

A7: CE General Management II

Comprehensive Strategies in Biomedical Metrology Focused on Patient Safety

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Description: Clínica Imbanaco implemented a Comprehensive Metrological Risk Management Module (CMRMM) in its in-house biomedical metrology laboratory at a high-complexity institution in Santiago de Cali. This initiative emerged from the need to optimize preventive and predictive maintenance for biomedical equipment, which is critical for ensuring patient safety. Based on the ISO/IEC 17025:2017 standard, the project established systematic conformity verification procedures through technical analysis, internal audits, and continuous training for specialized staff.
The CMRMM is structured around several strategic pillars:
Standardization of protocols and procedures: Calibration methodologies were updated in line with international best practices, thereby strengthening traceability and documentation. This approach creates a technical history that facilitates monitoring, measurement precision, and overall process efficiency.
Periodic Internal Audits: A rigorous program of monthly internal audits was introduced to identify potential deviations or equipment failures in real time. These audits help maintain high-quality standards in the operation of medical technology.
Assurance of Result Validity: The initiative ensured result validity by incorporating participation in proficiency tests, stability studies, calibration of retained items, control chart analysis, and both intra- and inter-laboratory comparisons. These measures significantly enhance the accuracy and reliability of measurements.
Continuous Training of Technical Staff: Continuous training of technical staff has been prioritized through workshops and regular update sessions on calibration standards and techniques, along with establishing a direct communication channel between the metrology laboratory and the clinical areas to ensure prompt feedback on any equipment anomalies.
These actions have yielded significant improvements in medical care. For example, a 70% reduction in user errors related to calibration mistakes has been observed, leading to more precise diagnoses and treatments. By ensuring the validity of results, the laboratory has reduced measurement uncertainty and variability, allowing for rapid detection and correction of deviations in medical equipment. Moreover, optimizing internal processes has accelerated the compliance declaration time for medical technology from five days to one day, facilitating faster responses in emergencies. Improved organization and internal control have also resulted in an estimated 35% reduction in operating costs compared to the high expenses incurred with external calibration services. Presently, the metrology laboratory is accredited for measuring pressure, mass, temperature, and relative humidity. This accreditation enhances the clinic's prestige, demonstrating a strong commitment to international quality standards and corporate excellence, thereby fostering greater trust among healthcare professionals and patients. **Conclusions:** In conclusion, the implementation of the CMRMM has transformed the management and execution of calibrations within our high-complexity clinic. Continuous standardization efforts have resulted in a robust, proactive

system based on proven methodologies and a dedicated technical team. The outcomes are a 70% reduction in calibration errors, faster compliance declarations, and a 35% decrease in operating costs directly benefit patient safety. These results demonstrate that ensuring precise and reliable measurements through rigorous validation activities is essential for delivering high-quality diagnoses and treatments. Furthermore, attaining in-house accreditation has yielded substantial cost savings compared to previous external service contracts.

A7: CE General Management II

Developing a MCDM Tool for the Comparative Assessment of Medical Devices

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Selecting medical devices within healthcare institutions is inherently complex, as it requires the simultaneous evaluation of multiple criteria such as clinical efficacy, cost, durability, and ease of use. Relying on a single Multi-Criteria Decision-Making (MCDM) approach can leave a degree of uncertainty regarding recommendation robustness. To address this, we developed an interactive, MATLAB-based tool integrating multiple MCDM weighting and ranking methods, enabling rapid and parallel comparisons.

We applied this tool to two published case studies, the first evaluating five mechanical ventilators and the second assessing seven ultrasound machines. Our application reproduced both case studies' original recommendations accurately when inputting reported criteria and subjectively chosen weights. However, employing statistical, objective weighting methods like CRITIC and ENTROPY altered the recommended ventilator, indicating that the way weights are derived can influence the results. In contrast, the top-ranked ultrasound device remained consistent across all weighting methods when combined with the ranking approaches used in the case study, reflecting the recommended device's dominance in most criteria. The tool also highlights the inconsistencies between different ranking methodologies; algorithms based on the "ideal solution" principle (e.g., TOPSIS, ELECTRE, PROMETHEE) favor options that excel distinctly in specific criteria, whereas compromise-seeking approaches like VIKOR prioritize alternatives that do not have criteria with deep vulnerabilities. Presenting results from multiple perspectives allows stakeholders to assess the sensitivity of recommendations when different weighting or ranking methods are employed. By integrating multiple MCDM methods into a single user-friendly platform, this work significantly reduces decision-making uncertainty and rapidly provides practical insights.

A7: CE General Management II

Technology Observatories as a Supporting Tool for Health Technology Management

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Background/Objectives: The increasing complexity of healthcare systems, combined with the rapid evolution of medical technologies, has intensified the need for evidence-based decision-making. In this context, health observatories have emerged as strategic instruments to organize, analyze, and disseminate qualified information that supports public policy, planning, and management. These platforms vary in scope and structure but commonly aim to monitor indicators, conduct health surveillance, and guide decision-making processes. This study aims to map and analyze international experiences with health observatories, identifying their institutional models, objectives, and contributions. Additionally,

it proposes the application of observatories as tools to support Health Technology Management (HTM). **Methods:** A rapid literature review was conducted, following methodological guidelines provided by the Brazilian Ministry of Health (2021) and the PRISMA (Preferred Reporting Items for Systematic reviews and Meta-Analyses) statement. Searches were performed in the PubMed and SciELO databases using the keywords "health observatory" and "technological observatory in health". Studies were selected based on relevance, full-text availability, and thematic pertinence. The screening process included title and abstract review, followed by full-text reading. A total of 18 studies were selected, focusing on institutional arrangements, governance structures, geographical scope, and their impact on decision-making and management health strategies. **Results:** The results highlight a wide diversity of health observatory models, shaped by institutional arrangements and regional priorities. Some observatories are dedicated to themes such as human resources, epidemiological surveillance, or health system performance, while others operate across multiple areas, integrating technical, normative, and operational data. Their focus and scope vary according to national needs. Globally, organizations like the World Health Organization (WHO) coordinate observatories that compile essential health statistics to support public decision-making. Despite their potential, common challenges were identified, including data fragmentation, lack of standardization, limited infrastructure, and weak intersectoral coordination. These issues occur even in high-income countries, suggesting that observatory effectiveness depends more on institutional and technical capacity than economic development. Successful experiences also highlight the importance of engaging users, professionals, and communities in the use of health information. **Conclusion:** Based on the findings, the study proposes that health observatories can be effectively applied to support HTM as integrated platforms for technical, regulatory, and operational information. These observatories could contribute across all stages of the health technology lifecycle, prior to assessment, planning, acquisition, implementation, monitoring, and even decommissioning, while also supporting professional and user training. Aligned with the HTM model developed by the Biomedical Engineering Institute of the Federal University of Santa Catarina (IEB-UFSC), which is structured around the pillars of infrastructure, human resources, and technology, observatories could help systematize evidence, technical requirements, safety protocols, performance indicators, and real-world data. Future perspectives include the development of case studies, practical validation in healthcare services, and articulation with public policies on technological innovation.

A7: CE General Management II

Guide to the Strategic and Responsible Management of Medical Equipment

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Summary: The "Guide for the Strategic and Responsible Management of Medical Equipment" (2025) by the Spanish Society of Electromedicine and Clinical Engineering (Sociedad Española de Electromedicina e Ingeniería Clínica, SEEIC) offers a comprehensive framework to optimize the life cycle management of medical equipment in healthcare settings. It emphasizes responsible and strategic management to increase value beyond monetary terms, including diagnostic effectiveness, safety, and sustainability. The guide addresses global inefficiencies, noting that between 40% and 70% of medical equipment in certain countries is underutilized or non-operational. **Introduction:** The guide is inspired by the transformative role of medical technology in modern healthcare and the deficiencies identified in medical equipment management, especially in Spain, while reviewing models developed in other parts of the world, particularly the Australian model. It focuses on Non-Implantable Active Medical Devices (Producto Sanitario Activo No Implantable, PSANI), regulated by the Spanish standard UNE 209001:2002 IN, and leverages the UNE-ISO 55000 standard to propose a systematic approach for managing these assets—from planning to disposal—driven by the need to align resource use with health outcomes and social expectations. **Methodology:** The document synthesizes 221 bibliographic references, citing 81 of them, including several global systematic reviews and guidelines that justify the document's subsequent development. It proposes a Medical Equipment Management System (Sistema de gestión de equipos medicos, SIGEM) with five phases: inventory data acquisition, replacement planning, asset incorporation (via a decision-making algorithm), operation/maintenance, and disposal. Qualitative and financial analyses, stakeholder collaboration, and life cycle cost assessments are central to the methodology. It also proposes an implementation model for SIGEM, providing various tools

such as synthetic technical-economic values (valores sintéticos técnico-económicos, VSE), healthcare values (valores sanitarios, VSA), and political-social values (valores político-sociales, VPS) to guide acquisition decisions, along with evaluation models from the state of Victoria, Australia, to assess proper equipment operation and maintenance. Moreover, it stresses that medical equipment management must be strategic—implicating governments and political leadership—and responsible, considering economic, social, and environmental perspectives. Evaluation and **Results:** The guide proposes validating its hypotheses through a structured approach, introducing a set of variables aligned with cost, financial dimension, clinical effectiveness, resource efficiency, accountability, equity, and sustainability. The results suggest that strategic management can maximize the useful life and effectiveness of equipment, avoid wasting costly resources, return part of the value of taxes or investments to society or stakeholders, reduce environmental impact, and improve health outcomes. However, it highlights the lack of direct studies linking medical equipment to health outcomes in Spain, advocating for further research and alignment.

A7: CE General Management II

Proposition on Hospital Asset Management: An Electronic Solution to Prevent Loss of Portable Equipment

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This project introduces an innovative and cost-effective electronic solution to mitigate the chronic loss of portable medical equipment in healthcare environments. By integrating a low-cost alert circuit programmed to activate after a predefined period, the system provides a proactive reminder to healthcare teams, ensuring assets are returned to their designated base. The technology assessment demonstrates a significant positive impact, with a projected 90% reduction in equipment loss, resulting in substantial cost savings and enhanced operational efficiency. As a practical and scalable innovation, this solution offers a powerful model for effective asset management, proving especially valuable for optimizing resources in resource-scarce settings.

B1: HT Innovation & Impact

Innovative Trial Designs Using Tele-Holter Monitor to Meet Global Cardiovascular Risk Screening Demands

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Introduction: This study aims to improve the screening capacity and follow-up of the treatment of patients with symptoms that may be heart-rhythm related in public hospitals without cardiology services. To this end, it is proposed to use the Holter Monitor device with telemedicine tools to identify irregular heartbeats or palpitations during 24 hours. This is intended to anticipate cardiovascular events and carry out the appropriate interventions to avoid them. The ideal goal would be to diagnose and treat any abnormal heartbeats or rhythms that may be causing symptoms like chest pain, tiredness, shortness of breath, dizziness, or fainting through technological innovation that improves accessibility and universal coverage. We consider that the Teleholter method is particularly relevant in Paraguay for the screening, follow-up, and control of heart-rhythm related symptoms to meet the demands at the national level. **Methods:** This is a multicenter descriptive observational feasibility study, where 1,449 records of the electrical activity of the heart over 24 hours were collected between August 2023 and November 2024. The register of heartbeats or rhythms was obtained remotely with a Holter monitor connected to a telemedicine platform. Subsequently, a team of cardiologists

evaluated the results to determine the feasibility of the diagnosis and management of abnormal heartbeats or rhythms in remote patients. Electronic heartbeats or rhythms, register, and diagnostic results were sent via a telemedicine platform. **Results:** The remote study of 1,449 patients with symptoms that may be heart-rhythm related was conducted in 13 hospitals nationwide. Most patients were between 50 and 59 years old, followed by the 60–69 and 70–79 age groups. The mean age was 51.0 years; 60.2% were female. The main findings were atrial extrasystole and atrial tachycardia (35.9%), normal (26.1%) supraventricular extrasístole and ventricular extrasystole (21.4%), ventricular extrasystole (8.2%), atrial fibrillation (1.1%), and supraventricular tachycardia (1.1%). An average of 53% adherence to treatment was determined among patients diagnosed with abnormal rhythms. **Conclusions:** Our results suggest that it is feasible to use this disruptive technological innovation for the development of a remote resilient capacity for the diagnosis of patients with symptoms that may be heart-rhythm related through a Holter monitor and telemedicine platform in public hospitals without cardiology services in Paraguay. As healthcare tech evolves, the Teleholter shapes the development of powerful strategies for heart's electrical pattern screening over a period of 24 to 48 hours. This test can help by showing any abnormal rhythms, heart rate, or missed beats (palpitations).

B1: HT Innovation & Impact

Technological Advancements in Rapid Diagnostic Testing: Introducing the Quantitative Rapid Diagnostic Test (qRDT)

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This paper describes the advantages of using Rapid Diagnostic Reader on Rapid Diagnostic Tests and introduces the concept of Universal Quantifiable Units, emphasizing the technological innovation and potential of the Rapid Diagnostic Reader (RDR) in overcoming existing challenges in RDTs. Technological advancements in diagnostic testing are transforming healthcare by enabling faster, more reliable disease detection, particularly in point-of-care (POC) and resource-limited settings1. Despite their widespread use, traditional Rapid Diagnostic Tests (RDTs) face limitations, including subjective interpretation, inconsistent results, and the absence of quantitative data. This paper introduces the Rapid Diagnostic Reader (RDR), a novel solution designed to enhance the accuracy, consistency, and interoperability of RDTs. By leveraging Quantifiable Units (QUs), the RDR standardizes result interpretation across platforms, bridging the gap between qualitative and quantitative testing. Additionally, the RDR integrates seamlessly with electronic health records (EHRs) and laboratory information management systems (LIMS), promoting data-driven clinical decisions and improved public health outcomes. This paper explores the challenges in current RDTs and demonstrates how the RDR offers a scalable, innovative pathway toward precision diagnostics.

B1: HT Innovation & Impact

Healthcare Technology Foundation—Little Steps to Big Impact

By Dan Clark*

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The Healthcare Technology Foundation (HTF) was founded on the principle that achieving improvement in the safe use of healthcare technology requires diverse stakeholders to come together to utilize their collective knowledge on the design, use, integration, and servicing of healthcare technology, systems, and devices. Initially a USA-based not-for-profit, the HTF joined GCEA post-COVID to bring its experience and expertise onto a global platform to extend the reach of its support. Now this newly merged body looks to make a significant impact on an international scale by

supporting a range of projects and initiatives.
In this presentation, we will review the background to the HTF, its ethos and purpose; we will describe the growth of the new HTF into a global player in the field of clinical engineering innovation; we will look at its structure and functions; describe how it funds projects to improve healthcare through technology, and explain the types of projects it can support. We will also discuss potential partnerships and collaborations, and appeal for participation and support, especially in terms of fundraising.
We know that all over the world, there are huge challenges facing healthcare. We know that technology is often the solution to these difficult challenges. We also know that often, small-scale projects and innovations can lead to huge patient benefits. The Healthcare Technology Foundation seeks to identify these opportunities and support through direct funding, project management support, and networking capabilities so that little steps really can deliver big impact.

B1: HT Innovation & Impact

The OntoNova Prototype for an AI-Guided Design Platform for Healthcare Innovation

By Fred Hosea[1,*], Jans Aasman[2], Michael DeBellis[3]

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OntoNova AI-Guided Design Platform
The OntoNova initiative introduces Phase 1 of a pioneering Artificial Intelligence (AI) platform engineered to transform healthcare innovation through improved design-stage intelligence. Phase 2 development aims to build a consortium of stakeholders spanning academia, government, philanthropy, and industry.
Overview, Strategic Vision
The OntoNova Stage1 prototype is an advanced knowledge-management and design guidance platform for healthcare innovators, using state-of-the-art AI technologies, leveraging neurosymbolic architecture, and integrating the explicit reasoning of semantic knowledge graphs with the adaptive power of Large Language Models (LLMs). This hybrid approach addresses critical needs for explainable, trustworthy, and actionable AI in healthcare, overcoming many limitations of siloed data and opaque machine learning systems. The OntoNova team, comprising world-class experts in AI, knowledge graphs, and healthcare innovation, demonstrates OntoNova's capacity to accelerate innovation, enhance quality, and facilitate cross-disciplinary collaboration. The long-term vision is to evolve OntoNova into a Global Health Innovation Registry and a network of Continental Innovation Hubs in WHO regions, promoting equitable access to cutting-edge healthcare solutions worldwide.
Technical Architecture, Capabilities
OntoNova is built on the award-winning AllegroGraph platform, recognized globally for its leadership in semantic web and graph knowledge-based technology, integrating:

Neurosymbolic AI: Combines knowledge graphs (for structured, explainable reasoning) with LLMs (for natural language understanding and adaptability), enabling robust, transparent decision support.
Retrieval-Augmented Generation (RAG): Allows users to interact with the platform via natural language, retrieving relevant knowledge and recommendations from the underlying knowledge graph.
Intelligent Agents: Autonomous agents provide real-time support, automate design tasks, and facilitate collaboration among innovators and experts.
User Interface: An intuitive, graphical interface supports browsing, input, feedback, and dialog, making advanced AI accessible to non-technical users.

Innovation Process and Impact
OntoNova guides healthcare innovators through a structured, AI-assisted process encompassing project registration, proposal analysis, design guidance, gap identification, exploration, partnership facilitation, prototyping, and certification. The system is structured around a comprehensive set of 36 "Critical Success Factors", ensuring that innovations align with global health priorities, regulatory requirements, and operational best practices.

Key benefits:

Accelerated Time-to-Market: Automating knowledge discovery and targeted guidance, OntoNova can reduce the time and cost required to develop and validate new medical devices and services.

Improved Quality and Compliance: The platform ensures that projects meet relevant international standards, regulatory mandates, and the needs of high-risk and underserved populations. Prioritizing system-lifecycle stakeholder involvement means the reduction or elimination of design errors that endanger patient safety and are costly to repair.

Collaborative Ecosystem: OntoNova's open knowledge graph fosters collaboration among innovators, researchers, and industry partners, breaking down traditional silos in healthcare innovation.

OntoNova redefines knowledge management in healthcare design, with applications across product design, service strategy, public health, and disaster management. Its roadmap includes phased expansion from a minimum viable prototype (MVP) to a robust global registry supporting thousands of use cases and stakeholders, using a hybrid model of sponsorship, intellectual property, and funding. OntoNova offers a future-proof, scalable solution that accelerates the development of life-saving medical technologies and sets new standards for innovation, collaboration, and equity.

B1: HT Innovation & Impact

The Impact of Different Implants on Magnetocardiography Signals

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With the increasing prevalence of population aging and chronic diseases, the use of medical implants in the human body has become increasingly common. However, there is limited research on the interference of these implants with magnetocardiography (MCG). This study aimed to assess the impact of different types of implants on MCG signals. The investigation was conducted by placing three distinct types of implants at various extracorporeal locations of participants. A magnetocardiography system was utilized for signal detection. The results indicated that orthopedic implants did not exhibit significant magnetic interference and did not substantially impact MCG signal outcomes. In contrast, certain types of intrauterine devices (IUDs) and cardiovascular implants were found to potentially induce localized signal distortion, with IUDs particularly affecting the accuracy of the final MCG readings. Our research underscores the importance of pre-screening for IUDs in MCG applications to avoid inaccurate diagnoses. Clinically, this study provides actionable guidance for interpreting MCG results in patients with implants, enhancing diagnostic reliability for the aging population with a high prevalence of such conditions. Future research should focus on quantifying artifacts associated with IUDs and developing correction algorithms to mitigate their effects. By addressing this critical gap in cardiac diagnostics, this work advances personalized medicine and supports the safer integration of implant technologies with advanced biomagnetic sensing.

B2: HT Assessment and Evaluation

Economic Analysis of New Robotic Surgical Platforms

By Paola Picozzi[1,2,*], Veronica Cimolin[1,3], Umberto Nocco[2], Silvi Federica[2], Puleo Greta[2], Chiara Labate[2]

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Over the past 20 years, robotic surgery has become increasingly widespread across surgical specialties, largely driven by the adoption of the da Vinci Surgical System (Intuitive Surgical). Despite its clinical success, the high costs associated with the technology remain a major concern. Recently, new robotic platforms—such as Hugo™ RAS (Medtronic) and Versius® (CMR Surgical)—have entered the market, aiming to offer more cost-effective alternatives. This study evaluates the direct economic impact of these new systems compared to the established da Vinci system. A retrospective cost

analysis was conducted on procedures performed at Niguarda Hospital in 2023 The study included 284 prostatectomies (200 with da Vinci, 77 with Hugo™, 7 with Versius®) and 77 partial nephrectomies (57 with da Vinci, 20 with Hugo™). The analysis considered the total cost of each robotic platform, including acquisition (rental, maintenance, and consumables), intraoperative costs (operating theatre, staff, electricity, and medications), and postoperative hospitalization. A key component of the study was the break-even analysis, designed to determine the number of procedures required for each system to become economically sustainable. A cost-effectiveness analysis was also conducted to identify the most advantageous platform in terms of value for money. Additionally, a sensitivity analysis explored the impact of variables such as maintenance costs and procedure volume on the long-term economic sustainability of each technology. The procedure duration was significantly longer with the Versius system (370.57 min) compared to da Vinci (286.23) and Hugo (302.74), directly increasing operating theatre costs: €3,751.76 for Versius, versus €3,003.88 for da Vinci and €3,117.64 for Hugo. Hospitalization and robot-related costs were similar across platforms, with slight advantages for Hugo and Versius over da Vinci. The average total cost per procedure was €7,831.71 for da Vinci, €7,867.17 for Hugo, and €8,430.77 for Versius. These differences were not statistically significant ($p = 0.09$). Break-even analysis, based on Lombardy Region DRG reimbursement rates, indicated thresholds of 165.72 procedures for da Vinci, 163.72 for Hugo, and 207.90 for Versius. As of 2023, Niguarda Hospital had likely achieved break-even with da Vinci, was approximately halfway there with Hugo, and remained far from it with Versius. These findings offer practical insights for healthcare facilities evaluating robotic platforms, emphasizing the need to consider procedure volume and cost-efficiency. Moreover, the study provides valuable guidance for policymakers and hospital administrators involved in the strategic planning and financial management of surgical technologies. In conclusion, this study contributes meaningfully to the economic evaluation of robotic surgery systems, underscoring the importance of a data-driven approach to inform the selection and adoption of technologies in healthcare settings.

B2: HT Assessment and Evaluation

Digital Twin Disruptive Development 4 Complex, Congenital Care (3D 4 3C)

By Raquel Canovas Paradell*, Laura Escot Garcia, David Viros Porcurna, Ferran Roses Noguera, Manel Escobar Amores

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The Problem: Congenital and complex pathologies exhibit significant genetic and clinical variability among patients, making it essential to tailor diagnosis and treatment to each individual's unique characteristics.
Solution: Revolutionize the current medical approach by integrating more personalized and precise diagnostic and therapeutic tools for each patient.
How: The "3D 4 3C Project" at Hospital Universitari Vall Hebron (VH) in Barcelona, Spain, aims to co-develop and adopt—through close collaboration with industry—disruptive digital solutions, such as digital twins, AI, and AR that address specific clinical challenges for individual patients.
This project will be implemented in four stages:

Stg1. Define the needs and the procurement strategy.
Stg2. Co-development of the digital twins in selected use cases.
Stg3. Co-developing personalized therapies based on the implementation of digital twins.
Stg4. Framework for adoption and scalability of digital twins.

During its first year 3D 4 3C has successfully fulfilled Stage1 goals:

Assessment of clinical needs: Identify unmet diagnostic and treatment needs in congenital and complex diseases across key medical specialties.
Market and technology maturity analysis: Evaluate the state-of-the-art in digital solutions and assess market readiness through a preliminary market consultation (PMC).
Prioritization and feasibility assessment: Prioritize use cases based on clinical impact, market maturity, scalability, and adoption potential, with expert input from clinical leads.

Contracting strategy design: Define the most suitable public-private contracting models for successful co-development, based on market readiness and development capacityj healthcare industry ecosystem by providing:

Promoting solutions that address real clinical needs.

Creating a collaborative data and innovation ecosystem to co-develop.
Enabling the adoption of digital tools in pediatric and complex conditions.
Validating and testing emerging solutions that are not yet technologically mature.

Results: In terms of clinical needs, the project has identified the specialties and pathologies with the highest potential interest based on their complexity, patient volume, expected patient benefit, and the current state or future potential of digital solutions. Identified specialties are: congenital heart disease, pediatrics, cardiology, robotic adult surgery, surgical navigation, pediatric surgery, neurovascular conditions, neurology, gynecology, and hepatology-oncology. Over 20 strategic lines have been defined, each aiming to address clinical questions related to the personalized diagnosis or treatment of a specific patient's pathology. A comprehensive review of the state of the art in technology was conducted, along with an in-depth analysis of the innovation ecosystem with more than 30 companies approached. Nine companies presented a total of 16 disruptive digital solutions directly aligned with the strategic clinical lines at PCM, launched by VH. Proposals included detailed information on the clinical area, technologies involved, TRL, and the estimated time and resources required to advance the technologies to a sufficient level of maturity.

B2: HT Assessment and Evaluation

Performance Assessment of an Oxygen Concentrator Developed in Peru: A Study Based on International Standards

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Purpose: The development and manufacturing of medical devices require a robust and standardized evaluation phase before commercialization. However, in countries like Peru, where most medical devices are imported, the lack of specific regulations limits availability and increases reliance on foreign products. Therefore, this study aims to present the performance assessment of CovOx, an oxygen concentrator developed in Peru. **Methods:** A performance assessment was established for the CovOx oxygen concentrator, based on the ISO 80601-2-69:2020, NTP-IEC-60601-1:2010, and ISO-3740:2019 standards. The study analyzes the results of visual inspection, alarm system, gas outlet temperature, acoustic pressure, stability, and electrical safety tests. **Results:** CovOx met all acceptance criteria. The maximum acoustic pressure measured was 72 dB, while the flow remained within the 10% margin of error. Oxygen concentration also stayed above 90%, meeting the required standards. **Conclusions:** This study establishes the foundation for future medical device manufacturing in countries like Peru. Through the development and validation of CovOx, this initiative enhances the potential to reduce import dependency while fostering the growth of local expertise in the medical device sector.

B2: HT Assessment and Evaluation

Medical Device Regulation in Israel: A Two-Track Strategy for Early Adoption of Innovative Medical Technologies

By Nadav Sheffer*

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Israel is considered an early adopter of innovative medical technologies, particularly in the medical device sector. The Israeli Ministry of Health (IMOH) has demonstrated the ability and has successfully implemented it to be the first regulator globally to approve patented medical devices manufactured in Israel. Section 6(a) of the Israeli Medical Devices Bill stipulates that the IMOH will not register a medical device, or approve any modification to such a device, unless it is convinced that the device is safe. This means the benefit of using the device outweighs the inherent risks (as almost all medical devices carry some degree of risk). Furthermore, the device must be effective and of the required quality for its intended

use, manufactured under proper production conditions, and its name must not be misleading regarding its properties in a way that could harm public health. These are standard requirements in leading health authorities worldwide for medical devices. Rigorously checking every medical device submitted for registration against the above conditions would demand significant human resources, time, and money. Therefore, the IMOH initiated an alternative registration pathway. The regulatory strategy embedded in the relevant section of the bill relies on approvals and oversight from recognized health authorities abroad instead of product-by-product examination in Israel. Hence, section 6(b) of the Medical Devices Bill is accompanied by a list of "recognized countries", detailed in the First Amendment to the Bill. This method reduces import costs and time to market, increases competition, and facilitates the entry of, among others, medium and small importers into the medical device market, as well as the introduction of new manufacturers and an expanded product variety. The primary goal of the described initiative in the medical device field is to facilitate the entry of advanced medical technologies into Israel. Concurrently, it aims to save the MOH's time, allowing it to dedicate its limited resources to approving innovative, patented Israeli technologies that have not yet been approved by other health authorities. In this regard, the initiative has been successful.

B2: HT Assessment and Evaluation

Consistency Evaluation of the Clinical Application Effect of Domestic and Imported Ultrasound Surgical Instrument Control Systems

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Objective: In this study, the evaluation of the clinical application effect of laparoscopic radical resection of distal gastric cancer made in China and imported after the market of ultrasound surgical instrument control system provided a reference for medical institutions to select ultrasound products, and ultimately benefited patients. **Description:** In this study, an open-label randomized non-inferiority trial design method was adopted, and 60 patients requiring laparoscopic radical gastric cancer undergoing laparoscopic radical gastric cancer surgery were selected in the Department of Gastrointestinal Surgery of our hospital according to the admission criteria, and were randomly assigned to the domestic group and the imported group in a ratio of 1:1. An evaluation system was established that included the standard surgical operation duration, the amount of blood loss under the standard surgical procedure, the drainage volume within 6 h after surgery, the drainage volume within 24 hours after surgery, the intraoperative incision and coagulation time, and the surgical field and smoke were obtained, and R software (version 4.4.1) was used for statistical analysis after obtaining real-world data. In this paper, the Shapiro-Wilk test is used to test whether the data conform to the normal distribution. If $p > 0.05$, the data is considered to be normally distributed. When $p < 0.05$, the difference between groups was considered statistically significant. In addition, the full analysis set (FAS) was used for the main analysis, and the sensitivity analysis was performed in patients younger than 70 years of age. Multiple imputation was used for data filling in the missing 5% of patients, predicted mean matching was used for continuous variables, and logistic regression was used for dichotomous variables. For continuous outcomes, an independent-samples t-test was used for comparison of differences between groups for normally distributed variables; The Mann-Whitney rank-sum test was used for comparison of differences between groups for non-normally distributed variables. For dichotomous outcomes, the chi-square test or Fisher's exact probability test was used for analysis. **Conclusions:** There was no significant difference between the domestic and imported ultrasonic therapy groups in the following indexes ($p < 0.05$), which were the duration of standard surgical operation, the amount of blood loss in the standard operation time, the drainage volume at 6 h after surgery, the drainage volume at 24 h after surgery, the number of gastrocolic ligament clotting times, the clotting time of gastrocolic ligament incision, the coagulation time of left gastric vein incision, the coagulation time of left gastric vein incision, the number of gastric wall vascular incision coagulation, the total incision and coagulation times, Total cleaved coagulation time, 24-h postoperative C-reactive protein (CRP), postoperative hospital stay, incidence of adverse events, and incidence of chyle leakage at 6 h postoperatively. There were significant differences in intraoperative visual field and smoke scores between the two groups ($p = 0.012$). The results of the sensitivity analysis

for all indicators were similar to those of the main analysis.

B3: HT Innovation - AI, Digital Twins & Machine Learning

TRFC-net: A Deep Learning Solution to Elevate Inexperienced Residents' Trochanteric Region Fracture Classification Accuracy on X-rays

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Purpose: Accurate classification of trochanteric region fractures on X-rays is crucial but comes with certain challenges for inexperienced doctors. Therefore, we built a trochanteric region fractures classification network (TRFC-net) based on deep learning algorithms to assist doctors. **Methods:** TRFC-net built three task modules for proximal femur detection, fracture image screening, and fracture classification. We used the RetinaNet object detection algorithm to detect the proximal femur region on X-ray and cropped it. After that, we used the Swin transformer classification network to screen the trochanteric region fracture images from the cropped images and subsequently classify the fracture image types. Gradient-weighted Class Activation Mapping (Grad-CAM) has been implemented to visualize the identified fracture features. To evaluate the practical performance of the TRFC-net in classification assistance, we compared the classification accuracy of three attending and resident doctors with and without using the TRFC-net. **Results:** TRFC-net achieved an overall classification accuracy of 0.902, and the F1-score reached 0.964, 0.875, 0.867, and 0.848 for non-fracture, A1, A2, and A3 classifications, respectively. Attending doctors achieved a classification accuracy of 0.939 ± 0.014, and statistically significant differences were observed between TRFC-net ($p = 0.038$) and residents ($p < 0.001$). TRFC-net exhibited a more notable impact on improving the classification accuracy of residents compared to attending doctors. Resident accuracy increased from 0.817 ± 0.013 to 0.924 ± 0.010, with the difference from attending doctors no longer statistically significant ($p = 0.361$). **Conclusion:** TRFC-net has not achieved the classification accuracy of attending doctors. However, it has effectively assisted inexperienced residents, helping them approach the attending doctors' classification level.

B3: HT Innovation - AI, Digital Twins & Machine Learning

Analysis of Ventilator Alarms Based on Machine Learning

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Objective: Applying machine learning methods to study the ventilation alarms of ventilators in clinical use, we obtain the important parameters affecting the alarms and the alarm prediction model, identify invalid alarms, and give clinical hints, so that the clinic can respond to the ventilator alarms efficiently to avoid the negative effects of alarm fatigue and other negative impacts. **Methods:** Establishment of a respiratory data management platform that conforms to standard data processes, analysis of eigenvalues based on respiratory alarm information from a single center to derive a ranking of important parameters, hyperparameter tuning modeling to predict the truth of the alarms, and validation of the machine learning model with confusion matrices and ROCs against a number of metrics. **Result:** The test set of 5936 ventilation-type alarms was evaluated, with 88% invalid alarms, 94% model accuracy, 0.92 ROC-AUC, and 0.823 F1-score. **Conclusion:** The use of machine learning facilitates clinical single-center data modeling, which can timely analyze and obtain the important parameters and alarm predictions of the real alarm of the ventilator, and through the ventilator data management platform, it can effectively prompt the clinical invalid alarms, thus reducing the pressure of the alarms on the healthcare personnel and improving the quality of medical care.

B3: HT Innovation - AI, Digital Twins & Machine Learning

A Review of Pulmonary Tuberculosis Auxiliary Diagnosis Based on Deep Learning

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Tuberculosis is one of the most common chronic infectious diseases worldwide, mainly pulmonary tuberculosis. Data from 2023 shows that there were 10.8 million new cases of tuberculosis globally, and it is also one of the key diseases under control in China. In recent years, the application of deep learning in the medical field has significantly improved the efficiency and accuracy of automatic diagnosis, providing effective tools for auxiliary diagnosis.

This article reviews the application research of deep learning in the auxiliary diagnosis of tuberculosis. Firstly, it introduces the global incidence of tuberculosis in 2023 and compares it with the growth rate in recent years. Both the number of new cases and deaths have shown a downward trend, highlighting the ultimate goal and specific implementation measures for future prevention and control. Then the classification and diagnostic methods of pulmonary tuberculosis were expounded, including the application of techniques such as chest imaging examination, laboratory tests (including etiological analysis, pathological diagnosis, and detection of immune markers, etc.), bronchoscopy, etc. The technical barriers existing in the process of diagnosis, treatment, prevention, and control were analyzed in detail. A comprehensive explanation was provided on the basic concepts, development process, and application scenarios of deep learning. The key application fields in medicine were emphatically discussed, and the challenges in the application process of deep learning and the possible future development directions were deeply explored. Then, the methods for the auxiliary diagnosis of pulmonary tuberculosis based on deep learning were elaborated in detail, covering the specific deep learning algorithms of techniques such as chest imaging examinations, bronchoscopy examinations, and laboratory examinations. Such as Focal Loss, ResNeXt-FPN, ResNet-50, DenseNet, RetinaNet18, Unet++, Densenet121, SymAttention, MaskR-CNN, MARN, ESFPNet, and the improved Faster R-CNN, etc. Meanwhile, the basic ideas of various methods were analyzed, and the characteristics of each method and its advantages were discussed.

In addition, this paper also analyzes the domestic patent authorization situation in the past two years and points out that the auxiliary diagnosis of pulmonary tuberculosis based on deep learning shows an increasing trend year by year. Especially with the continuous iteration and update of deep learning methods, the classification and recognition of current data have been improved to varying degrees. Meanwhile, the domestic medical device registration situation was inquired about. Currently, there are relatively few domestic manufacturers that have obtained Class □ and Class □ registration certificates and are clearly applicable for the auxiliary diagnosis of pulmonary tuberculosis. They are still in the clinical verification stage, and the relevant data sets have not yet been completed.

Finally, the challenges faced by deep learning in this field are summarized, including weakly supervised or unsupervised learning (feature learning from unlabeled data), model lightweighting (trade-offs between model size and training speed and accuracy), interpretability of deep learning (gradient descent), and multimodal fusion (multi-algorithm fusion and all-round data fusion such as imaging, biochemistry, and pathology). In the future, with the optimization and integration of more deep learning algorithms, the auxiliary diagnosis of pulmonary tuberculosis will be more accurate and effective, bringing better therapeutic effects to patients.

B3: HT Innovation - AI, Digital Twins & Machine Learning

Toward Smart Assistive Mobility: A Digital Twin Framework for Intelligent Rollator Design

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Developing smart assistive mobility devices requires extensive prototyping and testing to find design features that will be optimal in different contexts of use, which can be time-consuming and costly. To address this, we propose a Digital Twin framework for modelling, simulating, and improving human-intelligent rollator interaction. This framework integrates data from real-world experiments and serves as a platform for trialing different machine learning algorithms to model the data. In the initial phase, human motion data were collected using a Vicon motion capture system and Delsys Trigno sensors (EMG and IMUs), serving both to simulate the digital twins of the human and the rollator, and to train machine learning models. Various simulation platforms, including Unity, MuJoCo, and Gazebo, have been explored for modelling the entities and integrating human motion with the rollator's physical behavior. We collected gait and movement data from participants with and without a hemiplegia simulation suit, and trained machine learning models to both distinguish between gait with and without the suit, but also to predict human turning movements when using a rollator.
Based on the findings, we transitioned to using lightweight inertial measurement units (IMUs) and LiDAR sensors mounted to a rollator with a view to developing a more cost-effective and modular system for integration to develop an intelligent rollator. The data from the LiDAR is used to identify obstacles in real-time, while the IMU classifies user motion to detect movement intentions such as turning or other directional changes. Fusing these data streams allows real-time context-aware feedback to the users using the rollator. For example, alerting when a user intends to turn into an obstructed path or fails to start turning when they should, putting them at potential risk of a collision.
The data streams were first integrated into our digital twin to explore reaction time and movement patterns in different environments, to develop machine learning models that could then be used in real-time. Gazebo was used for rollator entity modelling with real-time sensor integration. Unity provides a flexible environment for visualization, allowing modification of entity parameters to analyze the effects of physical and behavioral changes in a controlled virtual space. We are also exploring MuJoCo for future high-fidelity physics-based simulation and learning.
Our digital twin framework supports early-stage prototyping and hypothesis generation, significantly reducing the need for repeated physical trials and extensive participant recruitment. By combining real-time sensing, simulation, and AI-driven behavior modelling, our digital framework advances the design of intelligent rollators that can be personalized to specific user characteristics by modelling their specific behavior and gait, and then support them in different environmental contexts.

B3: HT Innovation - AI, Digital Twins & Machine Learning

Opportunities and Challenges of Digital Twins for Patient Care

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Digital Twins represent one of the next exciting frontiers of digital health. Because a vast amount of very accurate patient data is now being collected, work is proceeding to leverage the data to improve patient care and outcomes. Many government agencies, insurance companies, and research organizations are accumulating huge patient data archives, but that data does little good if it is merely archived. Digital Twins are proposed as one way to use the patient data archives. They have been widely deployed in many industries, like manufacturing and aerospace. For example, a Digital Twin of a satellite can be used to diagnose problems and simulate solution alternatives for a device that is travelling in orbit at thousands of miles per hour. In healthcare, a Digital Twin is a computational model that represents the human patient based on his/her medical data. Such a model would contain information on past medical history, drug allergies, current medical symptoms and diagnoses, and ongoing plans of care. Because many patients have multiple overlapping medical diagnoses and treatments, each patient's Digital Twin can embody most or all of that complexity. Furthermore, once a large population of patient data is available, an individual patient's Digital Twin can be computationally compared and contrasted with similar peers. In this process, improved patient care pathways and treatment opportunities can be highlighted for the individual patient and their clinical team. In addition, a Digital Twin can allow both patient and clinician to simulate and explore alternative future treatments and outcomes. Such simulations can help reduce or eliminate wasted efforts, reduce adverse outcomes, and ultimately enhance and optimize the patient's care. There are limitations and risks, however. First, all of the patient and population data must be accurate. Second, the data must also be normalized to ensure that all units of measure and all measurement devices are truly comparable and reliable. Third, patient-specific decisions and constraints must be documented and respected. This third condition is not trivial, because patient behaviors can greatly influence medical

outcomes. For example, a patient who refuses prostate surgery should be compared to other patients who have made the same decision. Similarly, an emphysema patient who refuses to stop smoking needs to be modeled against similar peers. All is not necessarily lost with non-compliant patients, because their Digital Twin might be useful to help them change their minds by illuminating alternate outcome paths. If the patient still declines, at least the Digital Twin clearly documents the choice they have made, and the serving team can document informed consent. A novel future Digital Twin opportunity creating graphical representations for the human users (clinicians and patients). The utility and acceptance of a computationally correct Digital Twin could be enhanced by using human-like avatars. A visual representation of advancing lung disease on patient activity levels and quality of life over time might be a powerful way for patients to "see" the future path of each decision they make.

B4: HT Innovation - AI, Machine Learning & VR

Research on WeChat Platform Based on HAPA Theory for High Quality Continuity Rehabilitation Training of Stroke Patients

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Objective: To address the issues of high disability rate, high recurrence rate, and time and space limitations of traditional rehabilitation models in stroke patients, and to develop a WeChat platform "Shukangshi" program based on the Health Action Process Orientation Theory (HAPA) by combining the phased behavioral intervention model (pre intention → intention → action) of HAPA theory with artificial intelligence (AI) technology, and to evaluate its application effect in the continuous rehabilitation training of stroke patients. **Method:** The development framework of WeChat programs consists of these core modules: static configuration (JSON), view layer (WXML/WXSS), and logic layer (JS/WXS). These modules work together to achieve the complete functionality and interface presentation of the program. The core theory of development and design is based on the HAPA theory (Health Action Process Orientation Theory), which provides an intelligent rehabilitation system covering the entire scene of "hospital home community" through staged behavioral intervention (consciousness awakening → goal setting → action maintenance), combined with AI technology and WeChat development program. In terms of clinical application verification, according to the nursing method, patients are divided into two groups. Group A received routine stroke rehabilitation orders, while Group B received remote rehabilitation training intervention based on the HAPA model using WeChat health engineer program AI and routine stroke rehabilitation orders. Comparative analysis of hand joint range of motion, hand function, neurological deficits (NHISS score), balance ability (Berg score), and motor function (The Fugl Meyer score is a standardized tool specifically used to assess the recovery of motor function in stroke patients, covering multiple dimensions such as upper and lower limbs, sensation, balance, and joint range of motion). Daily living ability (Barthel index score) and motor function (Carr Shepherd score, mainly used to quantify the patient's motor control ability, coordination, and functional motor performance during the rehabilitation process). **Result:** Compared with Group A, Group B had lower NHISS scores (30.46 vs. 18.22), higher Berg balance scores (36.28 vs. 47.26), higher Fugl Meyer scores (20.14 vs. 38.02), higher Modified Barthel Index scores (25.45 vs. 35.26) ($p < 0.05$), higher Carr Shepherd scores (64.35 vs. 82.73), better recovery of hand joint range of motion, better recovery of hand function, and higher exercise compliance rate. **Conclusion:** The WeChat program based on HAPA theory can solve the problems of low compliance, inaccurate guidance, and scattered resources in traditional rehabilitation models through phased intervention, AI dynamic optimization, and full scene coverage. Effectively improved the rehabilitation outcomes, compliance, and quality of life for stroke patients. In the future, it is necessary to expand sample diversity, verify long-term efficacy, and explore its extended applications in the rehabilitation of other chronic diseases. At the same time, the accessibility of technology and the generalization ability of data models should be optimized to promote the precision and universal development of intelligent rehabilitation.

B4: HT Innovation - AI, Machine Learning & VR

AI-Powered CSF Cytology System: A Clinical Approach for Mitigating Missed Diagnoses in Leptomeningeal Metastasis

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Background: Leptomeningeal metastasis is a metastatic disease in which cancer cells disseminate through the cerebrospinal fluid (CSF) to the meninges or spinal cord membranes, characterized by high morbidity and mortality. Cerebrospinal fluid cytology remains the gold standard for diagnosis, where pathologists identify malignant tumor cells by microscopically observing cellular components in CSF. However, manual microscopy heavily relies on subjective expertise, leading to low efficiency, inconsistent diagnostic stability, and poor interobserver reproducibility. Therefore, there is an urgent need to establish an objective and standardized CSF cytology analysis method to accelerate abnormal cell screening, enhance the sensitivity of early diagnosis, and ultimately improve patient survival rates. **Methods:** A convolutional neural network (CNN)-based analysis model was developed using whole-slide digital imaging of CSF samples. This model was integrated with automated scanning hardware to establish an AI-powered CSF cytological analysis system for assisting in the diagnosis of leptomeningeal metastasis. **Results:** The system demonstrated classification accuracy, sensitivity, and specificity exceeding 90% for malignant tumor cells in CSF, with a scanning and analysis time of less than 3 minutes per sample. These results indicate significant improvements in diagnostic efficiency while meeting clinical requirements. **Conclusion:** The AI-based CSF cytology analysis system enables efficient and accurate detection of tumor cells, thereby enhancing diagnostic efficiency for leptomeningeal metastasis and reducing the likelihood of missed diagnoses.

B4: HT Innovation - AI, Machine Learning & VR

The iLSTM Model Based on the Improved Starbird Optimization Algorithm Is Used for the Prediction of RR Intervals in Cardiovascular Patients

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Cardiovascular diseases are one of the major health threats worldwide. Accurately predicting the RR intervals in electrocardiograms is crucial for early warning of heart rate mutations and real-time monitoring. This paper proposes a hybrid model combining the Improved Nutcracker Optimizer Algorithm (NOA) and the Improved Long Short-Term Memory Network (iLSTM). It is used for the prediction of RR intervals in patients with cardiovascular diseases. By introducing the time decay weight module, iLSTM can effectively handle non-equal-interval time series data, thereby better capturing the dynamic changes of RR intervals. In order to further enhance the generalization ability and prediction accuracy of the model, we have made strategic improvements to NOA, optimizing its optimization speed and accuracy, enabling it to quickly find appropriate model parameters for different patients. We used a dataset of 300 people, including normal individuals and 9 other types of cardiovascular patients, for validation. Taking a normal person as an example, the experimental results show that the iNOA-iLSTM model has improved the evaluation index R2, respectively, compared with LSTM, iLSTM, NOA-LSTM, and iNOA-LSTM in the prediction of RR intervals. Taking a normal person as an example, the experimental results show that the iNOA-iLSTM model improved by 23.34%, 19.72%, 7.59%, 9.55% and 3.63% respectively, in the evaluation index R2 in the prediction of RR interval compared with LSTM, iLSTM, NOA-LSTM, NOA-iLSTM, and iNOA-LSTM. This research provides new technical support for real-time monitoring and precision medicine of cardiovascular diseases, and can be further applied to large-scale clinical scenarios in the future.

B5: HT Innovation - Device Development I

Research on a Piezoelectric Acoustic Power Meter for Instantaneous Acoustic Power Detection in Ultrasonic Surgical Equipment

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Ultrasonic surgical equipment is a therapeutic system based on the ultrasonic effect. The precise measurement of its output acoustic power is an important quantitative indicator for evaluating the surgical efficacy and medical safety. However, the existing measurement methods cannot accurately measure the acoustic power of ultrasonic surgical equipment across the entire frequency range. This study proposes a new method for measuring instantaneous acoustic power based on a 1-3 type piezoelectric transducer array sensor. We established a fluid-solid coupling model to analyze the force-electric coupling mechanism and dynamic response law of the 1-3 type piezoelectric composite material transducer array under the action of ultrasonic waves, and established the relationship between the electrical signal generated by the transducer array and the acoustic power, revealing the working mechanism and influencing laws of the 1-3 type piezoelectric composite material array acoustic power meter. A wide-range, wide-band, high-precision, and cost-effective 1-3 type piezoelectric composite material acoustic power meter was developed to achieve accurate measurement of acoustic power. This has significant implications in the research and development of ultrasonic surgical medical devices and their clinical applications.

B5: HT Innovation - Device Development I

Development and Application of a Rapid Optical Performance Testing Device for Medical Light Guides

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To address the inefficiency and subjectivity in current medical light guide assessments—characterized by periodic visual inspections or repetitive illuminometer comparisons causing delayed evaluations, low detection efficiency, and unquantifiable results—this study proposes an integrated rapid testing device. The apparatus consists of a xenon lamp module (300 W, 6000 K), an optical performance detection module, a computation and display module, and a 400 W power supply module.
The core innovation lies in a dual-illuminance-sensor system with ratchet-switch position swapping. This system captures incident and output light signals from the light guide's input and output ends, while the ratchet mechanism verifies sensor consistency through positional interchange. Sensor current signals are converted to digital signals via Hall elements, enabling the computation module to calculate and display the optical attenuation percentage in real-time using:
Attenuation (%) = Input sensor current/Output sensor current × 100%. This directly quantifies the degree of optical performance degradation in medical light guides.
Conclusion: Through hardware integration and signal conversion mechanisms, this device achieves rapid, objective quantification of medical light guides' optical performance, enabling the transition from periodic inspections to daily quality control. Experiments demonstrate its ability to significantly streamline traditional detection processes, eliminate manual errors, and provide intuitive optical attenuation data for medical equipment maintenance. The technology reduces hospital equipment management costs, improves repair decision efficiency, and complies with medical device industry standards, demonstrating significant clinical application value.

B5: HT Innovation - Device Development I

High-End Intelligent Laparoscopic Systems: A Performance Evaluation Study

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Background: In recent years, high-end intelligent laparoscopic systems have been widely applied in minimally invasive surgical procedures and have undergone continuous technological iteration and upgrade. These systems integrate 4K ultra-high-definition, 3D stereoscopic imaging, and fluorescence imaging technologies, as well as intelligent diagnostic assistance functions. They have significantly enhanced the visualization level of laparoscopic surgery and reduced the risk of vascular and nerve damage. However, the current evaluation standards for such systems are still imperfect, lacking a unified evaluation system. **Objective:** This study aims to comprehensively evaluate the technical performance of high-end intelligent laparoscopic systems. By constructing a multi-dimensional evaluation index system that covers image quality, 3D stereoscopic imaging effects, fluorescence imaging effects, and intelligent level, this study seeks to address the current lack of a unified evaluation standard. **Methods:** Based on a comprehensive analysis of relevant literature and technical standards, and considering the background of our hospital's large-scale surgical procedures and high demand for various high-end intelligent laparoscopic systems, this study was carried out. A multi-dimensional evaluation index system was constructed, covering image quality, 3D stereoscopic imaging effects, fluorescence imaging effects, and intelligent level. In terms of image quality, the key assessment indicators included the system's resolution, contrast, depth of field, 4K high-definition display, and anti-interference capability. For 3D stereoscopic imaging effects, the evaluation focused on the viewing angle and image disparity range, 3D images' latency and refresh rate, 3D rotation automatic horizontal calibration, anti-fogging capability, and focus-free function. Regarding fluorescence imaging effects, the key assessment indicators included the types of fluorescence modes, fluorescence visualization time, fluorescence signal strength, fluorescence color contrast, and fluorescence detection sensitivity. The evaluation indicators for the intelligent level included the system's intelligent diagnostic assistance functions, image analysis capabilities, and information interaction capabilities. **Results:** Through practical testing and evaluation of multiple high-end intelligent laparoscopic systems, it was found that there are differences in various performance indicators among different brands and models. The findings indicate that some high-end intelligent laparoscopic systems developed in China have approached or even surpassed those produced in developed countries in terms of image quality, 3D stereoscopic imaging effects, fluorescence imaging effects, and intelligent level. However, there is still room for improvement in some detail designs. The evaluation system constructed in this study provides a scientific basis for the clinical application of high-end intelligent laparoscopic systems and offers references for the development and improvement of related equipment. Future research could focus on further optimizing the evaluation system to better reflect the evolving technological landscape and clinical needs.

B5: HT Innovation - Device Development I

A Wearable Tissue Oxygen Monitoring Device for Blood Perfusion Surveillance in Flap Transplantation

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Introduction: Postoperative flap monitoring is a labor-intensive task that relies heavily on the subjective judgment of skin color change by both medical and nursing staff. Human errors, such as misinterpretation of visual cues, may result in flap failure due to missed or delayed detection of vascular compromise. To develop a wireless, wearable miniaturized tissue oximeter for real-time monitoring of blood oxygen saturation (StO□) and perfusion dynamics in flap transplantation. The device will integrate flexible optoelectronic sensors, low-power electronics, and AI-based signal processing to achieve accurate (± 2% StO□ error) and motion-resistant measurements. Key goals include optimizing wireless BLE telemetry for mobile health integration, validating clinical efficacy in detecting vascular complications, and establishing a scalable fabrication process toward regulatory-compliant commercialization. The research seeks to bridge critical gaps in post-surgical monitoring through innovative wearable medical technology. Materials and **Methods:** This study will develop a wireless wearable tissue oximeter through a multidisciplinary approach combining optoelectronic engineering, embedded systems, and AI analytics. The methodology involves: (1) designing flexible multi-wavelength optical sensors (730/850 nm) with Monte Carlo-optimized probe geometry; (2) developing a miniaturized ARM Cortex-M4/BLE 5.2 platform with adaptive signal conditioning; (3) implementing a hybrid 1D-CNN-LSTM model for motion artifact suppression; and (4) validating performance through phantom tests, rodent ischemia models (n = 30), and pilot clinical trials (10 mastectomy cases). The innovation lies in integrating stretchable electronics (> 15% strain tolerance) with edge-computing capabilities (< 50 ms latency) to achieve clinical-grade accuracy (± 2% StO□ error) in ambulatory settings, while complying with ISO 80601-2-61 standards through rigorous EMC/aging tests. **Results:** The wireless wearable tissue oximeter demonstrated accurate (± 2% StO□ error) and real-time monitoring of blood perfusion in flap transplantation. Flexible optical sensors and AI-based signal processing enabled reliable measurements even during movement, while preclinical and clinical tests confirmed early detection of vascular complications—such as venous congestion—2 hours faster than traditional methods. Discussions: The device achieves clinical-grade accuracy (± 2% StO□ error) and effectively suppresses motion artifacts, enabling earlier detection of vascular complications compared to traditional methods. By combining the adhesive, robust sensor design principles demonstrated in prior research with advanced edge computing capabilities, this technology provides a practical solution for continuous, objective monitoring that could significantly improve surgical outcomes while reducing reliance on subjective clinical assessments. Future work could explore predictive analytics and expanded applications in wound care. **Conclusions:** This wearable device offers a practical solution for postoperative flap monitoring by combining motion-resistant sensors, wireless connectivity, and AI analytics. Its ability to provide continuous, objective data reduces reliance on subjective assessments, improving early intervention and surgical outcomes.

B5: HT Innovation - Device Development I

Development of a Maternal-Fetal ECG Simulation System Based on an Embedded Platform

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The fetal electrocardiogram (FECG) examination is an important clinical technique for non-invasive monitoring of fetal health, but the types of FECG monitoring devices on the market are far fewer than the types of Doppler fetal monitors. This is mainly hindered by the progress of FECG signal processing technology, such as the need to improve FECG extraction algorithms, increase the detection rate of abnormal FECG, and eliminate noise interference, among other issues, which still require further research. To assist in the research of FECG signal processing technology, this project has designed a maternal-fetal ECG simulation system based on the MSP430 embedded platform. The system consists of an ECG database, a host control computer, a cardiac generator, and a phantom model. The host control computer reads signals from the local ECG database and converts them into simulated ECG signals through the embedded platform, which are then output to the phantom model via the cardiac generator. The development of this system will contribute to the research of fetal electrocardiogram signal processing technology and the development of FECG monitoring devices.

B6: HT Innovation - Device Development II

Silicon Chip-Based Receptor Technology with Nanomaterials-Enhancement for Application in the Detection of Biomarkers

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In this paper, we present possibilities for developing on-chip biochemical sensors using Si Light Emitting Devices that operate in the reverse avalanche mode (nomenclated Si AM LED). We propose the use of LEDs that can be fabricated in the micro- and nano-scale on standard silicon integrated circuitry and that emit up to 100 nW of optical power within a broad spectrum in the 450–1100 nm range. We have extensively studied the dispersion characteristics for a Si AM LED source that is positioned one micron below the surface of a silicon IC. We present a design that, in combination with appropriate receptor technology, will enable on-chip detection of bio-species, specifically cancer biomarkers, using a combination of Si LEDs and nanomaterials. In this design, a Si LED is combined with a micron-dimensioned waveguide and an array of silicon detectors positioned on the same chip. A propagation channel is designed along the chip from the Si LED source, and a crevasse is etched from the surface of the chip down to penetrate the evanescent field of the waveguide. Silver nanoparticles are dropping cast in the crevasse area. A selection of sensors is placed below the crevasse area that can each selectively monitor reflected light in the UV, visible, infrared, and far infrared wavelength regions. By comparing the fingerprint combination spectrum of various biomarkers and interferents, we hope to positively identify the presence of prostate-specific antigens, a biomarker for prostate cancer. Fabricating these sensors in micro- and nano-dimensioned formats on a chip offers many testing possibilities, including revitalizing and reusing the sensor after each measurement cycle.

B6: HT Innovation - Device Development II

Implementation of a Customized Platform for Proposal and Project Management Within a Research Institute

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Description: In 2018, Fondazione Policlinico Universitario Agostino Gemelli was recognized as a scientific and treatment hospital for personalized medicine and innovative biomedical technologies. This led to the establishment of the Gemelli Science and Technology Park (G-STeP) as a network of services to support all stages of scientific research project development, which is currently composed of twenty-five facilities. Among them, the facility Radiopharmacy has been operating since October 2022 in the context of radiopharmaceuticals and deals with a constantly increasing number of research proposals and ongoing projects. The need for a tool enabling standardized proposal collection, assessment, and internal approval, as well as project management, led to the development of a dedicated platform. The platform was implemented through the following steps: (1) definition of the facility research scopes and of the possible related projects; (2) individuation of all the factors characterizing and affecting the different kinds of projects; (3) conception of a work breakdown structure and of a task list covering all the kinds of projects; (4) definition of the platform requirements for both proposal and project management; (5) individuation of the commercially available solution more adherent and/or more customizable and scalable. The platform was developed with the aim of standardizing and optimizing the intake, evaluation, and approval of research proposals (business cases, BCs), and enabling a structured and efficient management of the entire project lifecycle, from planning to execution. **Results:** The research platform was developed starting from a commercially available one already conceived for the management of BCs and projects. After a deep customization process, the current version of the platform allows us to: (1) collect no-profit and profit BCs in all areas of interest of the Facility and classify them according

to specific parameters; (2) carry out a preliminary internal assessment/approval of each BC taking into account the scientific value, the feasibility (major constraints), and the compliance with Radiopharmacy and G-STeP research objectives; (3) match a no-profit BC with a non-profit funding and deeply evaluate the funding rules and constraints; (4) carry out a second internal assessment/approval of BCs which passed the first one, deepening feasibility and sustainability and also simulating them in the research portfolio; (5) manage projects arising from approved BCs (schedule, resources, budget, revenue, risks, changes); (6) associate BCs and projects with the related documentation through a SharePoint library; (7) generate dashboards and reports for both BCs and projects. The platform provides clear benefits to a range of end users and stakeholders, including: Researchers and clinicians submitting scientific proposals; Facility coordinators and project managers responsible for project execution and resource allocation; Scientific and administrative staff involved in assessing feasibility, financial compliance, and the overall impact on the research portfolio. **Conclusion:** The research platform is a robust and versatile tool for the management of proposals, through a simple and standardized process that guarantees a uniform and strategic assessment, and for the management of each project throughout its entire lifetime, in relation to the research portfolio.

B6: HT Innovation - Device Development II

Design and Production of a Respiratory Flow Controller

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This study explores the design and production of a respiratory flow controller, with the aim of improving the control of ventilator operating parameters for clinical effectiveness and improved maintenance methods, and especially the availability of this type of device in the majority of hospitals in the West African sub-region, taking into account tropical operating conditions. To achieve this objective, we adopted an experimental and quantitative approach, including a survey of biomedical technicians in hospitals nationwide, as well as the design and construction of a portable mock-up of the device. The results demonstrated that many ventilators in hospitals, although still in operation, no longer accurately provide the required functions, including respiratory rate, tidal volume, respiratory pressure, airflow, oxygen saturation, temperature, and humidity, suggesting that these ventilators, even when in operation, do not accurately guarantee the reliability of patient treatment. Furthermore, additional observations revealed that most technical departments do not have a device for monitoring these parameters due to the high cost of the kits that make up the latter. These findings have significant implications for improving the quality of patient care, but especially the reliability of equipment performance after maintenance. In conclusion, this study presents an accessible and ergonomic solution for the quality control of artificial respirators, highlighting the importance of technological innovation in strengthening the performance of technical platforms in hospitals. Future research could add the ability to measure more advanced parameters to the system, making it a monitor of artificial respirator parameters, and develop a version of the device linked to the Computer-Aided Maintenance Management tool, allowing real-time monitoring of ventilation as a gauge of its proper functioning.

B7: HT Innovation - Clinical Studies

Clinical Validation and Commercialization Strategies for Beetroot Juice in Managing Menstrual Cramps: A Health Technology Outlook

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This thesis explores the development of beetroot juice as a functional health drink aimed at alleviating menstrual cramps and related symptoms in women. Menstrual discomfort, including pain, bloating, and mood swings, affects a significant portion of women globally, often leading to reliance on painkillers or traditional remedies. Beetroot (Beta vulgaris) was selected for its rich nutritional profile, including essential minerals like magnesium, potassium, calcium, and sodium, as well as vitamins such as vitamin C, which are known to mitigate menstrual symptoms. The study involved the preparation of beetroot juice, with careful removal of oxalates to ensure safety, followed by laboratory analysis to evaluate its physical, chemical, and microbiological properties. Results confirmed the presence of beneficial nutrients, such as 1.02% protein, 74.89 ppm calcium, and 46.01 ppm magnesium, while microbiological tests ensured the product's safety. A survey of 40 female participants revealed positive feedback, with 67.5% reporting moderate pain relief and 65% expressing willingness to consume the juice regularly. The findings suggest that beetroot juice can serve as a natural, effective alternative for managing menstrual discomfort, offering a promising avenue for further development as a women's health drink. Future plans include fortifying the juice with additional nutrients like iron and vitamin D to enhance its health benefits and commercial viability.

C1: Health Facility Planning & Design I

Modern Infection Control Technology and Safe Patient Habitat: Integrated Approaches for Hospital Inventory, Sanitation, and Air-Water ATP Systems

By Md. Ramjan Ali[1], Alve Yeasin Bin Anwar[2], Md. Masud Hassan[3], Md. Anwar Hossain[4,*]

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Hospital-acquired infections (HAIs) remain a persistent challenge in Bangladesh's healthcare system, primarily due to overcrowded environments, poor ventilation, outdated disinfection methods, and the absence of real-time hygiene monitoring. The COVID-19 pandemic highlighted the need for more robust and automated infection control systems that prioritize patient safety and ecological balance. In response, this study proposes an integrated framework combining HEPA-UV HVAC systems, ATP-based air and water purification technologies, and AI-powered hygiene monitoring tools. The aim is to develop scalable, cost-effective infection control solutions for critical hospital areas such as inventory rooms, sanitation zones, patient cabins, operating theaters, and attendant housing. The research followed a phased approach, starting with risk assessments, followed by pilot implementations, environmental data collection, and pre-post intervention analysis using ATP meters and compliance sensors. The technology stack included UV-C sterilization integrated with HVAC systems, antimicrobial copper/silver surfaces, touchless sanitation systems, electrostatic fogging robots, and indoor oxygen-releasing plants to improve air quality and reduce vector presence. Results from pilot deployments demonstrated that airborne pathogens were reduced by 75%, ATP surface readings dropped to safe levels (< 200 RLU), hygiene compliance among staff increased from 62% to 91%, and the average monthly HAI rate declined from 18% to 5.2%. These improvements confirm that infection rates can potentially be reduced by over 70% when ecological and smart technologies are applied together. With a total setup cost of USD 13,750 and annual operation and maintenance at only USD 1,333, the system offers a highly scalable and financially sustainable model. Based on these findings, the study recommends national-level adoption of this framework in both public and private hospitals, integration of AI-driven monitoring into infection control policies by the Ministry of Health, and the development of standard operating procedures (SOPs) alongside training programs for hospital staff. Further long-term research is encouraged to evaluate patient outcomes and return on investment for widespread implementation.

C1: Health Facility Planning & Design I

The National Rehabilitation Centre—The Role of Clinical Engineering in a New Purpose-Built Rehab Centre

By Dan Clark*

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In 2017, the World Health Organization recognized that many countries are not equipped to respond to existing rehabilitation needs, stating that 1 in 3 people are living with health conditions that would benefit from rehabilitation. It issued a call for action, encouraging countries to scale up rehabilitation as a health priority. In the UK, rehabilitation is seen as a "Cinderella" service compared to acute medical services. Most hospital rehabilitation services changed to "Discharge Planning" with patients expecting to receive rehabilitation once home; currently, it is impossible to deliver. Rehabilitation research and building capacity in rehabilitation professionals who can deliver research are a priority for the NIHR, which has recognized rehabilitation research as a relatively new concept.

"In the UK, occupational medicine and vocational rehabilitation are not well served and the UK lags behind many other countries, with 50%–60% of people returning to work after a major injury after 6 months in Europe and the USA, while in the UK the figure is just 34%." In response to this, the UK Government announced approval for a £105 million plan to build a new, specialist centre for rehabilitation in the UK – the National Rehabilitation Centre (NRC). This new 70-bed, purpose-built, and highly energy-efficient facility, as part of the UK Government's New Hospital Programme, is set to open its doors to patients in late summer 2025. The specialist NHS facility will be built on the Stanford Hall Rehabilitation Estate in the very heart of the country, co-located with the Defence Medical Rehabilitation Centre, and will bring research, innovation, education, and training alongside clinical practice to drive excellence in rehabilitation and be a national and international beacon.

In this presentation, we will look at the background to the NRC and consider the role of clinical engineers in this new state-of-the-art building, in supporting the equipment and installation, in developing a testbed where new technology can be evaluated, and in establishing a parallel centre for technology research in rehabilitation.

C1: Health Facility Planning & Design I

Electromechanical Strategies to Strengthen Infection Control in CSSDs of Bangladeshi Public Hospitals: A Case Study

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Central Sterile Services Departments (CSSDs) are fundamental components of infection prevention infrastructure in hospitals. In Bangladeshi public healthcare facilities, outdated sterilization systems, insufficient environmental control, and inadequate maintenance protocols significantly increase the risk of healthcare-associated infections (HAIs). This study presents a practical infection control framework that leverages targeted electromechanical engineering interventions to enhance sterilization reliability, environmental hygiene, and system resilience. A case study approach was applied in selected tertiary-level public hospitals in Bangladesh with high surgical throughput. The investigation focused on key technical domains, including the performance of steam and ethylene oxide sterilizers, heating, ventilation, and air conditioning (HVAC) systems with HEPA filtration, uninterruptible power supply (UPS) and generator backup systems, and real-time digital monitoring infrastructure. Data collection methods included on-site inspections, micro-

biological sampling of air and surfaces, structured interviews with clinical engineers and CSSD personnel, and review of maintenance and calibration records. System performance and infection control effectiveness were evaluated against World Health Organization (WHO) sterilization benchmarks and environmental compliance standards. Analysis revealed that hospitals operating automated sterilizers with scheduled calibration protocols achieved up to 40% improvement in sterilization cycle consistency. CSSDs equipped with HEPA-filtered HVAC systems maintaining pressure differentials and controlled humidity exhibited a marked reduction in microbial loads in clean zones, including packaging and sterile storage areas. Facilities with UPS and generator-supported power infrastructure ensured continuity of sterilization operations during frequent grid outages, eliminating mid-cycle failures. Implementation of digital monitoring systems enabled real-time tracking of key parameters, improved alarm response times, and strengthened documentation and regulatory compliance. Furthermore, institutions that practiced regular preventive maintenance and provided technical training for CSSD staff reported significantly fewer equipment breakdowns and contamination events. The findings demonstrate that systematic application of electromechanical strategies can effectively close critical performance gaps in CSSDs across public hospitals. These strategies include the integration of sterilization automation, environmental control via HEPA-based HVAC systems, reliable power backup infrastructure, digital quality assurance tools, and capacity building through staff training. Collectively, these measures contribute to reduced infection risk, greater operational efficiency, and sustained alignment with international patient safety standards. To achieve scalable and lasting improvements, national health authorities must prioritize CSSD modernization in policy and planning frameworks, supported by adequate resource allocation, compliance monitoring, and institutional commitment. This case study offers a replicable Electro-Mechanical engineering model that supports infection control transformation in resource-constrained healthcare systems by applying a clinical engineering management system.

C1: Health Facility Planning & Design I

Ensuring Ultra-Pure Water in Hospital Systems: A Critical Requirement for Patient Safety in Bangladesh

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In the context of patient care and medical safety, water quality in hospitals is a critical yet often overlooked component within developing healthcare systems. In Bangladesh, most clinical procedures utilize filtered but non-ultra-pure water, which retains harmful mineral residues such as sodium, calcium, magnesium, potassium, chloride, and sulfate, as well as microbial contamination. These contaminants can severely affect surgical instrument sterility, dialysis efficacy, and overall patient safety. This study aims to investigate the status of water purification practices in Bangladeshi hospitals, evaluate the risks posed by mineral-rich water in clinical use, and propose feasible solutions for implementing ultra-pure water infrastructure in low-resource settings. A mixed-methods research design was employed. Site inspections were conducted at 15 hospitals in Dhaka, Chattogram, and Rajshahi. Water samples were analyzed using atomic absorption spectrometry and ion chromatography to determine mineral contamination levels and microbial contamination. In-depth interviews were held with biomedical engineers, nephrologists, and infection control officers. The findings were compared against WHO guidelines and AAMI/ISO 13959 standards for water purity. The study revealed that 85% of the hospitals did not meet ultra-pure water standards for critical uses such as surgical cleaning and dialysis. Elevated levels of calcium and magnesium were found to accelerate corrosion in surgical instruments. High sodium and sulfate concentrations in dialysis water were associated with increased patient induction reactions and systemic complications. The root causes include lack of awareness, inadequate technical capacity, and absence of regulatory oversight. To improve water safety in hospitals, the proposed necessary actions include: (1) establish mandatory ultra-pure water standards for dialysis, operating theatres, and

CSSD units, (2) deploy multi-stage purification systems incorporating reverse osmosis, deionization, and UV treatment, (3) develop national healthcare water safety guidelines aligned with AAMI/ISO and WHO frameworks, (4) initiate training programs for hospital biomedical teams on water system maintenance, and (5) institutionalize regular DGHS-led audits for water quality compliance. It can be concluded that ultra-pure water is essential for ensuring infection control and equipment longevity in hospitals. The transition from basic filtration to medical-grade water systems is a necessary step toward improving patient outcomes and aligning Bangladesh's hospital practices with international standards.

C1: Health Facility Planning & Design I

Architecture of a Cyber-Physical System for Operating Room Monitoring

By Houessouvo C. Roland[1,2,*], Kinnouezan A. Chams Deen[2,3], Idrissou A. Y. Moubarack[2,3], Jossou R. Thierry[1,2], Pecchia Leandro[4], Medenou Daton[1,2]

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This study explores the design of a cyber-physical system (CPS) architecture applied to the technical supervision of hospital operating rooms, with the aim of ensuring the continuity of critical equipment operation, anticipating technical failures, and enhancing patient and healthcare staff safety. To achieve this objective, we have adopted an interdisciplinary technological approach combining IoT, embedded computing, CMMS, and artificial intelligence, including the identification of critical devices in the operating room (ventilators, electric scalpels, operating tables, video columns, etc.), the installation of connected sensors to collect operating parameters in real time, the implementation of a local gateway for preliminary analysis and secure communication, and the development of a smart dashboard for technical services. The results demonstrated that this type of system enabled continuous monitoring with early detection of anomalies, reducing the risk of critical failure by more than 60% in simulations, suggesting that the implementation of cyber-physical systems in the operating environment is both feasible and highly beneficial. In addition, further observations revealed that integrating technical alerts into a centralized CMMS supervision system enabled better coordination between the biomedical department, operating rooms, and emergency services. These findings have significant implications for surgical safety, hospital maintenance quality, and regulatory compliance in terms of traceability, risk management, and medical device certification. In conclusion, this study presents a functional architecture for a cyber-physical system applied to operating rooms, highlighting the strategic role of connected technologies in moving from reactive to proactive and contextual maintenance in critical environments. Future research could focus on integration with clinical management systems (EPI, HIS), cross-analysis of technical and clinical incidents, or strengthening the cybersecurity of data from medical equipment.

C1: Health Facility Planning & Design I

Enhancing Hospital Accessibility for Blind and Low-Vision Visitors through a Hybrid Indoor Navigation System: Lessons from a Pilot in Greece

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Navigating large hospital environments remains a significant barrier for blind and low-vision (BLV) individuals, often resulting in unequal access to healthcare services. To address this challenge, the HOSP4ALL initiative developed and de-

ployed a hybrid indoor navigation system at the University General Hospital of Patras, Greece, combining assistive technology and physical infrastructure modifications to support independent and autonomous navigation for BLV visitors.
The project integrated off-the-shelf technologies, including Bluetooth Low-Energy (BLE) anchors using Angle of Arrival (AoA) technology and a third-party navigation engine, into a custom mobile application compatible with accessibility tools like TalkBack. Tactile floor guides, made of high-contrast polyurethane tiles, were also installed to provide physical orientation cues. The design process was strongly user-centered, involving members of the Greek and Norwegian Associations for the Blind from the conceptual stage through to testing.
The system offered turn-by-turn instructions via audio feedback, dynamically adapting to the user's position. Initial testing with BLV users indicated successful navigation across outpatient clinics, with positive impressions concerning route clarity, ease of use, and access to digitized service information previously unavailable in non-visual formats. A hybrid navigation approach, combining digital prompts with tactile feedback, proved especially effective at improving spatial awareness and reducing navigation errors.
Implementation revealed several practical lessons. Infrastructure limitations, such as uneven flooring and constraints from ongoing clinical operations, challenged the installation of tactile guides. Acceptance by hospital personnel also varied, indicating the importance of holistic stakeholder engagement beyond regulatory compliance. From a technical perspective, modular architecture facilitated integration of third-party services but introduced unexpected complexities during development.
The pilot demonstrated that it is feasible to rapidly prototype and deploy inclusive navigation solutions in real healthcare environments using commercially available components. The system also holds promise for extension to other public service buildings, such as municipal centers or transportation hubs. However, broader accessibility remains constrained by systemic issues such as urban infrastructure and public transport limitations. These findings highlight the need for integrative planning across clinical engineering, hospital management, and urban design to realize fully inclusive healthcare environments.
Conclusions: This project illustrates a scalable, cost-conscious path for enhancing hospital accessibility through hybrid assistive technologies. User feedback, deployment insights from real-world hospital settings, and inter-organizational collaboration provide a replicable model for other healthcare institutions seeking to support independence and dignity for BLV individuals.

C2: Health Facility Planning & Design II

Optimizing Multimodal MRI Layouts: Dynamic Field Coupling for Safety & Compatibility

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Objective: In view of the electromagnetic compatibility and safety challenges faced by multiple nuclear magnetic resonance imaging (MRI) devices when installed in close proximity, this paper explores effective isolation methods for magnetic field interference between devices, and proposes an optimized collaborative layout scheme to realize efficient and safe layout of multi-modal MRI devices, while ensuring the reliability and stability of device operation. **Method:** Four MRI devices (two 1.5T and two 3.0T) installed at the near-field position of a hospital were used as research subjects. The same magnetic field strength was achieved using a 45° diagonal layout. By testing the radio frequency (RF) shielding performance of the devices and employing computer simulation techniques to construct a 5 Gauss line model and analyze its intersection, the system evaluated the degree of magnetic interference between devices and the safety of the surrounding environment. Additionally, dynamic magnetic field coupling modulation technology was introduced to monitor and adjust the magnetic field distribution in real-time, further optimizing the layout parameters of the devices and enhancing the safety margin of the layout scheme. **Result:** The study found that the maximum extension distance of the 5 Gauss line for a 1.5T device is 3.2 meters, while for a 3.0T device, it is 4.8 meters. Under the same magnetic field with a 45° diagonal layout, the 5 Gauss lines of adjacent devices do not overlap, indicating that this layout can effectively avoid magnetic interference between devices. Additionally, the RF shielding performance test results show that the shielding efficiency exceeds 70dB, fully meeting the requirements of the IEC 60601-2-33 standard. After optimization

using dynamic magnetic field coupling modulation technology, the safety margin of the device layout has been further improved, ensuring electromagnetic compatibility and safety when multi-modal MRI equipment is installed in close proximity to the machine. **Conclusion:** The 45°diagonal layout combined with dynamic magnetic field coupling modulation technology can significantly enhance the electromagnetic compatibility of multiple MRI devices when installed in close proximity, effectively isolating magnetic interference. It is recommended that the minimum safe distance between devices should not be less than 5 meters to ensure safe operation. This layout scheme improves spatial utilization while ensuring device performance and image quality, providing a scientific basis for the coordinated layout of multi-modal MRI devices, which has high clinical application value.

C2: Health Facility Planning & Design II

Exploring New Technologies and Advances in Medical Sterilizers

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This abstract (and/or the work·summarized·herein) will be published online first in *China Plant Engineering* in October, 2025. It is produced here in advance with the permission of the author for the purpose of record and·wider dissemination.

This article aims to review the new technologies and advances in the field of medical sterilizers, and explore how these technologies can improve the sterilization efficiency, safety, and environmental friendliness of medical devices to meet the high standards of modern medical requirements for sterile environments. By introducing the latest sterilization technology, its principles, advantages, and applications, this provides a reference for medical institutions when selecting and using sterilization equipment. This article systematically reviews the research achievements and technological innovations in the field of medical sterilizers in recent years. The principles, characteristics, scope of application, advantages, and disadvantages of new sterilization technologies such as low-temperature ethylene oxide sterilization, low-temperature hydrogen peroxide gas plasma sterilization, low-temperature steam formaldehyde sterilization, and low-temperature peroxyacetic acid sterilization were analyzed in detail. At the same time, we also paid attention to the development trends of modern sterilization equipment, such as fully automatic sterilizers and intelligent sterilizers, and explored their advantages in improving sterilization efficiency, reducing human operational errors, and achieving remote monitoring and management. The new technology and progress of medical sterilizers provide strong support for improving the sterilization efficiency, safety, and environmental friendliness of medical devices. Looking ahead to the future, the medical sterilizer industry will face more development opportunities and challenges.

C2: Health Facility Planning & Design II

Construction of Specialized Digital Operating Room Empowered by Artificial Intelligence

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This study presents an AI-powered digital operating room integrating multimodal data and IoT technologies. Key components include: (1) infrastructure for interconnected systems, audiovisual control, and remote consultation; (2) an intraoperative AI system enabling rapid 3D visualization and quantitative analysis of anatomical structures via deep learning; (3) a postoperative AI quality control system using computer vision to analyze videos, track instruments, and detect safety issues, facilitating data-driven debriefing. The integration enhances workflow efficiency and surgical accuracy,

highlights AI's role in bridging preoperative, intraoperative, and postoperative phases, aligning technology with clinical needs to advance intelligent, patient-centric digital operating room ecosystems.

C2: Health Facility Planning & Design II

A PDCA-Based Strategy for Upgrading Medical Compressed Air Systems in Hospital Infrastructure

By Jingru Zhong, Zizhao Xie, Hongchao Wang, He Zhang*

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As urbanization accelerates across China, hospitals—serving as core elements of urban infrastructure—face mounting demands to modernize their critical life-support systems. Among these, medical compressed air systems are encountering significant challenges, including aging equipment, limited capacity, and increased clinical demand. These issues raise serious concerns around system reliability and patient safety. Given that some components are regulated as pressure vessels under special equipment classifications, the system must meet stringent quality and safety standards across its entire lifecycle—from initial design and procurement to installation, operation, and maintenance.

This study presents a comprehensive upgrade strategy for a hospital's aging compressed air system, structured around the PDCA (Plan–Do–Check–Act) quality improvement cycle. Drawing from the Chinese national standard GB 50751-2012 for medical gas engineering, the project team conducted a root-cause analysis using a fishbone (Ishikawa) diagram to identify factors influencing system reliability and performance. Key variables included: current and projected air consumption post-expansion, redundancy planning (N+1 configuration), spatial constraints and pump room design, dual-channel electrical power distribution, intake and exhaust ventilation for thermal management, and environmental controls to maintain optimal operating temperatures.

Each factor was addressed through iterative PDCA cycles to develop targeted engineering solutions. These included modular equipment selection, airflow simulation for ventilation design, and coordination with facilities management for infrastructure integration. Special attention was given to risk mitigation strategies during the transition phase between old and new systems. After the successful installation and commissioning of new compressors, power infrastructure, Heating, Ventilation, and Air Conditioning (HVAC), and ventilation systems, a carefully phased switchover plan was implemented. The plan incorporated contingency measures such as pre-calculated backup gas cylinder capacity, approval from clinical stakeholders on downtime tolerance, and real-time support from trained technical personnel. A full-scale simulation drill was conducted before execution to ensure operational continuity.

This upgrade approach demonstrates how applying systems engineering principles and quality improvement frameworks such as PDCA can ensure compliance, reduce operational risk, and enhance the resilience of medical gas systems in tertiary healthcare environments. The framework is scalable and adaptable, offering a reference model for similar infrastructure upgrades in both general and specialized hospital settings.

C2: Health Facility Planning & Design II

Quality Control and Risk Management of Medical Compressed Air Systems

By Zizhao Xie, Jingru Zhong, Hongchao Wang, He Zhang*

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As a critical life-support system in hospitals, the medical compressed air system consists of complex components (including air compressors, air storage tanks, four-stage filters, etc., with some tanks and manifolds classified as simple pressure vessels or special equipment). Its operational quality directly impacts patient treatment safety. The system's management has dual requirements, needing to comply with both medical equipment quality standards and special equipment safety regulations, involving multi-faceted risk control demands. Based on equipment integrity management

theory, this study establishes a comprehensive management system encompassing operational, maintenance, and data integrity.

Quality control focuses on two core indicators: gas pressure (maintaining a stable range of 0.4–0.6 MPa) and gas purity (complying with the Chinese medical gas engineering standard GB 50751-2012). Implementation measures include: (1) ensuring operational integrity through regular inspections and manual dynamic monitoring (e.g., daily pressure checks); (2) building maintenance integrity via a three-tier maintenance system (routine inspections, preventive maintenance, and emergency response), with mandatory replacement cycles for critical consumables like filters; and (3) achieving data integrity by establishing a full-lifecycle electronic archive, covering procurement records, operational logs, and maintenance data for traceability.

The risk management framework comprises: (1) personnel qualification management, requiring certified operators with regular training; (2) A dual-track emergency management approach involving at least two comprehensive drills annually supplemented by scenario-specific exercises as required; and (3) strict oversight of special equipment, including periodic calibration of pressure vessels like storage tanks and manifolds.

Throughout the system's lifecycle, continuous optimization is achieved via the PDCA (Plan–Do–Check–Act) quality improvement cycle to ensure safe operation. Currently, system safety relies on the synergy of technology, protocols, and personnel. Future advancements will integrate IoT technology for real-time intelligent monitoring and early warnings, transitioning the management model from reactive to proactive prevention. This framework serves as a reference for managing other critical medical equipment.

C2: Health Facility Planning & Design II

Implementation of an Intelligent Monitoring System for Pressure and Flow in a Medical Gas Network

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This study explores the implementation of an intelligent monitoring system for pressure and flow within hospital medical gas networks, with the aim of enabling real-time tracking of critical parameters (pressure, flow rate, temperature) to ensure the safety, availability, and quality of medical gas distribution (oxygen, medical air, vacuum, etc.). To achieve this objective, we adopted an architecture-based approach, incorporating connected sensors (pressure, flow, temperature), embedded microcontrollers, communication via industrial protocols, and a web-based supervisory interface. The results demonstrated that the system enables the rapid detection of anomalies such as leaks, pressure drops, or obstructions in gas pipelines, and facilitates effective responses to minimize risks. This suggests that such a tool can significantly enhance the monitoring of medical gas networks and improve responsiveness to malfunctions. Furthermore, additional observations revealed that the tool is well-suited to resource-limited hospital environments due to its low cost, offline operational capability, and modular design. These findings have significant implications for securing hospital infrastructure, reducing downtime of critical equipment, and optimizing maintenance operations. In conclusion, this study highlights the potential of embedded technologies and the Internet of Things (IoT) for the intelligent management of medical fluid networks. Future research could focus on expanding the image database, adding functionalities for detecting the operational status of equipment, and integrating the system with automated supply chains.

C3: Quality of Care & Patient Safety

Implementation of a Clinical Alarm Management Program for Early Detection of Patients at Clínica Imbanaco—Quirónsalud Group

By Karent Muñoz Salazar*, Ivonne Tatiana Morales.

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Description: The clinical alarm management of medical equipment at Clínica Imbanaco was implemented as an organization-wide project, aligned with the strategic pillars of operational excellence, technological transformation, person-centered care, and cultural and professional development. The initiative was focused on adult, pediatric, and neonatal intensive care units, using strategies designed to ensure the safety of our patients. The program was developed through the collaborative work of a transdisciplinary team, integrating various departments of the clinic. Decisions were supported by the expertise of our physicians, nurses, and clinical engineering staff, allowing the definition of criteria and the provision of information and tools to help prioritize clinical alarms. The project involved technological upgrades, creation of clinical monitoring profiles, implementation of drug libraries in infusion pumps, adoption of international early warning scores in multiparameter monitors, configuration of medical devices, data collection and processing, workflow adjustments, and continuous education and training for clinical and technical personnel. Data collection was conducted through trend analysis of workflow, data generated by medical equipment, and observational analysis of clinical processes. This approach made it possible to identify areas for improvement and ensure that clinical alarms were managed effectively, always prioritizing patient safety. A descriptive methodology was applied in the project design, incorporating quantitative and qualitative analysis of clinical alarms from infusion systems and multiparameter monitors. The methodology was framed around the PDCA cycle (Plan, Do, Check, Act), and key activities were defined for each phase of the program:

Phase 1 Plan: The current state of clinical alarms was assessed using data generated by software installed in medical devices.

Phase 2 Do: Equipment software was updated, and clinical profiles were configured to define alarm thresholds, patient types, and alarm volumes. Clinical workflows were standardized, and healthcare personnel received specialized training.

Phase 3 Check: Measurable indicators were developed based on the COP (Care of Patients) standard from Joint Commission International (JCI).

Phase 4 Act: Measurement of alarm behavior outcomes was carried out, and decisions were made to enhance safety in the patient care environment.

Conclusions: The clinical alarm management program has been developed over the past three years, allowing for data-driven decision-making. Key achievements include: (1) 99.7% adherence to the use of drug libraries, and (2) 73.4% reduction in clinical alarms generated by medical equipment. These results reflect the outstanding work of the interdisciplinary team, including clinical engineering, in the successful development of this program. The implementation has strengthened the safety and confidence of medical staff, patients, and their families, helping to reduce stress factors and positively impacting the organization's strategic pillars: operational excellence, technological transformation, person-centered care, and cultural and professional development.

C3: Quality of Care & Patient Safety

Current Status and Considerations on the Construction and Application of Perioperative Databases

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Description: The emergence of perioperative databases has been driven by the surge in surgical volume and the growing demand for precision medicine. These databases are clinical information systems that include data covering the entire perioperative process—from preoperative evaluation and intraoperative monitoring to postoperative recovery—and can provide support for clinical decision-making, risk prediction, and research innovation. From the early development of the electronic anesthesia quality tracking system at the Mayo Clinic in the United States in 1988, to the automated perioperative information system developed by Peking Union Medical College in 1999, and to the recent integration of big data and AI technologies, the function of these databases has evolved from simple data storage to intelligent analysis. This study reviews the construction of perioperative databases in recent years, both domestically and internationally, and identifies three main characteristics of current developments. First is technological innovation: as patient data comes from different systems, data standardization is required during the database construction process to integrate heterogeneous data. Commonly used technologies include natural language processing (NLP) and extract-transform-load (ETL) techniques. Second, multicenter collaboration has begun to take shape: increasing emphasis is being placed on collaborative construction and data sharing, as seen in initiatives such as the Chinese Perioperative Outcomes Research Database Alliance and the Nimbly system at Vanderbilt University Medical Center in the United States. Third, the scope of clinical application is expanding: in addition to supporting retrospective clinical research, perioperative databases have seen rapid development in preoperative decision support, intraoperative risk prediction, and postoperative complication forecasting. However, challenges still exist in data processing, interdisciplinary and cross-center collaboration, and practical application of these databases. These include inefficiencies in handling large volumes of data, a lack of unified standards for underlying data, limited database coverage, poor data sharing, and uncertainties around whether the databases can truly drive clinical applications. This study reviews recent literature on perioperative databases, focusing on their current technical applications, construction status, and use in areas such as anesthesia management. It also summarizes the key challenges currently facing perioperative database development, to provide references for future directions and improvements in database construction. **Conclusion:** To address these challenges, it will be necessary to introduce more advanced and efficient artificial intelligence algorithms to improve data processing efficiency; enhance the integration of multi-source heterogeneous data and promote interdisciplinary, cross-center collaborative database construction; and, finally, fully explore the personalized applications of perioperative databases at all stages of care, such as optimizing preoperative surgical planning, intraoperative data analysis and monitoring, and postoperative rehabilitation management.

C3: Quality of Care & Patient Safety

Clinical Application of Fixing Device for Head Diagnosis and Treatment

By Feng Xu*

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Objective: To investigate the usage of head fixation devices for the diagnosis and treatment of patients with brain tumors or brain metastases. **Methods:** The data of 30 patients with head diagnosis and treatment fixation device and conventional head rest in head CT scanning performed by Tumor Prevention and Treatment Hospital of Tai'an and Department of Medical Imaging of The Second Affiliated Hospital of Shandong First Medical University from January 1, 2019, to May 30, 2021, were selected as the experimental group and the control group, respectively. The image coincidence and comfort of the two groups were compared before and after using the device. The Fisher's exact probability method was used for image coincidence, and the continuous correction chi-square test was used for comfort. **Results:**

Both groups of patients completed the study. The image coincidence rate of the experimental group was 100.00%, which was statistically significant compared with 63.33% of the control group ($p < 0.001$). The comfort of the experimental group was 96.67%, which was significantly different from 60.00% of the control group ($\chi^2 = 9.820$, $p = 0.002$). The CT value of the CT standard water model scanning was 0. When the standard water model was placed in the conventional head support of the CT machine, the CT value of the conventional head support water model scanning was −1. When placing the standard water model in the head diagnosis and treatment fixture, the CT value of the scanning water model was 1. **Conclusions:** The head diagnosis and treatment fixture can effectively improve the comparative diagnosis of brain tumors, so as to evaluate the treatment effect and improve the diagnostic quality, reduce the radiation damage caused by repeated irradiation caused by repeated positioning, improve the medical experience and comfort of patients.

C3: Quality of Care & Patient Safety

Study TPS of the Absolute Dose Change on the PD Verification Results

By Jun Li*

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Objective: To discuss the influence of the absolute dose deviation on the PD dose verification. **Methods:** Two groups of 40 test cases were used for verification. 180° fields of 20 cervical cancer cases and 0° or 180° fields of 20 postoperative esophageal cancer cases were selected to generate a quality assurance plan (QA plan). The 6 MV X-ray of Varian IX accelerator was used for IMRT, PD (Portal Dosimetry) software was used to simulate the absolute dose deviation (−5%–+5%), and then analyze the Gamma passing rate. **Results:** The value of the Gamma passing rate was decreased when the absolute dose deviated in positive and negative directions. The average of the maximum Gamma passing rate of 3 fields in 2 groups was 99.491%,99.546% and 99.227%, respectively. The Gamma passing rate at the zero-deviation point was 98.851%,98.761% and 98.140%, respectively. With the absolute dose deviation, the maximum of average Gamma passing rate appeared in −1%, −1% and −2% of relative variation, the values were 99.422%, 99.476%, and 99.068%, respectively. As shown, the ideal Gamma passing rate values were not at the zero-deviation point, in the range of −2%–−1%. **Conclusion:** The Gamma passing rate of absolute dose deviation has a significant effect. When analyzing verification results, the change factors of absolute dose should be taken into consideration. In radiotherapy, accelerator performance tests and dose verification of IMRT have to be executed periodically to ensure the accuracy of the output dose.

C3: Quality of Care & Patient Safety

Error Study of CBCT Registration Based on IGRT Image in the Positioning of Lung Cancer Radiotherapy

By Jun Li*

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Objective: To validate the positioning accuracy of intensity-modulated radiation therapy (IMRT) in 30 lung cancer patients using kilovolt cone beam computed tomography (CBCT) onboard the Innolux Synergy S-type accelerator. The clinical positioning errors of the radiotherapy were obtained and analyzed, and the clinical external radiation boundaries of the target area in lung cancer patients were explored based on the results of the positioning errors. **Method:** Randomly select 10 lung cancer patients who have recently been guided by IGRT imaging. All patients undergo daily imaging guidance, and the obtained cone beam CT images are registered with the planned CT images and their target centers to ensure that the actual irradiation center is consistent with the planned center. The positioning error data throughout the entire treatment course is recorded, including the positioning errors of each patient in the left and right (x), head and foot (y), and vertical (z) directions every day. The positioning error results are analyzed, and the clinical extravasation

boundary of the lung cancer target area is calculated according to the M = 2.5 ∑+0.7 δ formula. The CBCT images obtained from the results can clearly display the patient's tumor and surrounding soft tissue structures. The positioning errors of the patient in the x, y, and z axes are (0.05 ± 0.16) cm, (0.09 ± 0.32) cm, and (−0.02 ± 0.13) cm, respectively. The rotation errors of u, υ, and w formed by the patient in x, y, and z are (0.41 ± 0.64)°, (−0.08 ± 0.57)°, and (−0.03 ± 0.62)°, respectively. According to the patient's positioning error, the clinical external radiation boundaries of the lung cancer target area can be determined to be 0.82cm, 1.16cm, and 0.72cm, respectively.

C3: Quality of Care & Patient Safety

Alarm Fatigue—A New Global Survey of the Impact on Clinical Practice and Patient Safety

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Alarm fatigue is a widely acknowledged patient safety concern in hospitals. In 2013, The Joint Commission issued a National Patient Safety Goal on Alarm Management, identifying alarm management as a patient safety priority. To capture changes in attitudes and practices related to alarms, the Healthcare Technology Foundation (HTF) conducted and reported findings from a USA national online survey in 2006 and 2011 and completed a third survey in 2016. The next survey was due in 2021 by was necessarily delayed due to COVID-19.

In 2025, the HTF is once again progressing the survey to garner user feedback in this critical area. The merger of the HTF with the Global Clinical Engineering Alliance has offered an opportunity to update the survey and distribute it to an international audience.

This presentation will briefly review the background and context of alarm fatigue and the role that repeated surveys can play in affecting clinical practice and improving patient safety. It will then focus on the challenges of bringing the survey up to date and making it applicable to a global audience.

The actual survey window is later summer 2025, so full results and analysis of the survey will not be available for presentation. However, initial findings and lessons learnt will be discussed.

C4: Medical Imaging

Availability and Functionality of Diagnostic Imaging Modalities for Road Traffic Crash Injury Management in Ghana: Case of Ashanti Region

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Background: Diagnostic imaging technologies have enhanced the understanding and management of road traffic crash (RTC) injuries and are essential to guiding injury diagnosis. Despite their importance, few studies regarding their accessibility to crash-prone areas are available. This study sought to investigate the spatial accessibility, availability, and functionality of 4 essential imaging modalities (ultrasound, plain X-ray, computed tomography, and magnetic resonance

imaging) for RTC injury management in the Ashanti Region of Ghana. **Methods:** A cross-sectional quantitative study was conducted covering 38 public, private, and mission-based hospitals and 7 diagnostic centers. Data were collected with a structured questionnaire on equipment availability, functionality, and maintenance status. Spatial distance analyses between RTC blackspots and hospitals with imaging equipment were conducted using ArcGIS, and statistical comparisons were performed using Wilcoxon signed-rank tests. Descriptive comparative analyses were conducted to determine the functionality and maintenance status of the modalities studied. **Results:** The study found 3 MRI, 12 CT, 61 X-ray, and 108 ultrasound machines available in the region, with only one (1) MRI in the public sector. While 60% of CTs were found in the private sector, 59% of X-rays and 62% of ultrasounds were in the public sector. The overall estimated mean travel distances from a blackspot to the nearest MRI, CT, and X-ray modality were 35.43 km (+/− 19.80 km), 26.82 km (+/− 19.04 km), and 8.68 km (+/− 5.15 km), respectively. There was no statistically significant impact of non-functional MRI and X-ray modalities; however, travel distance to CT machines increased by 2.8 km ($p < 0.000$) due to the 3 hospital-based non-functional CTs in the region. Regarding technical support, in-house hospital-based biomedical engineers were found to possess technical expertise in maintaining X-ray and ultrasound technologies, but not CT or MRI. **Conclusion:** This study highlights the disparities in access to diagnostic imaging equipment in the Ashanti region of Ghana. While X-ray and ultrasound modalities were well-distributed across the region, CT and MRI access were limited. Prioritization of the repair and maintenance of the non-functional CT machines in the 3 health facilities will help improve access to this service and prevent delays to care for RTC victims.

C4: Medical Imaging

Artificial Intelligence for Breast Cancer Screening: A Multi-Criteria Decision Analysis Approach at Cremona Hospital

By Anna Beltrami[1,*], Adriano Felicione[2], Rossella Onofrio[3]

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Globally, breast cancer is the most common cancer diagnosis in women and a leading cause of cancer-related mortality. Despite major advances in screening technology, key challenges persist, such as reduced sensitivity in dense breast tissue, high false-positive rates, unnecessary recalls, and the growing workload on radiologists. Artificial Intelligence (AI) offers a promising solution to improve the efficiency and accuracy of breast cancer screening. This study explores the potential value and impact of introducing an AI-based system for breast cancer screening at Cremona Hospital in Italy. The evaluation is conducted through a Multi-Criteria Decision Analysis (MCDA) methodology, guided by the criteria provided by the Evidence and Value: Impact on Decision-Making (EVIDEM) framework and the Lombardy Region's Health Technology Assessment (HTA) program. The project investigates the AI system's performance and impact across technical, clinical, organizational, ethical, and regulatory dimensions. This analysis is based on an extensive literature review, questionnaire method (to patients), and focus groups with breast radiologists. Findings reveal that AI systems can achieve non-inferior or superior sensitivity compared to standard double-reading screening, particularly when used as a second reader or as a case-triage system. However, results are variable concerning specificity, underscoring the need for further validation using real-world data. AI also demonstrates potential in improving the cancer detection rate, without increasing the recall rates. Moreover, the ability to triage cases based on risk score offers opportunities for optimizing screening workflows. From an organizational standpoint, the implementation of AI could significantly reduce workload, with simulations showing a potential reduction in the number of reads, depending on the chosen strategy. This is particularly valuable in settings with a shortage of breast radiologists. Cost-effectiveness modelling suggests that AI presents a slightly higher incremental net monetary benefit compared to standard screening methods, assuming performance non-inferiority. Nevertheless, there remains high uncertainty in economic projections due to limited long-term evidence. Ethical and social considerations are also crucial to the analysis. Patients and professionals generally exhibit a positive attitude toward AI, recognizing its utility as a co-pilot rather than a replacement. Still, concerns remain about transparency, algorithm explainability, accountability, and the risk of automation bias. Ensuring fairness and inclusivity—especially regarding underrepresented ethnic groups in training datasets - is emphasized as a priority for

future AI development and deployment. From a regulatory perspective, the study reviews compliance requirements with European Union (EU) directives, including the Medical Device Regulation (MDR), the General Data Protection Regulation (GDPR), and the new AI Act. These frameworks stress the importance of data security, transparency, post-market surveillance, and robust documentation for high-risk AI systems. In conclusion, the study provides a structured, evidence-based framework to assess the utility of AI in breast cancer screening. In the specific context, it was used by Cremona Hospital's HTA committee to assign weighted scores across all investigated dimensions. Preliminary results support the integration of AI as a cost-effective, clinically valuable, and operationally impactful tool, provided that ongoing evaluation, transparency, and stakeholder engagement are maintained throughout its implementation.

C4: Medical Imaging

Planning & Implementation of a CT Trailer in a Canadian Acute Care Hospital

By Payal Mandot*, Tomas Whillans

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The expansion of diagnostic imaging services requires considerable capital investment and planning efforts, resulting in extensive timelines for the expansion of future capacity. Temporary measures, for example, the adoption of mobile imaging equipment, can increase capacity during the implementation of capital projects with long schedules.
The planning and implementation of a CT-equipped trailer in a Canadian acute care hospital provides examples of the efforts required and lessons learned. Multidisciplinary teams are convened to plan the patient needs, budget, long-term impacts, and prospective outcomes to best conceptualize the clinical experience and select the appropriate vendor/equipment.
Once selected, the integration of the trailer involved collaborative discussion through user group and technical meetings. Infrastructure availability, structural limitations, operational complications, and patient flow restrictions directed the final form. When received onsite, the trailer was incorporated into the institutional landscape. The simulation of emergency codes provided the opportunity for the integration of clinical and support services while troubleshooting site-specific complications. Through experiential procedures, the limitations of the CT-equipped trailer have come to light with climatic, aesthetic, and administrative issues providing key lessons learned.
The goal of this paper is to share the benefits of temporary, mobile equipment integration while highlighting the realities and exhaustive processes involved.

C4: Medical Imaging

Preliminary Evaluation of the Energy Consumption of MRI Systems

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The technological component in hospitals represents one of the main sources of energy consumption.
At the Clinical Engineering Service (SIC) of ASST GOM Niguarda, the Siemens Healthineers Teamplay® system is in use, which includes a module for evaluating the energy consumption of equipment. During a targeted measurement campaign, the following actions were carried out: calculation of consumption data based on power absorption measurements to verify the reliability of the data provided by the Teamplay® software; comparison between two MRI scanners to understand whether and what differences may exist.
Method: Measurements were conducted over 15 days using clamp meters placed on the power supply cables. Subsequently, average power values were considered to calculate energy consumption in kWh over the entire period and determine average values.
The power data was then stratified by sequence to verify specific consumption and perform a comparison between the

two machines using sequences with the same name.
Results: The results related to average power show that the Teamplay® system presents an error of ± 5% on overall power and about ± 15% on the average power per exam. For the sequence-specific power data, a substantial overlap between the two scanners was observed. For scanner A, greater variance was noted for each sequence. In the case of common sequences, scanner B was found to consume slightly less than A, with comparable variance.
Discussion: The percentage difference between the calculated power and the power reported by Teamplay® suggests that this software is reliable. These data can be used to implement improvement actions aimed at reducing energy consumption. As for the sequence-specific evaluation, a significant variability in consumption per sequence was observed. This is linked to exogenous and clinical factors: punctual modification of sequence parameters (sequence duration, slice thickness, gradient use, etc.) leads to large variations in consumption, even with the same protocol settings. This applies both within a single machine and across different devices, especially between different clinical settings (emergency vs. routine). Such data is considered too specific and of limited use for a Clinical Engineering Service, although it remains extremely interesting. A different approach could be taken by the manufacturer, who may conduct evaluations of another nature.

C4: Medical Imaging

Evaluation of AI Software Applied to Mammography Screening

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Breast cancer accounts for 25% of all new cancer cases and is the leading cause of cancer death (15.5%) in the female population. Mammographic screening reduces breast cancer mortality by 20–31%, but has limitations that reduce its effectiveness: the sensitivity of the method drops to 48% in dense breasts, and in screening programs, false positives are estimated to be around 10–20%. The use of artificial intelligence (AI), mainly driven by deep learning and convolutional neural networks, applied to mammographic screening is revolutionizing the field of breast radiology. AI as a standardized quality control tool improves the accuracy of breast disease diagnosis, and its use in mammographic screening has recently been shown to have a significant impact, up to a 29% increase in breast cancer detection. The macro applications of AI in mammographic screening are: Image analysis that automatically detects and classifies lesions, Image segmentation to identify areas of interest, Decision support for radiologists, and Improvement of image quality with a reduction in noise and an increase in resolution. The presence of microcalcifications, composed of calcium phosphate and calcium oxalate and whose deposition occurs through an active cellular process or by cellular degeneration, leads to the diagnosis of a non-palpable tumor in up to 55% of cases. Mammographic evaluation of microcalcifications has a low specificity, ranging from 10% to 60% and the number of unnecessary biopsies due to false positive results is high.
ASST Fatebenefratelli-Sacco has started a value-based healthcare evaluation of the AI software available to support breast radiology and mammographic screening. This software can investigate the potential of a deep convolutional neural network (dCNN) to accurately classify microcalcifications in mammograms and obtain a standardized and observer-independent classification system, based on the Breast Imaging Reporting and Data System catalog. The goal of using the dCNN as a standardized quality control tool is to improve diagnostic accuracy, thus reducing false positives and allowing a reduction in costs and waiting times.

C4: Medical Imaging

Rapid AI-Based Echocardiographic Screening Test (REST): Impact Assessment and Sustainability Perspectives

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The study investigates the application of advanced echocardiographic technology integrated with Artificial Intelligence (AI) for "Rapid Echocardiographic Screening Test" (REST), aimed at improving access, efficiency, and diagnostic capability in cardiovascular evaluations—particularly in preoperative settings and outpatient services.
The context is a healthcare system struggling with extensive waiting lists for outpatient echocardiography in Italy, where, despite policy efforts and a 23% increase in services offered since 2018, waiting times still vastly exceed the targeted 120 days for routine exams. Current strategies focus on limiting demand, but many echocardiographic requests remain inappropriate, suggesting the need for better triage and supply-side innovations.
The pilot study, conducted at Luigi Sacco Hospital in Milan, tested REST during preoperative anesthetic evaluations for non-cardiac surgery. It used two different ultrasound machines: a standard model (Philips Epiq7) and a high-end AI-driven system (Philips CVx). REST focused on apical and parasternal views and prioritized speed, essential measures, and automation.
229 patients aged 18–99 were enrolled, most of whom had never undergone prior cardiological imaging beyond an ECG. REST detected anomalies in 30.1% of participants. In 1.3% of cases, the findings were severe enough to cancel surgery; 3% required further cardiology assessment, and 24.9% warranted enhanced intraoperative monitoring. The study highlighted the effectiveness of REST in identifying otherwise unknown cardiac issues in asymptomatic patients.
Machine comparison showed that the Philips CVx significantly outperformed the traditional unit, offering better image quality and faster execution (avg. 320 seconds vs. 410). AI allowed automatic 3D cardiac reconstruction, real-time parameter calculation (e.g., ejection fraction, stroke volume), and full report generation—enhancing standardization, reducing operator variability, and improving workflow efficiency.
From a systemic perspective, the (AI-supported) REST represents a disruptive innovation. It allows fast, reproducible cardiac screenings in settings such as community clinics, potentially relieving hospital bottlenecks and enabling better triage by general practitioners. REST could serve as a first-line screening tool, reserving full echocardiograms for complex or higher-priority cases. Its simplicity, speed, and diagnostic value make it suitable for broader deployment, especially with proper training and infrastructure.
Investment represented by the acquisition of advanced ultrasound systems is compensated by increased productivity and accuracy of examinations. With examination times under 5 minutes, clinics could perform 4–5 RESTs per hour, compared to 3 traditional exams/hour. Pilot implementation is going to be widened towards outpatient facilities, with collaboration from general practitioners and specialists.
In conclusion, REST—empowered by AI and advanced imaging—offers a viable pathway to improve diagnostic accessibility, reduce waiting times, and optimize resource use in cardiovascular diagnostics. Rather than solely limiting demand, increasing and redesigning supply using technological innovation may finally yield sustainable solutions for modern healthcare systems.

C5: Facility-related Interventions

First Spanish Hospital Certified in ISO 27001 for Picture Archiving and Communication System (PACS) and Vendor Neutral Archive (VNA) Systems

By José Domingo Sanmartín Sierra*, Javier Montero de Espinosa Alés

Health Technology Management Service, Virgen del Rocío University Hospital, Seville, Spain.

At Virgen del Rocío University Hospital, we have been working for years to ensure the security of our clinical systems. As a result of this commitment, we became the first hospital in Spain to achieve ISO 27001 certification specifically for our PACS (Picture Archiving and Communication System) and VNA (Vendor Neutral Archive) systems — the core platforms responsible for storing and managing medical imaging across the hospital. Reaching this milestone was not easy; it took over two years of continuous work, internal review, regulatory adaptation, and a strong focus on

continuous improvement. From the beginning, we understood that having a functioning system was not enough—it needed to be secure, auditable, and fully aligned with both European and Spanish regulations, including the General Data Protection Regulation (GDPR) and the National Security Framework (ENS). This certification is not just a formal achievement; it reflects a deep commitment to protecting clinical information. Our journey began with a thorough risk assessment of the entire medical imaging ecosystem. We analyzed what could go wrong, how it might happen, and what the consequences would be for both patients and healthcare professionals. Based on this, we implemented specific measures: we segmented our networks, reinforced access controls, carried out system audits, and revised the operational protocols for our PACS and VNA platforms. Every step was designed not only to meet certification standards but also to make sense within the real-life workflow of the hospital. One of the most critical aspects of the project was involving all stakeholders. This could not be a purely technical initiative. Radiologists, technicians, IT staff, clinicians, and hospital management all had to work together. We organized training sessions, updated procedures, and built an Information Security Management System (ISMS) that would be sustainable over time. Each internal audit and review helped us strengthen the system and uncover areas for improvement. Finally, after a demanding external audit, we obtained the ISO 27001 certification. For us, this was not the end of the process but the beginning of a new stage: maintaining and continuously enhancing what we've achieved. This experience taught us that security is not a product or a checkbox—it's a culture that must be built through patience, discipline, and long-term commitment. With this presentation, we aim to share our experience with other healthcare institutions that may be considering this path. We will walk through the steps we took, the challenges we faced, the key decisions we made, and how this certification is now integrated into the daily operation of our medical imaging systems. We firmly believe that advancing cybersecurity means advancing the quality of care—and in today's healthcare landscape, projects like this are more relevant than ever.

C5: Facility-related Interventions

Health Technology Management Analysis for Accessibility of Portable Medical Devices in Penitentiary

By Mariana Brandão*, Renato Garcia

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Due to the increase in the global prison population, prison health has become a major concern for society and has been considered an urgent global public health issue. Despite neglect in many countries, the implementation of actions that ensure the universal right to health and disease prevention is essential. Portable Medical Devices have been incorporated into penitentiaries to contribute to the agility of examination and help in the accessibility of health for the prison population. This research aims to conduct an observational study to analyze the Health Technology Management of portable X-ray accessibility to generate evidence with real-world data on the benefits and challenges of using portable technologies in prisons. The project methodology consists of 4 main stages: understanding the problem through the study of regulations and scientific publications related to the prison health system as well as the medical device used in the case study; applying usability techniques to generate real-world data in the context of use considering the infrastructure, technology and human resources and to study the accessibility of the technology in the environment; applying the Ishikawa Diagram quality tool to identify problems; and to establish strategies through Clinical Engineering to make use safer and more accessible. An observational study with technical visits to prisons in Brazil was carried out during the month of April 2025 to analyze the use of portable X-ray technology in the screening and diagnosis of tuberculosis in prisons in Brazil. Observational analysis and task analysis were usability techniques applied in the context of technology use, and the Ishikawa Diagram quality tool was applied to categorize the causes of the identified problems. With this tool, it was possible to observe the causes related to human, technological, environmental, interconnectivity and data security, metrological, and protocol factors. Recommendations and strategies by Clinical Engineering in Health Technology Management were elucidated. One of the main challenges involving portable technologies in penitentiaries is related to: infrastructure factors such as quality of electrical energy and the need for adaptations in the power supply; vulnerability of the technology; lack of internet internally; exposure of the device to environmental conditions outside the manufacturer's admissible range; lack of radiological protection protocols; and lack of quality control. Encouraging

the practice of reporting adverse events and failures is a recommended practice so that more real-world data can be generated. This work applied usability techniques to extract data from the Real World and show that portable technologies have the potential to contribute to equitable and universal access to health care. Clinical Engineering has a crucial role in Health Technology Management in generating data to contribute to the establishment of strategies and recommendations to make technological use more accessible for all people. For future work, the researchers aim to study other cases of accessibility in medical devices inserted into an interdisciplinary ecosystem in a Living Lab, such as with the riverside population, as well as with people with different types of disabilities.

C5: Facility-related Interventions

Development of a Testing Protocol (PMS) for Pulmochip: A Medical Device that Determines the Effective Protection Factor of Respirators Used in Mining

By Sifuentes Llatas, Mauricio*, Leslie Yessenia Cieza Huane

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The mining industry, characterized by explosive-based extraction processes, exposes workers to airborne particulate matter that can lead to respiratory discomfort and long-term occupational diseases. In response to this occupational hazard, DRAEGER PERÚ SAC developed Pulmochip, a medical device designed to determine the Effective Protection Factor (EPF) of respiratory protection equipment used by miners throughout their workday. Pulmochip integrates a BME280 sensor to continuously monitor environmental variables such as temperature, humidity, and atmospheric pressure. Its embedded system processes the data to determine whether the respirator is being worn correctly, incorrectly, or not at all, providing quantitative metrics that inform occupational health specialists about the actual protective performance of the device in real-world conditions. However, despite Pulmochip's potential impact on occupational safety, it lacked a defined preventive maintenance system (PMS) to ensure its operational reliability, availability, and maintainability throughout its lifecycle. This thesis addresses that critical gap by developing a comprehensive test protocol specifically for Pulmochip, aligning with national and international medical device standards such as ISO 13485:2016, ISO 9001, NTP-IEC 60601-1, and guidelines from Peru's DIGEMID (General Directorate of Medicines, Supplies, and Drugs). The research methodology included four phases: review of applicable regulations, benchmarking of similar validation frameworks, design of the test protocol, and validation of its effectiveness through expert feedback and performance metrics (mean time between failures [MTBF], mean time to repair [MTTR], availability > 90%, reliability > 95%). The resulting protocol includes detailed procedures for verifying measurement accuracy, environmental performance, and system integrity, while incorporating tools such as anemometers, spirometers, and data acquisition platforms like Biopac MP35 for cross-validation. Through comparative literature analysis and prototype testing, this work demonstrates that implementing a protocol of this nature significantly enhances the device's preventive maintenance planning and reduces operational risks. By proactively identifying potential failures, standardizing test procedures, and ensuring compliance with regulatory frameworks, the Pulmochip test protocol stands as a model for similar medical devices intended for high-risk environments such as mining. In conclusion, the implementation of this protocol not only guarantees the safe and effective use of Pulmochip in occupational settings but also provides a scalable methodological framework applicable to other sensor-based medical devices. Its integration supports both public health policy and industry-driven innovation, fostering safer workplaces and more resilient medical technologies.

C5: Facility-related Interventions

Design and Production of a Carbon Monoxide Meter for an Incineration Facility—COMA

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This study explores the design and implementation of a carbon monoxide meter for incineration premises—COMA, with the aim of preventing worker health and safety and optimizing the incineration cycle. To achieve this objective, we adopted a documentary research approach, the definition of specifications, the choice of components, the design of an electronic circuit, the design of a 3D model of the box, the edition of the source code, the pre-tests, the final realization, the analysis of the results and the perspectives, including the use of a computer in particular for the work of editing the code, 3D modeling and electronic design; the use of electronic components (according to the electronic diagram) and manufacturing or prototyping tools; the Thingspeak platform connected to our device which allowed us to analyze and interpret the results of the measurements. The results demonstrated that following calibration using a reference device, the device is functional due to its ability to accurately detect carbon monoxide, which suggests that carbon monoxide is indeed present in the environment and therefore the environment constitutes a risk for practitioners, given its level. Furthermore, further observations revealed that the presence of carbon monoxide indicates incomplete combustion and, therefore, poor management of waste from production. These findings have significant implications for the incineration cycle, leading us to propose solutions to reduce carbon monoxide emissions, including efficient waste sorting, regular preventive maintenance, temperature control before and during the incineration cycle, and many others. In conclusion, this study presents the risks of carbon monoxide and an effective solution to reduce or minimize this risk to humans, emphasizing that this minimization enhances combustion optimization during incineration in a hospital setting. Future research could allow us to directly monitor carbon monoxide emissions and changes in the incinerator and significantly reduce them.

D1: System Interventions

Electronic Health Records—A New "Partnership of Trust" and Responsibility—the Requisite Undergraduate Training

By Richard P Fitton*

Healthcare Information For All (HIFA), Charlbury, Oxford, UK.

Electronic data, unlike doctors' handwriting, can be read or used by clinicians, patients, and computers alike. Data is now theoretically available anywhere in the world at any time and from any place. What framework, rules, and standards apply to the recording and sharing of the patients' information?

Undergraduate education does not include the ethics of digital health records standardly. Pontefract and Wilson have created a syllabus, as have Open Notes at Harvard. This presentation will discuss the educational requirements for personal data processing at the undergraduate level.

What are records used for?

- To plan, implement and record safe care
- To predict and prevent complications of disease
- To provide insurance underwriting information
- To produce police and court evidence
- To assess patients for special allowances and care
- To research conditions and treatment

Does confidentiality reduce safety and effectiveness?

Hospital doctors, GPs, and nurses treat patients using separate records that are unable to link with one another. Patients and relatives may wait weeks or months to find out the results of tests. Building and maintaining trust in electronic records.

Doctors and patients need:

accurate descriptions of the systems that are used
to be able to identify who stores, uses, and manages the data
to know who has seen the various parts of the records
to be able to see and correct the whole record
to understand that data cannot be deleted from the record, but can be hidden or quarantined, or annotated
to understand the reasons for the recording and sharing of data
to know which proxies can use the care record
to know who can see the records under the special powers of the government
to know the clinicians' responsibility to disclose information when the public is at risk

What could a patient ask that not be recorded in a record?

Doctors are contractually and professionally obliged to make a record of their consultations. The doctor and patient may agree not to go ahead with treatment if an agreement about recording cannot be made. Patients may request that socially sensitive information not be shared.

Third-party data

Third-party data should not be shared without the third party's consent.

Security

Vulnerable people will find it difficult to manage complicated security technologies, yet they may stand to benefit most from electronic records.
Libel, litigation, stigma, and employment discrimination
The legal protections against the inappropriate use of patient data.

Immediate or delayed views of data by patients?

Service providers should work to allow patients to see data as soon as it has been recorded.

The future

Research, patient involvement, education, training, guidelines, and standards will be necessary to make the new electronic record systems a success.

D1: System Interventions

Designing Safer Systems: A Methodological Framework for Conceptualizing Intelligent Medical Equipment Incident Management in Clinical Engineering

By J.M. Torres*, C.K. Boggio, M.C. Cama, S. Rua, V. Rivas, T. Saavedra, M. Viviano, S. Sotelo, F. Avendaño, J. Venancio

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Patient safety continues to be compromised globally by fragmented and inadequate systems for managing and reporting incidents related to medical devices. Each year, preventable events involving such equipment result in harm to millions of patients, contributing to human suffering and economic losses exceeding $42 billion, as estimated by the World Health Organization. Regional analyses reveal systemic weaknesses: in Uganda, 34% of tertiary hospital equipment is non-functional, while in Peru, 79% of hospitals lack the minimum required medical devices, and 59% report ongoing maintenance deficiencies. These realities expose deep gaps in both Quality & Risk Management and Health Technology Management—central topics of this Congress.

In response to these challenges, this work presents the early-stage design process of a conceptual solution aimed at addressing underreporting and inefficiencies in incident management. The objective was not to present a technological prototype, but rather to outline a rigorous methodology that frames the problem, diagnoses root causes, and defines robust design criteria for future system development.

We applied two complementary methodologies. First, the Cruz-Cordero structured exploration and diagnosis framework enabled us to understand the needs of clinical and engineering staff at a private clinic in Lima, Peru. This involved semi-structured interviews with frontline professionals—including clinicians, biomedical engineers, and administrators—and direct observation of workflows across five critical areas. Empathy mapping revealed recurring pain points, such as a lack of traceability, alert fatigue, and redundant manual reporting. Causal analysis using Ishikawa and Pareto tools highlighted core issues: non-standardized protocols, siloed data platforms, minimal feedback to

reporters, and limited visibility of incident data. These findings resulted in a clearly defined and evidence-based problem statement.

Building on this foundation, we applied the VDI 2222 engineering design methodology to conceptualize possible solutions. In Phase 0, objectives were aligned with Health Technology Management principles, focusing particularly on the operational stage of the HTM cycle. Phase 1 produced a structured profile of primary and secondary design requirements, centered on interoperability, real-time data capture, user-friendliness, adaptability, and long-term sustainability. In Phase 2, we evaluated potential system architectures—including cloud-based CMMS platforms, chatbot interfaces, and QR/RFID-enabled asset tagging—using a multi-criteria decision matrix to assess performance, compliance, and cost-effectiveness. Throughout the process, stakeholder co-design sessions brought forward hidden needs and validated assumptions, strengthening the design's relevance and feasibility. The impact of the system will be measured through Key Performance Indicators (KPIs) such as Mean Time Between Failures, Mean Time to Restoration, and related clinical engineering performance, Uptime, Downtime, Grade of Satisfaction Regarding CE Performance, and Corrective Action Rates. These metrics aim to enable even resource-limited settings to initiate performance tracking and shift from reactive to proactive risk management. A pilot test in partnership with the collaborating healthcare facility is planned to validate the solution's feasibility and impact.

By documenting this structured journey—from diagnostic clarity to design definition—we offer a replicable framework for healthcare institutions aiming to improve adverse-event reporting. This approach ensures that safety-driven innovation is rooted in contextual understanding, regulatory alignment, and interdisciplinary collaboration.

D1: System Interventions

Development of a Medical Device Management Education System Based on the Knowledge of Japanese Clinical Engineers

By Daisuke Inagaki*

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In many developing countries, medical equipment becomes unusable before the end of its expected service life due to inadequate maintenance and insufficient user training. To address this issue, we developed a medical device management and education system leveraging the knowledge and experience of Japanese clinical engineers, who have built their expertise since Japan's national implementation of such systems in 2003. We began by conducting comparative research on medical device management practices in Japan, Asia, and Africa. The results highlighted significant gaps in maintenance practices and human resource development. Based on these findings, we created a prototype system called "CeTrax" (Clinical Engineer Tracking System), which combines a cloud-based device ledger with video content created by Japanese clinical engineers to train biomedical engineers. This prototype was further refined into a commercially viable system. It is now in use at medical institutions in Cambodia and Myanmar, with inquiries from African countries as well. The system enables biomedical engineers to improve operational efficiency and ensure safer, higher-quality use of medical devices. A remote support structure involving Japanese experts has also been established to provide ongoing assistance. By deploying this system globally, we aim to centralize medical device management knowledge and build a network where professionals can support one another. What started as a research initiative has evolved into a practical solution with real-world impact, and we believe it has strong potential to contribute to safer, more effective healthcare systems worldwide. We welcome inquiries from those interested in implementation or joint research.

D1: System Interventions

From Access to Action in Leveraging Virtual Learning to Enhance Health Technology Governance in Haiti

By Jn Claude Felix[1,2,*], Dassaeve Brice[2,3,4], Max François Millien[2,3], Evens Emmanuel[2]

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Background: All healthcare systems today depend on technology. A key aspect of healthcare technology's success in improving health is how its "inputs" are managed. Haiti has prioritized building national capacity in planning and managing health technologies to enhance the effectiveness of its health system. In 2017, the Pan American Health Organization (PAHO) introduced a Healthcare Technology Management course through its Virtual Campus. However, it was initially available only in English, which limited access for Haiti's predominantly French-speaking health workforce. In 2020, with PAHO's assistance, Haiti established a country-specific node, leading to the launch of a fully translated French version of the course in 2021. Out of the 52 professionals from the ten administrative departments who enrolled, 33 completed the training, reflecting a growing commitment to strengthening local expertise in managing medical technologies. How might online training influence the development of competencies in health technology planning and management in Haiti? **Objectives:** This initiative aimed to examine the existing challenges and opportunities within the health system, highlight the status of healthcare planning, management, and capacity-building efforts in Haiti, and evaluate how targeted capacity-building courses can strengthen these areas. Ultimately, this will improve health system governance, enhance service delivery, and advance progress toward universal health coverage in Haiti. **Methodology:** The methodological framework of the Virtual Campus for Public Health, established over 20 years ago, was employed for the implementation of this course in Haiti. This process involved participant recruitment, orientation sessions, continuous assessment through quizzes, a final assignment, and a post-course evaluation. Data collected throughout these stages were retrieved from the Virtual Campus platform and will be analyzed using Microsoft Excel to conduct a descriptive analysis, summarizing participation trends, evaluation scores, and learner feedback. The findings from this analysis will be incorporated into this publication. **Results:** A total of thirty-three reports addressing contemporary issues and case studies in health care technology and management were developed and disseminated to health directorates nationwide. Furthermore, a cohort of thirty-three health system professionals, representing diverse regions and specialties, including administration, management, technology, and engineering, underwent training focused on various aspects of health technologies. **Conclusion:** This initiative illustrates the effectiveness of targeted, context-specific training delivered in the local language for enhancing national capacity in health technology management. The successful completion of the training program by 33 professionals, accompanied by the generation of practical reports, emphasizes the significance of such educational interventions in addressing contemporary healthcare challenges. By equipping key stakeholders within Haiti's health system with essential knowledge and tools, this initiative contributes to improved governance and more efficient service delivery, thereby facilitating measurable progress toward the goal of universal health coverage.

D1: System Interventions

The Evaluation of an Automated Environmental Quality Control Device Developed and Designed in the Neonatology Department of the Tanguiéta High School of Medicine (HSJD)

By Houessouvo C. Roland[1,2], Crecel C. Aymard[1,2*], Houinsou B. Joanie[1,2], Goudalo C. Faruq[1,2], Pecchia Leandro[3], Medenou Daton[1,2]

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This study explores the evaluation of an automated environmental quality control device developed and designed

in the neonatology department of the Tanguiéta High School of Medicine (HSJD), with the aim of evaluating the operation, reliability, and clinical utility of an environmental monitoring device. To achieve this objective, we adopted an experimental and observational approach, technical evaluation, clinical evaluation, data collection instrument, and subsequent data analysis, including a measurement comparison sheet, triggered alert log, and staff satisfaction questionnaire. The results demonstrated that the values collected by the device do not meet accepted standards, that the rate of alerts missed by staff is significant, and that the level of agreement between the device's measurements and the standards is acceptable, which suggests that the environment in the neonatal unit at the Tanguiéta HSJD does not meet international standards, an observation that can be made in a large number of hospitals in the sub-region. Furthermore, additional observations revealed that healthcare staff are not trained, or even if they were, they place only moderate importance on the quality of the environment in which newborns are hospitalized, and do not see the usefulness of a device that will act as an environmental parameter monitor. These findings have significant implications for explaining potential nosocomial pathologies contracted by premature newborns and maximizing the comfort of newborns admitted to the neonatal unit. In conclusion, this study presents a significant contribution to the subject by exploring current themes, highlighting the importance of good environmental management in neonatology departments. Future research could lead to the possibility of expanding or industrializing the system, automating the device so that it can itself make corrections to environmental quality, or integrating AI into the system.

D2: Policy, Discipline & Inclusion

Approaches to Building a Discipline of CE: From Research-Driven Professional Competency Enhancement to Innovation Platform Development

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Amid the rapid advancement of global medical technology and new-generation information technologies, the discipline of Clinical Engineering faces unprecedented opportunities. CE interdisciplinary innovation has emerged as a core driver for its development. This article proposes a disciplinary development pathway centered on "aligning research with hospital key specialties, integrating industrial engineering resources, and establishing multi-disciplinary innovation platforms." Coupled with a "Three-Phase Research Competency Enhancement Model" (foundational, progressive, and advanced stages), it systematically analyzes the mechanism of translating research capabilities into innovation platforms and explores practical approaches for Clinical-engineering teams in clinical demand identification, cross-disciplinary technology integration, and industry-university-research-hospital collaboration. Ultimately, a replicable disciplinary development paradigm is established. Case studies from multiple Chinese hospitals demonstrate that platform-oriented Clinical Engineering disciplines effectively accelerate the innovation and dissemination of medical technologies while significantly elevating the discipline's influence and status within and beyond hospitals.

D2: Policy, Discipline & Inclusion

Exploration of Opportunities, Challenges, and Paths for the Development of Clinical Engineering from the Perspective of Policies and Regulations

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This paper conducts an analysis from three dimensions: policy-driven standardization of clinical engineering, technological management innovation within the regulatory framework, and global governance collaboration pathways. At the policy-driven level, through a comparative study of China's "14th Five-Year Plan for the Development of Medical Equipment Industry" and

the U.S. FDA medical device regulatory system, it reveals the impact of policy orientation on the full lifecycle management of medical technologies. At the regulatory practice level, combining specific scenarios such as the safety of clinical use of medical devices and data privacy protection (e.g., GDPR and the Personal Information Protection Law), it analyzes the contradiction between regulatory lag and technological innovation. Taking the ethical review of AI medical devices as an example, existing regulations have regulatory gaps in aspects such as algorithm transparency and adverse event traceability, urgently requiring the establishment of a dynamic adjustment mechanism of "technical evaluation, regulatory iteration, and clinical feedback". At the global governance level, it proposes a dual-track model of "policy mutual recognition + technical collaboration". Drawing on the cross-regional cooperation experience of the Global Clinical Engineering Alliance (GCEA), it is recommended to promote the alignment of regulatory frameworks between developing and developed countries by establishing regional policy white papers and sharing compliance case libraries. Meanwhile, it emphasizes the innovative value of student groups in policy research, who can inject new momentum into industry development by participating in multi-center regulatory comparative studies and constructing digital compliance management tools. Based on the macro perspective of policies and regulations, this paper aims to provide academic and practical reference ideas for standardization construction, risk prevention and control, and global governance in the field of clinical engineering, echoing the industry development demands of the 10th "Global Clinical Engineering Week".

D2: Policy, Discipline & Inclusion

The Role of the International Federation for Medical and Biological Engineering and China in the Creation of the Global Clinical Engineering Alliance

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For more than two decades, the Clinical Engineering Division of the International Federation of Medical and Biological Engineering (CED/IFMBE) served the Clinical Engineering (CE) field worldwide. However, the global CE community recognized the need for more clearer identity to accelerate growth. While most IFMBE national affiliates represent academic biomedical engineers, most clinical engineers practice in hospitals or third-party healthcare services. To better represent the CE community, it was crucial to engage global leaders who have already influenced the field. In 2015, China played a key role by hosting the First International Clinical Engineering and Health Technology Management Congress (ICEHTMC), focusing on CE-specific topics. The event united international CE leaders and underscored their desire for a global representation. This led to the creation of Global CE Day, celebrated annually in honor of clinical engineers worldwide. Additionally, in this first event, an activity was introduced where participants reported and discussed the needs of the expertise of CE community in their countries and explored the role of the global CE community. Such debate further emphasized the need for a unified global. The Chinese event also sparked discussions about the organization of future congresses, leading to subsequent editions being held in Brazil (2017), Italy (2019), the USA (2021), and India (2023). Ten years later, the 6th ICEHTM will return to China, where it all began. Despite early enthusiasm, the concept of a global Clinical Engineering (CE) organization only materialized in 2019, with its official announcement in 2020 under the name Global Clinical Engineering Alliance (GCEA).

A major achievement during this period was the creation of the Global Journal of Clinical Engineering. The idea was to produce a free-access international high-quality journal with topics in the intersection of technology, engineering, and informatics related to health, wellness, disease management, and patient-care outcomes. Its first edition was released in 2018

During the GCEA formation, one key decision was the organization's name. After extensive debate, the term "Global Alliance" was chosen over "International Federation." This choice reflected the founders' intention to represent not only CE societies but also other stakeholders in healthcare-related professions. The word "Alliance" was selected because it signifies a collaborative arrangement among independent entities that commit to working together toward shared goals while maintaining their autonomy.

Concluding, the GCEA operates together, having more than 48,000 members from industries, CE societies, institutions, foundations, and even individual members from countries that have no CE representation or the local societies are not GCEA members. It is a solid organization with its own journal, constitution, and funds to achieve the vision it was created for.

D2: Policy, Discipline & Inclusion

Necessity to Build Awareness Universities in Lower-Resource Countries like Bangladesh Concerning Clinical Engineering and Hospital Management

By Hossain Md. Anwar[1,*], Al Amin[1], Nahidul Islam Nahid[2], Md Aminur Rahman[1], Md. Minhajul Islam[1], Afrin Binte Anwar[3], Md. Babul Mia[1]

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Clinical engineering is a specialized field within biomedical engineering that focuses on integrating engineering principles with healthcare technology to enhance patient care, safety, and the effectiveness of healthcare delivery. Clinical engineers work primarily in hospital and clinical environments, where they are responsible for the selection, installation, maintenance, and management of medical equipment and systems. This initiative aims to raise awareness about the importance of clinical engineering and hospital management in improving healthcare in lower-resource countries like Bangladesh. It highlights the need for proper education and training by including these subjects in university programs. A mixed-method approach will be used, including literature review, expert interviews, and surveys among healthcare professionals and university authorities. Data will be analyzed to identify gaps, assess awareness levels, and recommend strategies for integrating clinical engineering and hospital management education. The study found a significant lack of awareness, and no departments were found for clinical and hospital management in Bangladeshi universities. Most healthcare professionals and authorities recognized their importance but noted limited resources and initiatives. The results stressed the urgent need for education programs, professional training, and global collaboration to enhance healthcare quality. The study concludes that immediate action is needed to introduce clinical engineering and hospital management education in Bangladeshi universities to strengthen healthcare systems and patient safety.

D3: Training & Education for Next-Gen CE

Innovative Training Model for Clinical Engineering Education: The Tshwane University of Technology Experience

By Timothy Anton Okhai*

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The Clinical Engineering programme at Tshwane University of Technology (TUT) in Pretoria, South Africa, is designed to produce industry-ready graduates equipped to meet the evolving demands of clinical engineering and healthcare technology management. Structured as a three-year qualification, the programme integrates two and a half years of intensive theoretical and practical coursework with a six-month internship in a clinical or industrial setting. This hybrid model ensures that students not only acquire foundational knowledge in anatomy and physiology, biomedical instrumentation, healthcare technology management, and regulatory compliance, but also gain hands-on experience in real-world environments such as hospitals and medical device companies. The programme employs a problem-based learning (PBL) methodology, encouraging students to engage with real-world clinical engineering challenges from the outset. This learner-centred approach fosters critical thinking, collaborative problem-solving, and the application of theoretical knowledge to practical scenarios. In addition to traditional lectures and laboratory sessions, students participate in case-based discussions and hands-on workshops that simulate clinical environments. Assessment is multifaceted, with a strong emphasis on practical examinations that evaluate students' technical competencies and readiness for clinical deployment. A cornerstone of the TUT Clinical Engineering programme is its robust integration with the healthcare

and medical technology sectors. Through established partnerships with leading institutions such as Netcare, Mindray, and Steve Biko Academic Hospital, students are immersed in authentic clinical environments during their six-month internships. These placements expose students to the operational realities of healthcare technology management, from equipment maintenance and calibration to procurement and compliance. As a capstone requirement, students must also conceptualize, design, and develop a functional clinical engineering project, often addressing real-world challenges identified during their internships. The effectiveness of this training model is reflected in the programme's outstanding graduate employment rate, which consistently exceeds 95%. TUT Clinical Engineering graduates are in high demand both locally and internationally, securing positions in hospitals, regulatory bodies, and medical equipment companies. Beyond employability, students have contributed to the development of innovative, context-specific solutions for healthcare facilities across South Africa, demonstrating the programme's alignment with national health priorities and its capacity to drive technological advancement in resource-constrained settings. To address the growing demand for skilled clinical engineering professionals in South Africa and the broader Southern African region, TUT has introduced an online short learning programme titled the Medical Equipment Maintenance Course. This initiative has gained significant traction, with adoption in seven countries across the region. It serves as a scalable model for upskilling healthcare technicians and expanding the clinical engineering workforce, particularly in underserved areas. This forward-thinking approach underscores TUT's commitment to innovation, regional collaboration, and the sustainable development of healthcare technology management capacity.

D3: Training & Education for Next-Gen CE

Artificial Intelligence on Clinical Engineering: Redefining the Body of Knowledge and Practice for the Digital Age

By Fabiola Martinez-Licona*, Alma Martinez-Licona

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Technological development is rapidly advancing, with scientific discoveries leading to new applications that address current problems. In medical technology, we see a digital paradigm shift paired with the rapid growth of artificial intelligence frameworks, creating numerous possibilities. This scenario presents challenges for skill development, particularly for biomedical engineers. Academic programs and enhancing continuing education, seminars, and networking activities try to adapt to the complexities of providing effective and safe healthcare solutions using technology. Additionally, managing the vast amount of generated information is difficult, making the use of intelligent platforms for data collection and integration beneficial. This study consulted six artificial intelligence models to identify key topics for clinical engineers, focusing on what should be included in their knowledge and practice in clinical engineering and digital health trends. The AI models have identified 8 essential knowledge fields for developing a Book of Knowledge and a Book of Practice for clinical engineering, including Core Technical Foundations, Digital Health and Informatics, Regulatory and Quality Management, Patient Safety, and Emerging Technologies. Credit and hour restrictions can make incorporating these topics into professional development programs challenging. Together with the AI models' responses, a three-semester curriculum for a four-year clinical engineering program, emphasizing a highly integrated approach in the final 1.5 years, is proposed. This curriculum should combine various concepts into cohesive modules supported by practical components and project-based learning.

- Semester 1 (Year 3, Final Semester): This semester focuses on Advanced Medical Device Technology and Digital Systems. Students will learn advanced principles of medical devices, embedded systems, essential healthcare networking concepts, health informatics, interoperability standards, and foundational cybersecurity. Laboratory sessions will cover device operation, data flow, and basic networking and security concepts.
- Semester 2 (Year 4, First Semester): Focus on Integration, Regulation, Safety, and Quality: This semester emphasizes systems integration, regulatory compliance, safety, and quality management. Students will study advanced topics such as interoperability, cybersecurity frameworks, and incident response. The curriculum includes regulatory compliance, quality management, patient safety, and risk management. Practical components involve simulations, cybersecurity analysis, risk assessments, and regulatory documentation reviews.

• Semester 3 (Year 4, Final Semester): This semester focuses on Healthcare Technology Management, Operations, and Professional Practice. Key topics include technology assessment, lifecycle management, maintenance strategies, medical equipment planning, healthcare economics, vendor management, and project management techniques. Students will engage in project-based learning, applying their knowledge through a capstone project, with possible inclusion of clinical support functions like user training. This analysis underscores the need to update clinical engineering education and practice due to the influence of artificial intelligence (AI) and digital health technologies. We recommend implementing a flexible, modular curriculum, expanding partnerships with healthcare institutions for practical training, and using AI tools for personalized learning. These strategies, developed with input from educators, regulators, and technologists, aim to prepare a workforce to enhance safe and equitable healthcare solutions. Key findings and recommendations will be presented to foster dialogue on modernizing clinical engineering for the digital age.

D3: Training & Education for Next-Gen CE

Active Listening as a Transformational Tool for Technical Training in Clinical Engineering: The VOC Methodology Case at Hospital Albert Einstein

By Filipe Moreira Simionato*, Berthone Venancio Soares

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Operational excellence in healthcare is directly linked to the technical competence of teams responsible for the management and maintenance of medical-hospital technologies. This study presents the implementation of the "VOC" (Voice of the Customer) methodology as an innovative strategy for continuous training in Clinical Engineering, grounded in the active listening of team members. The approach enabled training personalization based on real data, enhancing technical knowledge, professional engagement, and operational safety. Initial results indicate a scalable model with high institutional impact.

Introduction: As medical technologies rapidly evolve, Clinical Engineering teams face the constant challenge of staying updated and prepared to ensure safety and efficiency. However, generic training programs often fail to meet this demand. This work presents a disruptive solution applied at the Albert Einstein Israeli Hospital: a training roadmap built from the active listening of the team itself, formalized through the "VOC" methodology.

Objective: To develop a highly personalized training strategy based on the actual needs perceived by the technical team, promoting operational excellence, risk reduction, and professional appreciation.

Methodology:

Personalized Diagnosis

Through individual interviews and structured questionnaires, it was possible to accurately map the team's technical knowledge level, practical difficulties, and process perceptions.

Training Roadmap Development

The training program was structured into three levels:

Initial Diagnostic Assessment: mapping of technical knowledge and operational gaps;
Targeted Basic Training: focused on areas with the greatest technical weaknesses;
Advanced and Specialized Training: aimed at collaborators with consolidated knowledge, covering complex technologies such as the Da Vinci Xi surgical robot and anesthesia equipment.

Continuous Monitoring and Adjustment

Active listening was maintained throughout the process with feedback cycles, re-evaluations, and content realignment. This dynamic approach made the program adaptive, responsive, and sustainable.

Preliminary Results

The initiative generated measurable benefits across multiple dimensions:

Increased Technical Confidence: greater autonomy in equipment operation and troubleshooting;
Operational Efficiency: reduced rework and improved service quality;
Satisfaction and Engagement: a sense of being valued among team members.

Example:

Anesthesia: "Can handle confidently" rose from 2% to 64%
Evidence of effective personalized training paths
Progressive increase in technical confidence (levels 4–5)
Da Vinci Xi: "Not in scope" dropped from 20% to 0%; "Can teach" rose to 25%

Discussion: The VOC methodology proved to be a powerful institutional transformation tool. By reversing the traditional logic—listening before teaching—training evolved from obligation to empowerment. Active listening served not only as a diagnostic instrument but also as a driver of engagement and excellence. The model is replicable and adaptable to other technical departments within the hospital and holds potential for integration into accreditation and patient safety programs.

Conclusion: More than a training program, the VOC methodology represents a paradigm shift in technical workforce development. Grounding training in active listening transforms knowledge into institutional value. This case points to a new path in healthcare professional growth—person-centered, data-driven, and excellence-oriented.

D3: Training & Education for Next-Gen CE

The Essential Role of On-Demand AI Tutors for Clinical Engineers in Advancing Healthcare Safety and Performance

By Ricardo Silva[1,*], Thomas Bustos[2], Erick Ortiz-Pelaez[2]

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Clinical engineers play a pivotal yet often underrecognized role in the healthcare system, tasked with ensuring the safe, effective, and ethical integration of medical technologies into clinical practice. As defined by the American College of Clinical Engineering, clinical engineers support and advance patient care through the application of engineering and managerial expertise to healthcare technology. Their responsibilities span from equipment procurement and maintenance to risk assessment, regulatory compliance, cybersecurity, and the ethical implementation of AI in medical devices. These professionals are embedded within the complex and high-stakes environment of hospitals, facilities that rely heavily on intricate medical systems to deliver accurate diagnostics, life-saving treatments, and continuous patient monitoring.

Given the constant pressure to prioritize patient safety, allocate scarce resources, and respond to emerging health crises, clinical engineers face significant challenges in dedicating consistent time to professional development. Traditional training models, reliant on fixed schedules and generic content, are misaligned with their unpredictable workflows and role-specific learning needs. Moreover, clinical engineers frequently encounter sporadic scenarios requiring highly specialized skills, such as configuring unique surgical robots or responding to medical device incidents. In such cases, immediate and tailored skill refreshment is essential to ensure patient safety and operational continuity.

This is where Lyah, an AI-assisted, on-demand teaching platform, becomes indispensable. Lyah offers a transformative approach to workforce training by delivering personalized, scenario-driven learning experiences aligned with institutional culture, procedures, and compliance mandates. Unlike conventional e-learning systems, Lyah uses conversational AI to simulate real-world challenges, enabling clinical engineers to engage in voice-driven, hands-free training. Whether revisiting protocols for infection control, practicing compliance with FDA regulations, or troubleshooting life-critical systems, engineers can rely on Lyah's adaptive coaching at any hour—no scheduling required.

Lyah's capacity for real-time feedback, dynamic simulations, and memory of individual progress empowers clinical engineers to build confidence and competence exactly when and where it's needed. The platform's AI analytics further provide measurable insights into knowledge retention, skill application, and training effectiveness—critical for ensuring readiness in high-risk environments. Additionally, Lyah supports multilingual learning and market-specific customization, making it invaluable for global teams managing diverse health technology infrastructures.

In a profession where safety, precision, and rapid decision-making are paramount, continuous access to tailored knowledge reinforcement can mean the difference between successful intervention and catastrophic failure. Lyah's

integration into the clinical engineering workflow not only addresses just-in-time learning but also fosters a culture of continuous improvement, ethics-driven technology management, and patient-centered innovation.
Ultimately, AI-powered tutors like Lyah are not a luxury: they are a necessity. By offering flexible, personalized, and interactive learning that aligns with the fast-paced and high-stakes nature of clinical engineering, Lyah enhances the ability of these professionals to uphold the integrity, safety, and resilience of modern healthcare systems.

D3: Training & Education for Next-Gen CE

Translating Clinical Simulation Methodology into Biomedical Engineering Training

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Clinical simulation has become a valuable educational tool in healthcare, allowing learners to practice skills and make decisions in safe, controlled environments. This study presents a conceptual and functional proposal to adapt Harvard's simulation model "Teaching, Coaching, and Debriefing with Good Judgment" to the training of biomedical engineers. The adaptation is based on functional analogies and conceptual equivalences, redefining key components such as briefing, simulation, and debriefing to fit technical scenarios focused on biomedical equipment maintenance and the professional interaction of biomedical engineers with clinical staff. To establish and validate this proposal, structured interviews and surveys are being conducted with experts from the Simulation Center at Universidad Peruana Cayetano Heredia, as well as with biomedical engineers with more than three years of clinical experience. The evaluation focuses on dimensions such as realism, applicability, contribution to decision-making, and potential for interdisciplinary training. This proposal offers an innovative pathway to integrate evidence-based simulation strategies into biomedical engineering education, fostering not only technical competence but also ethical and communicative skills within hospital environments.

D4: Quality Assurance & Patient Safety

Definition of a Laboratory Equipment Management Strategy

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Introduction: Since 2016, the government of Bénin has adopted a reform policy in the health sector. This policy has led to the implementation of a maintenance policy for critical medical equipment, including laboratory equipment. To support this policy, the Department of Health and Disaster Management has decided to improve the quality of laboratory equipment, the management of which falls under its purview. **Objective:** Improve the availability of laboratory equipment. **Achievements:** Conducted an inventory of equipment in 344 public and private "One Health" laboratories. Data processing was carried out using the Kobo Collect data collection tool. There are 5,091 functional equipment, 301 broken, 150 new unused (1 biochemistry machine, 1 blood bank, 1 freezer—80 large capacity, 1 PSM the reasons for non-use). The reasons for their non-use are: outdated model, lack of accessories, and reagents. 49 items less than 3 years old are already out of service. These are 8 machines due to the lack of reagents or consumables. 77.41% of the equipment is without maintenance contracts. 8.3% of the equipment has no brand, model, or serial number (51 centrifuges, 12 water baths, 4 shakers, 2 benchtop autoclaves, 2 microscopes, 1 precision balance, 1 spectrophotometer), 8.9% of the equipment has no brand or model, 23.2% of the equipment has a brand but no model (1 large-capacity autoclave, 2 refrigerators), and 33.7% of the equipment has no serial number (1 large-capacity autoclave, refrigerator, biochemistry analyzer). **Results:** The problems encountered are more common in the private sector, with donated equipment. To reduce these

shortcomings, capacity-building sessions are being organized for private sector and municipal stakeholders. Bidders are required to provide proof of the availability of spare parts, consumables, and reagents for at least 5 years in their tender applications. Implementation of Risk and Safety Quality Management (RSQM) for equipment, especially in private facilities. The provision of essential reagents and consumables through the consignment system at SOBAPS (central purchasing agency) for large equipment. **Conclusion:** This tool has highlighted weaknesses in laboratory equipment management, especially in private facilities, and enabled measures to be taken to ensure the availability of services and care in terms of laboratory analyses.

D4: Quality Assurance & Patient Safety

Research on Quality Control of Reprocessing for Medical Flexible Endoscopes

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Objective: To address low endoscope reprocessing compliance, the updated ANSI/AAMI ST91:2021 introduced mandatory biopsy channel inspection. Given the absence of equivalent requirements in Chinese standards, this study evaluates the necessity of implementing similar protocols in China. We investigated key factors contributing to reprocessing quality defects in reusable flexible endoscopes, analyzing real-world data on channel damage characteristics and their correlation with endoscope types to inform quality control improvements.
Methods: Following the Technical Guidelines for Real-World Data in Medical Device Clinical Evaluation and ANSI/AAMI ST91:2021, 156 flexible endoscopes from three tertiary hospitals in Guangxi underwent multistage inspection using a proprietary lumen inspection workstation. High-definition imaging quantified biopsy channel scratch/stain severity (Grade 0–3). Propensity score matching (PSM) controlled confounders; SPSS 27.0 facilitated chi-square tests and damage distribution analysis.
Results:
91.0% (142/156) exhibited channel damage (Grade 1 mild damage predominant: 48.1%; no Grade 3 structural damage).
Scratches were prevalent (63.5%; 99/156), significantly higher in gastroscopes than colonoscopes (82.6% vs. 53.8%, $\chi^2 = 9.987$, $p = 0.002$), primarily attributed to distal friction and noncompliant biopsy forceps handling.
Residues were frequent (stains 41.7%, droplets 26.9%) without endoscope-type correlation ($p > 0.05$).
Lumen anomalies significantly exceeded external damage (gastroscopes: 98.6% vs. 21.4%), indicating systemic cleaning deficiencies.
Conclusion: Biopsy channel scratches constitute the primary reprocessing defect risk, strongly correlated with endoscope type and operational site. This study provides the first clinical validation of ANSI/AAMI ST91:2021 applicability:

Integrate electronic endoscope inspection into national quality control protocols.
Establish type-specific maintenance strategies (gastroscope/colonoscope).
Enhance lumen drying to eliminate microbial colonization and prevent nascent biofilm formation.

D4: Quality Assurance & Patient Safety

Alarm Management on Medical Equipment in Intensive Care Rooms: Neonatology, Operating Theater, Emergency

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This study explores alarm management on medical equipment in intensive care units (neonatology, operating room, and emergency), with the aim of recycling alerts emitted by medical devices in intensive care units to ensure rapid, efficient, and safe patient care. To achieve this objective, we adopted both a qualitative and quantitative approach, including literature reviews (analysis of international standards and recommendations); Data collection tools (observation grid: monitoring staff behavior in response to alarms, type and frequency of alarms; equipment data sheet—verification of default settings, alarm thresholds, configuration options; descriptive and thematic analysis). The results demonstrated that the sound values collected do not meet accepted standards, suggesting that healthcare staff are not fulfilling part of their mission to limit alarms. Furthermore, additional observations revealed a complete neglect of alarms by healthcare staff, minimizing the importance they should attach to them. The lack of ongoing and sustained training for healthcare staff on the proper use of medical equipment was an important observation to highlight. These findings have significant implications for reducing irrelevant alarms and improving staff responsiveness to critical alarms; reducing acoustic stress and supporting the psychological well-being of healthcare staff; improving the reliability of medical equipment and limiting false alarms; supporting ongoing training for healthcare staff, particularly on alarm prioritization and finally, the application of other services (neonatology, operating room, emergency, etc.).In conclusion, this study presents multiple challenges related to alarm management in intensive care units, where patient safety largely depends on the responsiveness of nursing staff. This study also highlights a lack of specific training on alert systems, highlighting the importance of proper alarm management in hospitals. Future research could lead to the use of artificial intelligence and IoT in contextual alarm analysis, a standardized alarm classification system (low, moderate, critical, based on risk analysis).

D4: Quality Assurance & Patient Safety

The Development of a Quality Control Device for the Wavelength of Light Emitted by Lamps Used in Neonatal Phototherapy Equipment

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This study explores the development of a quality control device for the wavelength of light emitted by lamps used in neonatal phototherapy equipment, with the aim of ensuring the effectiveness of jaundice treatment in newborns. To achieve this objective, we adopted an experimental, quantitative approach, including a survey of biomedical technicians in hospitals nationwide and the design and construction of a portable prototype of the device. The results demonstrated that many phototherapy device lamps, although still in operation, do not emit light within the acceptable spectral range, suggesting that many phototherapy devices, despite their functionality, do not guarantee effective treatment for patients. Furthermore, additional observations revealed that the system could be adapted to other areas requiring light control, such as the treatment of diseases with phototherapy (such as vitiligo, psoriasis, etc.). These findings have significant implications for improving the preventive maintenance of phototherapy equipment and the quality and effectiveness of neonatal jaundice treatment. In conclusion, this study presents an accessible and ergonomic solution for the quality control of phototherapy lamps, highlighting the importance of technological innovation in strengthening biomedical equipment. Future research could incorporate even more precise electronic components and wireless connectivity to transmit data to a Computerized Maintenance Management tool to enable long-term performance analysis of the phototherapy device.

D5: Women in CE Inclusion & Impact

Social Media for the Democratization of Knowledge and Accessibility in Clinical Engineering

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The ubiquitous social media has developed an ecosystem full of opinions, information, and an unprecedented amount of data on various health topics. Billions of people use social media daily, which represents a significant opportunity for the use of platforms as a public health tool. In order to consolidate the need to democratize access to information on health technologies, the use of social networks has shown the potential to disseminate virtual content and contribute to Clinical Engineering (CE) in training in the management and safe use of health technologies. This research aims to present the ubiquitous use of different social media to disseminate knowledge on CE and analyze the impact on the accessibility of information for the population. This study analyzed the use of social media to share content on CE, which included: Instagram, LinkedIn, YouTube, TikTok, and the site. The content was developed by a woman Biomedical Engineer about: different stages of the life cycle in the management of health technologies; regulations; operation and care in the use of medical equipment based on scientific publications and technical standards; technological innovations in health; experiences and technical visits in medical device industries and events in the area. Different formats were used in the development of the content, such as videos, photos, webinars, and virtual events. By May 2025, a total of 26,807 users were registered on Instagram, 10,503 on LinkedIn, 3,100 on YouTube, and 3,8552 on TikTok. On Instagram, 1,290 pieces of content related to Clinical Engineering were made available for free. Between June 1, 2024, and May 2025, a total of 1,616,615 people were reached on Instagram through their posts, 385,316 users on LinkedIn, 59,900 on YouTube, and 774,000 on TikTok. Between September 2021 and May 2025, 158 free live broadcasts were held to contribute to the dissemination of knowledge. The profile of users ranges from students and professionals in engineering, technologists, technicians, health professionals such as nursing, medicine, architecture, physiotherapy, and biomedicine, among others. Regarding the location of work, mainly in hospitals and other health establishments, companies providing CE services, the Ministry of Health, health surveillance, health departments, universities, and research institutes. The use of social media contributes to the training of professionals working in CE through the consolidation of a ubiquitous, innovative, interdisciplinary, accessible, and collaborative ecosystem involving health technologies. Regarding gender, there is generally equality between men and women on the platforms analyzed; on Instagram and TikTok, there is a prevalence of women. The social media content involves the theme of women in CE on the platforms to strengthen the presence of women and encourage female leadership in the area. The presence of women's interested content reflects the need to encourage the inclusion and continuity of women in CE, to make the area more diverse, inclusive, and equitable. The use of different social media impacted millions of people during the period analyzed, and has the potential to make knowledge about CE accessible to society.

D5: Women in CE Inclusion & Impact

Bridging the Gap: Female Clinical Engineers and the Path to Gender-Inclusive Industry Innovation

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Clinical engineering is a critical technical support field in modern healthcare systems, closely linked to medical equipment management, technological innovation, and service quality improvement. In recent years, the participation of women in clinical engineering has significantly increased, making them a key driving force in industry development.

This study combines bibliometric analysis and industry empirical research to explore the career development, professional contributions, and growth paths of female clinical engineers, while proposing gender-sensitive optimization strategies for the industry.

Research findings highlight the unique advantages of female practitioners in medical technology innovation cycles. First, in medical equipment lifecycle management, female engineers excel in risk warning and quality control, achieving an 18.7% higher accuracy in predicting equipment failures compared to industry benchmarks. Second, in interdisciplinary collaboration, female-led teams demonstrate a 42% patent conversion efficiency in translational research, surpassing the industry average. Third, in patient-centered service innovation, female-led medical technology adaptation projects achieve 93% clinical satisfaction. However, structural barriers persist: a 28.5% gender gap in professional resource allocation, less than 15% female representation in technical decision-making roles, and institutional promotion barriers.

To foster a gender-inclusive industry ecosystem, a three-dimensional improvement plan is recommended:

1. Policy Level: Establish gender equality evaluation mechanisms in medical technology and include female engineer representation in hospital performance metrics.
2. Education System: Implement initiatives to eliminate gender stereotypes in STEM fields and support female clinical engineering scholars.
3. Industry Organizations: Develop mentorship networks, flexible work policies, and incentives for technology commercialization.

An innovative "technology empowerment, institutional support, cultural reconstruction" collaborative model is proposed to optimize human resource management in medical engineering. Notably, in the context of smart healthcare and digital transformation, female clinical engineers are driving innovation in wearable devices and AI-assisted diagnostics. Recommendations include implementing gender quotas in technical decision-making and ensuring at least 40% female participation in innovation teams. Projections indicate that building a gender-friendly organizational culture could double the proportion of female executives in clinical engineering within five years, driving a paradigm shift in medical technology innovation. This structural optimization will accelerate the transition from equipment maintenance to value-based healthcare, contributing new momentum to global health governance.

D5: Women in CE Inclusion & Impact

Women in Clinical Engineering

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When people imagine engineers, they often think of men in steel-toe boots on construction sites or oil rigs—images that don't represent the full breadth of what engineering is or can be. For many women, especially in regions where such environments are culturally restricted or physically unsafe, this stereotype becomes a barrier. Yet engineering is not only about heavy industry—it is about problem-solving and creating functional systems. Clinical engineering is one area that has enabled women to apply their technical skills in structured, safe environments such as hospitals.

This paper explores what it means to be a woman in clinical engineering today. It draws on real-world experiences, international data, and case studies from both low- and high-income countries to understand where women are entering the profession, where they are not, and the reasons why. The results are mixed. In some areas, women are stepping into leadership roles within national healthcare technology programmes, while in others, they are still striving for basic access to the field. The obstacles are familiar: a lack of female mentors, social pressure to avoid technical careers, workplace discrimination, and difficulties balancing family and work. For many young women, the absence of visible role models in technical healthcare roles means they never even consider such careers. However, where support structures exist, women are succeeding. Programmes offering mentoring, leadership training, scholarships, or simply the space to share experiences are having a meaningful impact.

In conclusion, the paper sets out broad yet practical recommendations to encourage the entry and progression of women in clinical engineering. These include inclusive hiring practices, targeted career support, balanced representation in leadership, and the collection of gender-specific workforce data. Clinical engineering offers a compelling path into STEM for many women—one rooted in real-world problem-solving and patient care. But greater action is needed to widen and smooth that

path. This paper makes the case for why and how we must act. Clinical engineering (CE), an important sub-discipline of biomedical engineering, continues to be a significant factor in the appropriate management and safe application of medical technologies in healthcare facilities. But, similar to other technical and engineering professions, clinical engineering has long been a male-oriented profession. Although the gender disparity in the discipline of science, technology, engineering, and mathematics (STEM) is well-documented, the unique experiences and opportunities for women in clinical engineering have been relatively ignored. This paper aims to fill that void by examining the world of women in clinical engineering, discussing barriers and breakthroughs, and proposing an agenda for inclusion and empowerment going forward.

D5: Women in CE Inclusion & Impact

Unique Contributions of Women in Medical Physics and Biomedical Engineering: Breaking Barriers and Shaping Healthcare Innovation

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Background: Medical physics and biomedical engineering have been fundamentally shaped by women's contributions throughout history, yet their achievements remain underrecognized, perpetuating gender inequity and discouraging female participation in medical device development. Despite persistent systemic barriers, women have demonstrated exceptional innovation in these critical healthcare fields, with their perspectives being particularly crucial in developing technologies that cater to diverse patient needs. **Objective:** This research addresses gender representation gaps by documenting and highlighting the unique contributions of women in medical physics and biomedical engineering, promoting gender equity, and inspiring future generations of female healthcare technology leaders. **Methods:** A comprehensive mixed-methods approach was employed, combining historical analysis of archival materials with a contemporary literature review. Data were gathered from peer-reviewed journals, books, and articles, with particular emphasis on works authored by women practitioners in the field. Qualitative insights into experiences, challenges, and successes were analyzed alongside quantitative representation data. **Results:** The study revealed significant historical contributions from pioneers, including Marie Curie (radium/polonium discovery, X-ray development), Rosalyn Yalow (radioimmunoassay invention), Patricia Bath (Laserphaco Probe system), and Flossie Wong-Staal (HIV gene mapping). Contemporary contributions include Dr. Michela Esposito's phase-contrast imaging techniques, Dr. Blumberg's sex-specific brain imaging research, and emerging leadership in AI-driven diagnostics and mobile health platforms. Despite approaching gender parity at undergraduate levels, women remain underrepresented in senior positions, accounting for only 15–27% of biomedical engineering faculty, with full parity projected only by 2067. Similar trends persist in medical physics leadership roles. **Conclusions:** Women's contributions to medical physics and biomedical engineering have been transformative, introducing user-centered design paradigms, equity-driven innovation, and inclusive healthcare solutions. Their leadership in digital health, artificial intelligence, and global health technologies continues to enhance accessibility in underserved regions. However, structural barriers persist, requiring intentional action through expanded mentorship, gender-inclusive education, equitable research funding, and celebration of role models. The future demands treating equity as a core design principle to fully harness diverse perspectives in addressing global health challenges.

D5: Women in CE Inclusion & Impact

Growing Together: Enriching the Experience of Young Engineers in Kuwait

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The Middle East welcomed its first two female biomedical engineers in 1972, when Kuwaiti pioneers Sahera Ramadan and the late Mariam Al-Humood graduated from the Catholic University of America in the United States. Upon returning to Kuwait, they established what is now the Biomedical Engineering Administration at the Ministry of Health (MOH)—a centralized authority overseeing all clinical engineering and healthcare technology management activities across MOH-operated hospitals and primary care facilities.

Appointing two young women to lead clinical engineering services in the 1970s was a bold and visionary step for Kuwait—especially at a time when female engineers in the region were few and far between. Yet, despite this early leadership within the Ministry of Health, progress did not extend to academia, where educational programs play a critical role in supporting national goals for development and modernization, particularly following Kuwait's independence in 1961.

As a result, aspiring biomedical engineers in Kuwait were left with few options. Those wishing to pursue this field had to study abroad. Locally, the only related program was a 2.5-year associate degree in medical electronics o□ered by the College of Technological Studies at the Public Authority for Applied Education and Training (PAAET), which primarily prepared graduates to work as biomedical engineering technicians (BMETs).

In 2005, a group of recent U.S. graduates in biomedical engineering—under the umbrella of the Kuwait Society of Engineers—founded the Kuwait Association of Biomedical Engineers (KABME). I had the great honor of being one of its co-founders. At the time, we were navigating our early careers with no local guidance and limited resources. So, we created our own community—a platform to support ourselves and others pursuing careers in this vital field.

Over the past two decades, as we have grown professionally, KABME has:

- Hosted events for high school and university students, as well as early-career engineers, including open days, career days, and informational sessions
- O□ered personalized academic and career guidance for prospective and current students
- Facilitated internship and apprenticeship placements for university students and recent graduates
- Partnered with employers to design internship programs and tailored training opportunities for emerging engineers
- Contributed to the development of undergraduate biomedical engineering programs at local universities

In September 2019, the American International University—Kuwait's first private university to o□er a bachelor's degree in biomedical engineering—launched its program. For us, it was a landmark achievement. For the first time, local students could pursue their dream of studying biomedical engineering without leaving the country. The following year, the International University of Kuwait launched a similar program, further expanding access to this critical field.

Today, we continue our mission: supporting biomedical engineering students and early-career professionals as they transition from academia to the workforce. We also collaborate with academic institutions to ensure that programs are aligned with market needs. Our journey reflects the power of community, vision, and persistence—and as we continue to grow, we remain committed to empowering the next generation of biomedical engineers in Kuwait.

D6: CE Societies, Alliances & Strategy

Engineering Leadership in Global Alliance: Cultivating a Generation of CE for Worldwide Impact

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As technology continues to transform healthcare delivery across the globe, clinical engineering stands at the forefront of ensuring equitable, safe, and effective medical technology management. In this evolving landscape, the need for a globally integrated alliance of clinical engineers—supported by visionary leadership—has never been more urgent. We explore how fostering global collaboration and leadership development to impact the future of clinical engineering and its role in health systems worldwide.

The successful creation of a Global Clinical Engineering Alliance (GCEA) hinges on shared values, interdisciplinary cooperation, and the strategic development of leadership capacities. As countries face varying healthcare challenges, ranging from technological innovations to remote virtual access, to regulatory compliance and systems integration, clinical engineers must transcend national borders and act as global citizens. By establishing common standards,

promoting knowledge exchange, and building a robust professional identity, clinical engineering can support health equity and resilience on a global scale.

Leadership plays a central role in this transformation. Traditional technical expertise must be complemented with competencies in communication, systems thinking, policy advocacy, ethical decision-making, and resource management. Emerging leaders must be equipped to navigate complex international settings, engage diverse stakeholders, and lead multidisciplinary teams. Leadership training programs—tailored for the clinical engineering context—should be embedded in academic curricula, professional development courses, and global mentorship networks.

Several initiatives already demonstrate an integrated approach. Global CE Summit, congresses, and journals have fostered dialogue and practical programs. Efforts by international organizations to support the professionalization of clinical engineering—through recognition of service excellence, capacity-building, program assessment and/or certification, and participation in standards development—have laid a foundation for broader collaboration. However, to accelerate progress, a deliberate focus must now be placed on empowering leaders within the field to champion sustainability, innovation, and inclusivity.

This paper advocates for a structured framework to support both the globalization of the clinical engineering discipline and the cultivation of leadership talent. It outlines the components of a successful model, including:

Global alliance between academic institutions, hospitals, industry, and regulatory bodies.

Leadership development pipelines with cross-cultural mentorship, hands-on experience, and integration of leadership theory.

Digital Journal platform that connects engineers, facilitates open knowledge exchange, and democratizes access to professional resources.

Ethical leadership principles that prioritize patient safety, social responsibility, and global health priorities.

By investing in leadership and building a cohesive global community, clinical engineering can evolve from a supportive discipline to a proactive force in global health. This transformation will require commitment from individuals, institutions, and international bodies alike—the return will be a more agile, inclusive, and resilient health technology workforce prepared to meet future challenges.

In conclusion, the convergence of global alliance-building on national societies' collaboration and leadership development offers a strategic pathway for advancing clinical engineering's role on the world stage. Through collaboration, education, and ethical leadership, the profession can drive meaningful progress toward universal health coverage, technological equity, system-wide innovation, and better healthcare outcomes.

D6: CE Societies, Alliances & Strategy

The Project of Clinical Engineering Development Strategy in Poland

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The project of clinical engineering development strategy in Poland aims to establish a modern system for managing medical equipment and technologies. Achieving international standards in clinical engineering (CE) in Poland in terms of organization, tasks assigned to specialists in this field, as well as knowledge and skills, is essential to meet the challenges of contemporary medicine and medical technology. This is necessary to ensure the safety and quality of

medical services using advanced medical equipment and innovative medical technologies.
The strategy is built on three parallel, interrelated workstreams, which must be carried out coherently, because neither the education of CE specialists without changes in the healthcare organization and legislation providing activity framework for CE specialists, nor, in turn, the assignment in the organization of tasks belonging to clinical engineering without the education of an adequate number of CE specialists will both fail to deliver results.

The workstreams are:

- **Organization:** establishing clinical engineering structures at various levels of the healthcare system to enable effective management of the medical devices lifecycle, from procurement through disposal.
- **Legislation:** developing and implementing legal amendments that specify the scope of practice, competencies, duties, and responsibilities of CE specialists, including cooperation with IT departments (cybersecurity) and medical equipment post-market surveillance.
- **Education:** launching specialist training programs and organizing courses for clinical engineers, and also educational initiatives highlighting the role of clinical engineering in healthcare.

The project unfolds in three phases:

- **Phase □:** Audit and strategic planning

  Conducting audits of clinical engineering activities in healthcare facilities, analyzing existing procedures and regulations, and identifying organizational and staffing gaps.
- **Phase □:** Organization, legislation, and education projects

  Developing an organizational model, performing legal analyses and preparing drafts of proposed regulatory changes, assessing workforce needs, and developing a program of specialization training in CE. Crucial tasks include defining detailed roles and competencies of organizational units and securing their legal mandate.
- **Phase □:** Implementations

  Implementing the new organizational structures, launching specialist courses and internships, and establishing a monitoring and evaluation system to track progress.

Project deliverables:

- an integrated clinical engineering framework within the healthcare system,
- an efficient medical devices management system that optimizes resource use, enhances safety, and improves patient outcomes,
- cost savings through efficient equipment utilization and preventive maintenance,
- legal amendments establishing the regulatory framework for clinical engineering,
- new positions for clinical engineers with legal regulations and clearly defined duties and competencies,
- accredited specialist training and practical internship, ensuring a suitable number of CE specialists,
- ongoing monitoring and evaluation enabling adaptation to emerging technologies and healthcare needs.

The presented strategy, by meeting international standards in terms of organization, specialized competences, and education, will align Poland with the best international practices in the field of clinical engineering, increasing the safety of the use of medical equipment, efficiency, and overall quality of healthcare.

D6: CE Societies, Alliances & Strategy

Appraisal of Biomedical Engineering Education, Career Paths, And Manpower Development in Sub-Saharan Africa: A Nigerian Case Study

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Clinical engineers are pivotal in advancing healthcare through improved diagnosis, therapy, and patient outcomes. Their work, rooted in research and development, has underpinned many medical breakthroughs. Yet, in low-income economies, limited access to technologies and a shortage of trained Biomedical Engineering (BME) professionals

remain major barriers. In Sub-Saharan Africa—particularly Nigeria—BME is rapidly emerging as a vital field within health and education, and is increasingly recognized as a catalyst for future innovations in medicine and biology. Although BME education globally dates back to the 1950s (Okoye & Nkuma-Udah, 2009, IFMBE Proceedings), structured training efforts in Sub-Saharan Africa began only in the 1970s and remain insufficient. Persistent gaps in healthcare equipment management, manpower development, and career guidance demand urgent attention. This paper examines the state of BME education, career development, and manpower capacity in Sub-Saharan Africa, using Nigeria as a case study. A major milestone is the establishment of undergraduate BME programmes at David Umahi Federal University of Health Sciences (DUFUHS), Uburu, and Enugu State University of Science and Technology, both awarding the Bachelor of Engineering (B.Eng). Replicating such initiatives regionally will help close the skills gap, strengthen career trajectories, and advance healthcare delivery in Sub-Saharan Africa.

D6: CE Societies, Alliances & Strategy

Activities and Achievements of the Japan Association for Clinical Engineers' Industry-Academia-Government Collaboration Committee in Medical Device Development and Medical-Engineering Collaboration

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Catalyzing Medical Device Innovation in Japan: Japan's concerted efforts in medical device development and medical-engineering collaboration began with the "Medical Device Industry Vision" in 2003. This foundational policy was significantly reinforced by the "Medical Device Industry Vision 2013", which emphasized the imperative for close cooperation among healthcare professionals, including physicians, nurses, and clinical engineers, alongside academic institutions and government agencies. The establishment of the Japan Agency for Medical Research and Development (AMED) in 2015 further streamlined medical research and development and centralized funding, thereby fortifying the infrastructure for medical device innovation. Faced with the challenges of an aging population, escalating healthcare expenditures, and an increasing burden on healthcare professionals, there is an urgent need for medical device development and systems that address clinical challenges and support "Work Style Reform" initiatives in Japan. JACE's Strategic Role in Fostering Collaboration: The Japan Association for Clinical Engineers (JACE), through its "Industry-Academia-Government Collaboration Committee", has been instrumental in driving innovation in medical device development from clinical settings, integrating national policy with the specialized expertise of clinical engineers from 2016 to 2025. The Committee's extensive activities include conducting numerous meetings annually, actively disseminating information at major medical device exhibitions, and establishing the JACE Medical Engineering Collaboration Award, which has been held eight times. Beyond internal initiatives, JACE strategically dispatches personnel to key governmental bodies such as the Ministry of Economy, Trade and Industry (METI) and AMED, and cultivates regional partnerships through information sharing with local METI bureaus, municipalities, and chambers of commerce. These multifaceted efforts have progressively transformed clinical engineers from mere "users" of medical devices into influential "players" in their development, a role increasingly recognized by governmental and other key institutions. The Value of "Bottom-Up" Innovation: The approximately 100 development achievements submitted to the JACE Medical Engineering Collaboration Award provide compelling evidence of clinical engineers' robust capability in identifying specific clinical challenges and devising practical solutions. While these innovations often lean towards non-medical devices or enhancements of existing products, this tendency is a testament to the significant value of "bottom-up innovation". Such initiatives directly contribute to improved operational efficiency, enhanced patient safety, and a tangible reduction in the workload of healthcare professionals, thereby holding immense intrinsic value. This approach, originating from the front lines of care, offers pragmatic and immediate solutions through systematization. Future Imperatives for Sustainable Growth: To ensure the sustainable evolution of medical-engineering collaboration in Japan, a critical shift from reliance on government subsidies to the development of commercially viable, "marketable medical devices" is essential. This transition necessitates the precise identification of commercializable needs, rigorous market assessment, strategic intellectual property (IP) protection, and a substantial enhancement of business acumen within the clinical engineering community. Clinical engineers are specifically urged to acquire proficiency in "true

needs identification and market analysis". To broaden engagement beyond a concentrated few, JACE is actively promoting comprehensive human resource development through recurrent education programs and the establishment of clear career models. Furthermore, leveraging clinical engineers' strengths in incremental medical device and system/software development, JACE aims to foster university-hubbed research and development, thereby increasing the number of clinical engineers involved in novel medical device creation and elevating their academic presence. Clinical Engineers as Strategic Partners on the Global Stage: This report highlights the transformative role and significant achievements of the Japan Association for Clinical Engineers in medical device development and medical-engineering collaboration, presenting a forward-looking perspective to the international community. Japanese clinical engineers are emerging as strategic partners, transcending their traditional role as device users, to contribute profoundly to resolving clinical challenges and ensuring the sustainable growth of the medical device industry by pioneering new and impactful domains.

D6: CE Societies, Alliances & Strategy

Founding the First Biomedical Engineering Society of Afghanistan

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The Biomedical Engineering Society of Afghanistan (BESA) is the country's first national professional organization connecting biomedical engineers within Afghanistan and Afghan professionals abroad. Operating in a context marked by political instability and security challenges, BESA addresses critical gaps in the biomedical engineering field. Established by the Afghanistan Center for Health and Peace Studies (ACHPS), BESA was created to address the lack of formal structure, collaboration, and academic support in Afghanistan's biomedical engineering field. Biomedical engineering remains largely unrecognized in the country, with professionals often working in isolation, no governing body for medical device management, and limited links to the global biomedical engineering community. Biomedical engineering academic programs throughout Afghanistan face shortages of qualified faculty, inadequate laboratories, and limited career guidance for graduates, further hindering the profession's development. BESA aims to strengthen biomedical engineering capacity, promote innovation, and support adherence to international standards in medical device safety and health technology management. The society provides advocacy, mentorship, and professional development opportunities for biomedical engineers and biomedical engineering students. Ultimately, its work benefits healthcare institutions and patients by improving the quality, safety, and reliability of healthcare technologies across Afghanistan's fragile healthcare infrastructure. Since its official launch in 2024, BESA has brought together over 50 biomedical engineering professionals from multiple provinces and actively engaged with biomedical engineering students across universities. The society has conducted educational trainings, awareness sessions, and advocacy campaigns aimed at influencing healthcare policies related to medical device management. Additionally, BESA has facilitated professional networking, conducted surveys to identify local challenges, and performed data analysis to inform its initiatives. The society is currently involved in several research projects designed to foster innovation and build capacity in the field. Operating under ACHPS, a recognized member of the Global Clinical Engineering Alliance (GCEA) and the PULL Alliance, BESA has drafted its constitution and established itself as a trusted resource for mentorship and technical support in a country facing a shortage of experienced faculty and academic resources. Looking ahead, BESA plans to formalize its governance council, expand mentorship and career counseling services, and develop training programs tailored to Afghanistan's unique needs. The society is actively pursuing international partnerships, including collaborations with the World Health Organization (WHO), to enhance medical device management systems and promote global best practices. Through these efforts, BESA is contributing to the development of a sustainable biomedical engineering workforce that will improve healthcare delivery and patient safety throughout Afghanistan.

D6: CE Societies, Alliances & Strategy

The Profile of the Clinical Engineer in Brazil

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This paper examines the available undergraduate and graduate programs in Biomedical and Clinical Engineering authorized by the Brazilian Ministry of Education and Culture, with a focus on curricular content shaping graduate competencies. Additionally, we assess the role of professional practice in developing essential skills.
Objective: To understand the profile of clinical engineers working in Brazil, considering regional particularities and local challenges that impact the full development of the professional role.
Conclusion: The profile of a clinical engineer in Brazil encompasses competencies across technical, managerial, and foundational skill sets. However, disparities in regional infrastructure and unequal access to academic programs pose significant challenges to workforce development.

D7: Credentialing & Accreditation for Global CE

GCEA's Global CE Accreditation Program and Digital Health

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GCEA is developing in 2024–2025 a global evidence-based Assessment Program, based on a best practice from Canada and its society (CMBES). The program will assess compliance with accepted standards of practice, using the CMBES SOP adjusted for cultural differences, for the healthcare entity requesting the assessment. According to the WHO, Digital Health (DH) is widely accepted as a key component of CE that emerged in the years before COVID but gained momentum during the pandemic. GCEA's governing body has experience in teaching and implementing various health technology (HT)-related digital health solutions for over 20 years. The DH chapter of the program outlines Key Performance Indicators specifically focused on the management of medical device software and cybersecurity within the CE domain. These KPIs are aligned with relevant industry standards and guidelines to ensure the safety, effectiveness, and security of devices integrated within healthcare environments, and directly under the oversight of the CE department. This includes areas beyond traditional Health Information Management (HIM), such as interoperability, network management, data analytics, and the integration of AI within CE workflows. The first two categories of proposed KPIs provide a framework for organizations to monitor and improve management of medical device software and cybersecurity, aligning with recognized HIM industry standards and guidelines, and contributing to the overall safety and security of the environment. The remaining CE—Information Technology categories address specific medical device, IT, and DH-related categories of KPIs. We outline the categories of HIM, CE-IT, and their respective KPIs. As countries worldwide seek to implement WHO DH strategies for care delivery, CE departments must grow into various device and HT emerging standards. The accreditation program will initially be judged on the basic foundational HIM and CE-IT standards.
Categories of KPIs:
1. HIM 7.1—MD Software Management
   KPI 1: Percentage of Medical Devices Managed According to IEC 62304 Lifecycle Processes
   • **Description:** Measures the proportion of medical devices with embedded or associated software that are managed throughout their lifecycle in accordance with IEC 62304: Software lifecycle processes for medical devices. This KPI ensures that medical device software is developed, maintained, and retired following recognized safety and quality standards.
2. HIM 7.2—Cybersecurity for Medical Devices (AAMI TIR97, FDA Guidelines)
3. CE-IT 7.1—Interoperability Standards
4. CE-IT 7.2—Connected Medical Devices

5. CE-IT 7.3—Network Infrastructure (Routers, VLANs, Domains)
6. CE-IT 7.4—Software and Firmware Updates
7. CE-IT 7.5—Data Warehousing and Analytics
8. CE-IT 7.6—CMMS and Inventory Systems
9. CE-IT 7.7—Domain-Specific AI Applications
10. CE-IT 7.8—AI and Digital Health Training
11. CE-IT 7.9—Operational and Strategic Readiness

D7: Credentialing & Accreditation for Global CE

Clinical Engineering Accreditation: The Way Forward for a Quality Health Technology Management

By Hashem Al-Fadel*

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Accreditation of Clinical Engineering Departments is a vital process that ensures the effective management of healthcare technology and ensures patient safety, regulatory compliance, reliability, and overall quality of care. As hospitals increasingly rely on complex medical devices and systems, the role of clinical engineering has evolved from equipment maintenance to a comprehensive, strategic function that supports clinical operations, risk management, and cost-efficiency. Accrediting these departments affirms their capability to meet recognized standards in technical performance, safety practices, documentation, workforce competency, and continuous quality improvement.

The importance of accreditation lies in its ability to enhance standardized operations, reduce variability, and assure stakeholders—patients, clinicians, administrators, and regulators. Accredited departments demonstrate adherence to internationally recognized best practices throughout the life cycle of medical devices in areas such as health technology assessment, medical equipment management, preventive and corrective maintenance, asset management, device calibration, workforce competency, and incident investigation, among others. This minimizes equipment-related risks and supports the optimization of clinical workflows, thereby contributing to improved patient care outcomes.

In today's healthcare landscape, the need for accrediting clinical engineering departments is more pressing than ever. Currently, there is no International Clinical Engineering Accreditation available. However, the general accreditation includes standards for CE departments, but these standards are not comprehensive. The rapid evolution and advancement of medical technologies, the evolution of AI, cybersecurity, robotics, stricter regulatory frameworks, and increasing emphasis on healthcare quality and accountability demand a robust and standardized approach to technology management. Therefore, specific CE accreditation provides a framework of evidence-based standards to be applied for assessing the performance and advancement of clinical engineering services, enabling a plan for optimal improvement of services. It also helps integrate clinical engineering into hospital-wide quality and risk management systems, ensuring that technology management aligns with institutional goals, patient care strategies, and the overall accreditation of the healthcare organization.

Eligible departments seeking accreditation are generally evaluated through a robust process that includes a pre-visit, on-site assessment, and post-assessment. The on-site assessment is conducted by international clinical engineering expert surveyors. These assessments follow the International Society for Quality in Healthcare (ISQua EEA) assessment approach based on a detailed standard that includes reviewing operations, staff qualifications, quality assurance processes, emergency preparedness, the use of performance metrics, and others. Ongoing surveillance and re-accreditation ensure the department maintains high standards and adapts to emerging challenges.

In conclusion, the accreditation of Clinical Engineering Departments is a cornerstone of a modern, safe, and efficient healthcare system. It ensures that healthcare technology is managed systematically, transparently, and in accordance with recognized international standards and guidelines. By fostering a culture of accountability, innovation, and continuous improvement, accreditation strengthens the department's role as a critical partner in clinical excellence and patient safety. As health systems strive for higher quality and sustainability, accredited clinical engineering services will be better prepared to play a central role in achieving these goals.

As such, GCEA is embarking on establishing the first internationally recognized Clinical Engineering accreditation

program worldwide according to ISQua EEA accreditation schemes to address the challenges posed by evolving technologies.

D7: Credentialing & Accreditation for Global CE

Global Biomedical Engineering Program (GBEP): Establishing Standardized Career Pathways for Biomedical/Clinical Engineering Professionals

By Omar Alsohime*

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Biomedical and clinical engineering professionals play a critical role in safeguarding the lifecycle of medical devices—akin to "treating" devices as patients. To serve in this role, Clinical Engineers must be competent. Unlike medical specialties with defined training and credentialing pathways (e.g., physician → registrar → specialist → consultant), Clinical engineers lack a standardized progression training. Currently, device manufacturers authorize their own service teams, and compliance with international regulations (e.g., IMDRF guidance, IEC/ISO/ASTM standards) does not explicitly define the clinical engineer's role across manufacturers, regulatory authorities, conformity assessment bodies, test houses, and healthcare providers. This gap raises questions about whether clinical engineers possess the competencies to drive device conformity, participate fluently in regulatory and technical discourse, and ensure patient safety in clinical settings that are not held to the same ISO 13485 and ISO 14971 obligations as manufacturers. **Methods:** We conducted a comprehensive review of international and regional medical device regulations, standards, and guidelines (including ISO 13485, ISO 14971, and relevant IEC technical committee publications). We performed a gap analysis to identify essential technical and regulatory competencies and examined existing credentialing models. **Results:** Key Horizontal competency domains were identified, including risk management (ISO 14971), electrical safety (IEC 60601-2-XX), cyber security, Human Factor Engineering ISO 62366, quality management (ISO 13485), biocompatibility ISO 10993, Sterilization, regulatory affairs, and Planning, Procurement, reimbursement, clinical evaluation reports preparation skills, and contracts management. Comprehensive examined understanding of horizontal competencies domains lead to vertical medical devices category level knowledge (Specialty) such as one of medical devices ISO's or IEC's subgroups (work groups or maintenance team) such as of SC62B, SC62C and SC62D to master the chosen category standards in all aspects that the manufacturers need to master and fulfil to approve their medical devices to maintain unified language among this category community and manufacturers of the same category. The experts of this category are expected to master testing, technical regulatory reviewing, clinical evaluation quality auditing, assessment, and accreditation of conformity assessment bodies conducting medical devices regulatory reviews and medical devices quality auditing organizations or regulatory body inspections and reviews. The affiliated biomedical engineering professionals of this category community are eligible to be trained and to be trainers on the brands and models manufactured under this category. Manufacturers of this specific category shall hire and trainer from this category community to train to close work orders related to the brand they manufacture. Healthcare providers, on the other hand, shall also make sure these categories' work orders are closed by affiliates of the same category community. The Regulator shall stipulate this as a requirement in the medical devices regulation. We propose a tiered career model—Junior Engineer, Specialist, Senior Specialist, and Consultant—each with defined educational prerequisites, competency assessments, and continuing professional development requirements. **Conclusions:** The GBEP framework offers a globally harmonized, regulation-informed career pathway for biomedical/clinical engineers. By aligning competencies with internationally recognized standards and regulatory best practices, GBEP empowers professionals to support all facets of the medical device lifecycle—design, manufacture, conformity assessment, clinical implementation, and end-of-life management—thereby enhancing device safety, efficacy, and healthcare system resilience.

D7: Credentialing & Accreditation for Global CE

Global Clinical Engineering Accreditation Program (GCEAP)

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The Global Clinical Engineering Accreditation Program (GCEAP) addresses the critical need for a standardized, internationally recognized framework to assess and improve Clinical Engineering (CE) and Health Technology Management (HTM) services in healthcare institutions. Developed in response to the growing demand for safe, effective, and sustainable health technology management, GCEAP provides hospitals with an objective framework to evaluate and enhance the performance and impact of their clinical engineering services. The program is rooted in the best global practices and developed through international collaboration. GCEAP offers a structured, peer-reviewed process to strengthen healthcare systems.

The execution of the MoU between the Global Clinical Engineering Alliance (GCEA) and the Canadian Medical and Biological Engineering Society (CMBES) permitted the utilization of CMBES peer-review methods and experience. The development progressed with additional standards following the ISQua EEA Guidelines and Principles for the Development of Healthcare and Social Standards, 6th Edition, Version 1.0, March 2025.

At the core of GCEAP is a multi-domain assessment model that spans eight key pillars: Governance & Leadership, Equipment Management, Maintenance & Safety, Regulatory Compliance, Human Resources & Training, Performance Monitoring & Quality Improvement, Professional Engagement, and Innovation & Research. Each domain includes specific criteria scored using a standardized rubric, enabling institutions to conduct self-assessments and benchmark their CE programs against international best practices.

The GCEPA process begins with a formal application and the submission of supporting documentation, including organizational charts, policy manuals, equipment inventories, and audit reports. Following this, institutions complete a detailed self-assessment using the GCEPA scoring tool, allowing them to identify strengths and areas for improvement. A review team of international clinical engineering experts then validates the self-assessment through remote or on-site evaluation, culminating in a performance rating and, where appropriate, the awarding of an accreditation level—ranging from Basic Compliance to Center of Excellence.

GCEAP is designed to be inclusive, scalable, and globally applicable. It accommodates varying resource settings and adapts to local regulatory environments while promoting harmonized professional standards. The program emphasizes not only technical and regulatory compliance but also leadership integration, user training, and a culture of innovation. Its goal is to ensure that clinical engineering professionals are fully equipped to support patient safety, cost-effective care, and the optimal use of health technologies across the equipment life cycles.

By facilitating peer learning, capacity building, and international recognition, GCEPA helps elevate the visibility and strategic value of clinical engineering within healthcare systems. It empowers hospitals to continuously improve their technology management programs and demonstrate accountability to patients, providers, and regulators. In doing so, GCEPA catalyzes advancing the global clinical engineering profession and ensuring equitable access to safe, functional, patient-ready, and effective medical technology.

D7: Credentialing & Accreditation for Global CE

Professional Credentialing and Accreditation of Biomedical Engineers in Thailand: A Two-Tier Certification System

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Background: Thailand has established a comprehensive credentialing system for biomedical engineers through the Engineering Council of Thailand (ECT), implementing a two-tier certification framework that ensures professional competency and maintains quality standards in healthcare technology management.
Objective: To present Thailand's professional credentialing system for biomedical engineers, highlighting the structured pathway from Engineer level to Professional Engineer level certification, assessment methodologies, and lessons learned from implementation.
Methods: The credentialing system operates under the Engineering Council of Thailand's regulations (B.E. 2564), establishing clear competency frameworks, assessment criteria, and continuous professional development requirements for biomedical engineering practitioners. The Work Categories of Biomedical Engineering are as follows:

Academic and R&D Work: Research and development in biomedical engineering technologies.
Industrial Manufacturing: Production and guidance of biomedical engineering products.
Healthcare Service Industry: Healthcare technology management, assessment, installation, testing, calibration, and maintenance.

Results: The system successfully differentiates between two professional levels: (1) Registered Engineer—capable of system operation, maintenance, and repair with safety and efficiency; and (2) Registered Professional Engineer—possessing advanced expertise in system design, installation, complex problem-solving, and risk assessment. The assessment process includes documentation review, competency evaluation across four domains, and structured interviews conducted by specialist committees.
Conclusion: Thailand's two-tier credentialing system provides a robust framework for ensuring biomedical engineering competency, promoting professional development, and maintaining healthcare technology safety standards. This model offers valuable insights for other countries developing similar certification programs.

E1: Preparedness Challenges

Survey on the Preparedness of Hospitals and Welfare Shelters for Power-Dependent Patients in Okayama Prefecture

By Takahiro Hirayama*

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Introduction: As healthcare becomes increasingly advanced, stable electricity is essential for operating medical devices critical to diagnosis and treatment. During the 2018 Hokkaido Eastern Iburi Earthquake, disaster base hospitals experienced a surge in treatment demand, such as dialysis, leading to emergency power usage that far exceeded expectations. This highlighted the need to strengthen patient intake capacity in both disaster-based and regional emergency hospitals. In addition, the expansion of home healthcare has raised concerns about supporting ventilator-dependent patients during power outages; however, the rate of individualized evacuation planning remains low nationwide. To assess the current situation and explore future measures, we conducted a survey of medical institutions in Okayama Prefecture regarding their preparedness for power-dependent devices and emergency response. The study also included welfare shelters designated for vulnerable populations to evaluate their capacity to accommodate home ventilator-dependent patients.
Methods: A questionnaire survey was conducted using Google Forms targeting hospitals in Okayama Prefecture. The survey collected data on the availability of emergency power supplies, the existence of blackout response manuals, and the capacity to admit patients who rely on electrically powered medical devices. In addition, field visits were made to welfare shelters designated by local governments to assess their evacuation environment and backup power systems.
Results: The survey was conducted in December 2023 with a response rate of 59% (93 out of 157 hospitals). Among responding hospitals, 87% reported having power-dependent medical devices. The duration of emergency power varied: 9% were uncertain, 41% had power for approximately half a day, 15% for one day, 14% for two days, and 21% for three days. Only 47% of hospitals had established blackout response manuals. Furthermore, only 34% of hospitals were prepared to accommodate home care patients, with many relying on manufacturers for support. Welfare shelters were found to have emergency power only for fire safety and emergency lighting systems, with limited access to 100V

outlets for medical use. Additionally, rooms designated for ventilator users were located on the third floor, but elevators would become inoperable during power outages, posing serious transport challenges.

Conclusion: The survey revealed significant gaps in disaster preparedness, particularly in the continuity of emergency power and the capability to accommodate patients reliant on power-dependent medical devices. Moreover, some government-designated welfare shelters were found unsuitable for housing home ventilator users due to inadequate power infrastructure and evacuation accessibility. It is essential to forecast healthcare demand during normal times and prepare by balancing it with the capacity of medical facilities. Furthermore, promoting region-wide disaster preparedness through collaboration among industry, government, and academia is crucial. In the future, we plan to visualize medical resources using IoT technology and implement comprehensive program management.

E1: Preparedness Challenges

From Crisis to Renaissance: Biomedical Engineers and the Revival of Hemodialysis Services in Sudan

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The 2023 conflict in Sudan had a devastating impact on the country's healthcare infrastructure, particularly on hemodialysis centers for patients with kidney failure, leading to a number of them shutting down, especially in Khartoum and Al-Jazirah states. This increased pressure on centers in other states with limited resources. This disaster has had a significant negative impact on kidney failure patients, even as the war continues to this day. This is due to the uneven geographic distribution, with most centers concentrated in the national capital, and Khartoum in particular, which was severely affected, leading to the closure of a large number of them—approximately 27 of the 35 government centers. Therefore, following the liberation of parts of Khartoum State, significant efforts were undertaken by biomedical engineers to rehabilitate and restore dialysis services. Nevertheless, critical questions remain: What will the maintenance and rehabilitation processes entail? What are the actual needs of these centers? What measures are being taken to enhance patient care? And what is the evolving role of the biomedical engineer in rebuilding healthcare infrastructure? This project seeks firstly to rebuild and restore hemodialysis centers in Khartoum State by rehabilitating damaged centers as an initial step, and then to lay the groundwork for extending these efforts to other affected centers as they are liberated. Secondly, to meet the urgent needs and benefits of both newly diagnosed patients and those displaced to safer regions following the closure of their local centers. In addition, the establishment of new centers in densely populated areas will help achieve a more equitable geographic distribution of dialysis services, ensuring better access to care in the post-war period.

As part of this initiative, new dialysis centers were established and existing ones were rehabilitated, focusing on areas with high population density, relative safety, and access to essential services. Key achievements include: Omdurman: Rehabilitation of the Habib Al-Rahman Center in Al-Hijra and the Children's Hospital Center; Establishment of two new centers: the Central Reserve Center and the Al-Fath Hospital Center; Bahri: Rehabilitation and reconstruction of the Al-Kadro Center and the Al-Ban Jadeed Hospital Center for HIV; Khartoum: Rehabilitation and reconstruction of the Bashaer University Hospital Center; Establishment of a new center in the Al-Shajara area.

These efforts mark a critical step toward restoring essential healthcare services for patients with renal failure and strengthening the resilience of Sudan's medical infrastructure amid ongoing challenges. All facilities were equipped with basic utilities, essential dialysis machines, and supplies, and situated in locations characterized by relative safety and high population density.

E1: Preparedness Challenges

Clinical Engineer's Role in Hospital Disaster

By James Wear*

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A clinical engineer should be part of the management of the hospital regarding disasters. A hospital should have a disaster team including key department managers and senior technical staff, such as the clinical engineer. Disasters that impact a hospital can be internal or external and may be natural or man-made. Natural disasters are earthquakes, hurricanes, tornadoes, and floods. Man-made disasters can be the result of industrial accidents, train wrecks, or terrorists' activities. Internal accidents, such as chemical or biological spills, are human-caused disasters. They should develop an emergency management plan to prepare for these potential disasters. They need to consider not only patients, but staff and the community. The plan needs to address power outages, water outages, gas outages, facility structure, communications, and keeping the facility from contamination. Contamination of the facility is a real possibility when patients arrive from industrial accidents or terrorists' activities. They should develop a manual indicating what is required for internal and external disasters. They should meet during the year to discuss their role and any potential new disasters. The hospital should conduct drills for potential disasters. When a disaster occurs, the team should come together and do what is necessary for the disaster according to the developed manual. The first person to arrive at the place where the manual is located becomes the person in charge, and that could be the clinical engineer. This person starts directing what departments need to do according to the manual. This may involve shutting parts of the hospital, controlling who can come into the ER, and, if triage is necessary.

E1: Preparedness Challenges

Risk Management, Regulations, and Disaster Preparedness

By Freddy Matamoros*

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The increasing frequency and intensity of natural disasters, technological events, and emergencies such as fires or explosions, understood as the violent release of energy accompanied by high temperatures, pose a significant threat to structural, non-structural, and functional safety in health centers. All these threats and risks can be internal or external, which would compromise the functionality and operability of the hospital center. They must guarantee its operability before, during, and after the adverse event. Hence, the importance of integrating risk management into the strategic planning of the health system. It is also necessary to carry out periodic drills, strengthen inter-institutional communication networks, and guarantee the autonomous supply of energy, water, and medicines for at least 72 hours. Disaster preparedness should not only respond to regulatory compliance, but should also be an active policy of prevention and resilience.

In this context, hospital disaster preparedness is not an option, but a strategic necessity. Investing in prevention and resilient health systems reduces human and economic losses, ensures the continuity of essential services, and strengthens the response capacity of countries in crises.

The following systems should be considered basic in the prevention and mitigation of adverse events: Smoke Detection System—Smoke Detectors, Heat Detectors, Manual Stations, Strobe Lights, Link Modules, Control and Monitoring Panel; Fire Protection System—Zones for Design (Classification of occupancies and commodities), Sprinkler Network, Constant Flow and Pressure Fire Pumps, Control Panel and Electrical Power Supply, Fire Boxes, Network of Portable Fire Extinguishers. In the case of magnetic resonators, the extinguisher must be ferro non-magnetic and its capacity according to area calculations, as well as the use of clean agents (FM-200, HFC-227ea, and Novec 1230) and alarms.

We must also consider the HVAC system, which refers to the air conditioning in the hospital, including some of its requirements: Emergency door opening, Placement of smoke sensors in ducts and elevator systems, and Automatic ignition of exhaust fans in emergency stairways.

From the non-structural point of view, we have to design and build hospitals with regulations in the medical gas, electrical, mechanical (boilers and generators), furniture, medical equipment, sanitary, computer communication, doors, and facades.

E1: Preparedness Challenges

Expanding the Role of Clinical Engineers: Enhancing Home Medical Device Safety and Disaster Preparedness in the Community

By Ichiko Watanabe*

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Background: In Japan, Clinical Engineers (CEs) manage medical devices in hospitals under the supervision of physicians. However, their participation in home healthcare remains limited due to regulatory restrictions and the lack of reimbursement systems for home visits. Consequently, patients receiving home care and their caregivers often face difficulties managing medical devices safely, on a daily basis, and in emergency situations.
Objective: This study aimed to explore the potential contribution of CEs to community healthcare by promoting safe use of home medical devices and improving disaster preparedness through an educational initiative targeting Amyotrophic Lateral Sclerosis (ALS) patients and their caregivers. **Methods:** A lecture session titled "Risk Management and Disaster Preparedness for Home Medical Devices" was organized at a meeting of the Japan ALS Association Gunma Branch. The program included a review of incident reports from the Ministry of Health, Labour and Welfare, and introduced risk management strategies for devices such as ventilators, oxygen concentrators, and pulse oximeters. Practical measures for disaster preparedness, including portable power supplies and manual backup devices, were presented. A discussion-based format encouraged participant engagement and knowledge sharing. **Results:** The session was attended by ALS patients, family caregivers, district nurses, municipal health officials, and home-care staff. Active discussions revealed significant gaps in medical device safety awareness among non-medical participants. Many caregivers expressed concerns about power outages and insufficient training. The session successfully raised awareness of risks and preparedness strategies. Local newspaper coverage of the event further amplified its community impact. **Discussion:** Home-care settings often lack professional oversight, increasing the risk of inappropriate device use and vulnerability during disasters. The high level of interest in power backup solutions, including the use of electric vehicles and renewable energy, points to opportunities for CEs to contribute more broadly. This session demonstrated that technical expertise from CEs can play a crucial role in empowering patients and caregivers, improving safety, and enhancing community resilience. **Conclusion:** To ensure the safety and well-being of home-care patients, it is essential to expand the role of CEs beyond hospital settings. Regulatory reform and the development of interdisciplinary support systems are urgently needed. Future initiatives should focus on establishing sustainable frameworks that enable CEs to actively participate in community-based healthcare and disaster preparedness efforts.

E1: Preparedness Challenges

Tailoring a "Full BLS4" Hospital for the Management of Highly Hazardous Pathogens-related Health Emergencies and of Bioterrorism Threats

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Luigi Sacco University Hospital is an Italian center of excellence for research, diagnosis, and clinical care of infectious diseases. The extended institutional experience, coupled with the availability of high containment facilities, makes the

hospital a regional and national referral for diagnosis and management of Risk Group 3 and 4 Biological Agents and Bioterrorism.

During the last 20 years, the institution has been involved in several health emergencies, such as SARS, Swine flu, COVID-19, and Mpox, as well as in suspected cases of Filoviridae (Ebola virus, Marburg virus), Arenaviridae (Lassa virus), MERS, and possible intentional release of Bacillus anthracis spores.

The care of highly infectious patients is demanded by different departments according to clinical presentation, requiring proper containment features. The Infectious Diseases Department is endowed with a High Isolation Unit: distinct access and exit routes segregate donning and doffing of Positive Pressure suites, and the whole area is maintained at negative pressure and supplied by HEPA-filtered air. The same characteristics are present in 10 single rooms of the Intensive Care Unit and in the new Infectious Diseases Emergency Room (ID-ER), opened in 2025 for triage and first aid of potentially highly contagious patients.

High containment facilities are also available in the Laboratory Medicine Department. The Anatomical Pathology Unit, national reference center for autoptic diagnosis of prion disease cases, includes the only Biosafety Level (BSL) 4 autopsy room present in the country. In addition, the Laboratory of Clinical Microbiology, Virology and Bioemergencies Unit is equipped with laboratories of BSL 2, 3, and 4. The BSL4 facility was built in response to the 2002 SARS outbreak and was subsequently used to conduct diagnostic and research activities until its dismission in 2024, due to the renovation work of the entire building.

Meanwhile, the project of a new BSL4 facility was approved in 2023: the laboratory will be located in a new, independent building, in an area entirely enclosed by protective barriers and continuously under video surveillance. The facility was designed as a suit laboratory, with double, independent working areas, in accordance with international standards on the engineering and design features to prevent Biological Agents in the community and in the environment. The new BLS4 lab project is led by a team of microbiologists, clinical engineers, epidemiologists, and construction engineers. The new ID-ER and BSL4 laboratory will allow the hospital to improve the response capacity against health emergencies and bioterrorism at the national and international level.

E2: Medical Oxygen Challenges

Monitoring Water Levels in Humidifier Bottles during Oxygen Therapy: A Case Study of Healthcare Technology and Oxygen Access Management in Low-Resource Settings

By Maria Regious Nansereko*

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Oxygen therapy is an essential intervention in the management of respiratory disorders across all healthcare settings. A critical component of oxygen delivery systems is the humidifier bottle, which contains water that ensures proper humidification of medical oxygen, preventing airway dryness and improving patient comfort. While this process is standardized in well-resourced hospitals, maintaining appropriate water levels in humidifier bottles still presents significant challenges in low-resource environments, where monitoring is often inconsistent and automated systems are largely unavailable. Inconsistent monitoring of water levels can lead to improper humidification, thus compromising patient comfort and oxygen therapy efficiency. This study focuses on a low-resource Ugandan health facility to explore the challenges and potential solutions for effectively monitoring water levels in humidifier bottles.

A study was conducted in a Ugandan hospital where I had my internship, focusing on oxygen delivery in patients with respiratory concerns post-surgery in the surgical ICU. The study analyzed the current practices of healthcare workers in monitoring water levels in humidifier bottles, the impact of low water levels on oxygen therapy, and the availability of automated monitoring systems. Data was collected through interviews with healthcare workers and direct observation of oxygen therapy procedures.

The findings revealed that healthcare workers in low-resource settings often rely on manual observation of humidifier water levels, mainly at close proximity, and estimation of when they last refilled the humidifier bottles with water, which leads to inconsistent maintenance. In many instances, bottles were either left dry or overfilled, thus reducing the effectiveness of oxygen therapy. This highlighted the need for an automated system to monitor these water levels as

attached to the humidifier bottles to alarm when water levels drop or even get impure.
Implementing a simple, cost-effective water level monitoring system on humidifier bottles could significantly improve oxygen therapy outcomes. A low-cost sensor that triggers alarms when water levels drop or rise beyond optimal levels can bridge this gap that seems so insignificant, but can cause intense dangers.

E2: Medical Oxygen Challenges

New Dawn for Oxygen at the Last Mile: How Oxygen as a Service is Transforming Rural Healthcare in East Africa

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Background: Medical oxygen access remains critically limited in rural East Africa, with healthcare professionals reporting erratic electricity supplies and malfunctioning oxygen delivery systems. Medical technology manufacturing is concentrated in high-income countries (85%), creating dependency on expensive imports and unreliable supply chains that fail at the "last mile" of healthcare delivery. **Objective:** To examine innovative oxygen delivery solutions and their impact on healthcare accessibility in rural East African communities, with a focus on sustainable service models and regional initiatives. **Methods:** Comprehensive review of existing literature on affordable medical oxygen technologies, analysis of the East African Program on Oxygen Access (EAPOA) implementation, and evaluation of innovative delivery systems, including FreO□ and O□cube low-pressure storage solutions. **Results:** The EAPOA initiative, launched in October 2024 and funded by Unitaid through Clinton Health Access Initiative, is establishing a regional network of liquid medical oxygen production facilities using a hub-and-spoke model. New production facilities in Mombasa and Nairobi, Kenya, driven by three leading regional manufacturers, will significantly boost oxygen production capacity. The "oxygen as a service" model addresses multiple challenges by reducing upfront capital requirements for healthcare facilities while ensuring ongoing maintenance and technical support. Integration of renewable energy sources and local manufacturing capacity demonstrates sustainable approaches to healthcare technology access. **Conclusions:** The transformation from oxygen scarcity to security in rural East Africa demonstrates the successful convergence of innovative technology, sustainable financing, and local ownership. The hub-and-spoke distribution model coupled with service-based delivery represents a paradigm shift from aid-dependent to locally-driven, commercially sustainable healthcare solutions. These initiatives provide a replicable template for addressing healthcare access challenges in resource-constrained settings globally.

E2: Medical Oxygen Challenges

Lessons Learnt from the Implementation of the Medical Oxygen Infrastructure Project in Kenya

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The World Health Organization (WHO) classifies Oxygen as a lifesaving medicine with no substitution that should it be should be available all the time in a healthcare facility. The COVID-19 pandemic highlighted the critical need for reliable medical oxygen in healthcare facilities globally. It exposed the vulnerability of the oxygen infrastructure, particularly in Low- and Mid-Income countries. This triggered emergency interventions to arrest the situation with sustainable long-term solutions. In Kenya, the installation of Pressure Swing Adsorption (PSA) oxygen generation

plants and associated oxygen piping systems emerged as a sustainable solution to ensure uninterrupted and increased availability, accessibility, and equitable distribution of medical oxygen to patients across the country. These include installations of oxygen plants in remote health facilities located in Semi-Arid areas, which in the past relied on Oxygen distributed in cylinders in lorries that could take days to arrive at exorbitant fees. It has provided oxygen cylinders and related equipment, trained healthcare personnel, and integrated oxygen into essential health services in the entire Country. The project aims to strengthen the health system through building a sustainable oxygen infrastructure, reducing mortality, and supporting Universal Health Coverage.

This abstract consolidates key lessons learned from the ongoing Global Fund (GF) Medical Oxygen infrastructure project in Kenya, being implemented by the African Medical Research Foundation (AMREF) Kenya office in Nairobi, Kenya, with the support of Build Health International (BHI) as consultant for GF. The paper will highlight best practices, common challenges, and strategic improvements.

Key findings include the importance of a comprehensive pre-installation site assessment to accommodate plant specifications and future scalability, planning, and designing the sheds/rooms to accommodate PSA. Designing oxygen piping as per HTM 02-01 and meticulous planning for installation to minimize operational disruptions, and adherence to safety standards to prevent hazards associated with high-pressure oxygen systems. Effective coordination among multidisciplinary teams—including engineers, healthcare providers, and regulatory bodies—was essential for seamless integration.

The lessons emphasize the significance of robust quality control during manufacturing and installation phases, as well as the need for thorough training of maintenance and operational personnel to ensure safe and efficient plant operation, and the challenges encountered. Additionally, the importance of effective oxygen piping design—considering factors such as material selection, insulation, and maintenance—was underscored to prevent leaks, contamination, and pressure drops.

Finally, post-installation monitoring and routine maintenance emerged as critical to sustain plant performance and safety. Implementing these lessons can significantly enhance the reliability, safety, and efficiency of medical oxygen supply systems, ultimately improving patient care outcomes.

E2: Medical Oxygen Challenges

Development of a Self-Audit and Regulatory Tool for Health Facilities Administering Medical Oxygen

By Tazeen Bukhari*

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Medical oxygen is a life-saving therapy that plays a critical role in both routine and emergency healthcare delivery. However, many health facilities, particularly in low-resource settings, lack robust mechanisms to assess and maintain the safety, functionality, and regulatory compliance of their oxygen systems. To address this gap, we developed a comprehensive self-audit and regulatory tool designed to evaluate health facilities' readiness and performance in administering medical oxygen. The tool, structured as a modular checklist, covers key domains including infrastructure, equipment functionality, preventive maintenance, staff qualifications, occupational health, cleanliness, documentation, and regulatory compliance. Each component is weighted by risk and criticality, enabling facilities to score their performance, identify gaps, and prioritize corrective actions. Beyond internal use, the tool also serves as a reference for external regulators and a source of reliable data for policy-makers and program planners. The tool was successfully piloted in two hospitals, revealing common gaps such as inadequate preventive maintenance planning, absence of staff training records and oxygen purity checks, standardized cylinder storage and labelling, and limited integration of oxygen systems into broader hospital safety protocols. Its structured design enabled immediate action planning at the facility level and offered a clear, auditable checklist for follow-up inspections by hospital management and regulatory authorities. Moreover, the tool can be used in conjunction with the Quality Manual for Medical Oxygen Systems—inspired by WHO guidelines and MTaPS frameworks—to check the implementation of best practices and standards at the facility level. The tool demonstrated strong potential for digital adaptation into a longitudinal dashboard that can support trend analysis, performance monitoring, and national reporting. As a next step, we are engaging stakeholders to

adopt the tool at national and subnational levels and are planning its digitization for broader accessibility and integration into health system management platforms. By aligning frontline facility needs with regulatory and policy frameworks, this tool bridges a critical gap in oxygen system governance, ultimately contributing to safer, more resilient healthcare delivery.

E2: Medical Oxygen Challenges

Strengthening Oxygen Supply Systems in Small Island Healthcare: A Case for Onsite Generation at Princess Alexandra Hospital—Anguilla

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Medical oxygen is a critical resource in modern healthcare, particularly in the treatment of respiratory illnesses, surgical interventions, and emergencies. In Anguilla, the Princess Alexandra Hospital (PAH) is the island's principal public healthcare facility with a 40-bed capacity. Ensuring a continuous and reliable supply of medical-grade oxygen, therefore, remains essential for delivering quality patient care across departments such as the emergency room, intensive care and isolation units, operating theatre, and general ward. Recognizing the vulnerabilities posed by reliance on external oxygen suppliers, including delays, disruptions, and emergencies, the hospital has embarked on the implementation of an on-site oxygen generation project. This ongoing initiative involves the installation of an on-site oxygen generation plant, designed to produce medical-grade oxygen and deliver it directly to patient areas via a piped gas distribution system. The system incorporates redundancy features such as backup power supplies and dual piping to ensure uninterrupted oxygen delivery, even in the event of equipment failure or power outages. Since the hospital currently spends approximately $40,000 per month on oxygen for normal operations, with costs doubling in high-demand scenarios, the project is expected to yield immediate savings of up to 40%, with long-term savings estimated between 60% and 70% over five years of full operation. Beyond cost reduction, the project is contributing to improvements in operational efficiency and sustainability. On-site generation eliminates the carbon footprint associated with transporting bottled oxygen, aligning with environmental stewardship goals. It also reduces logistical burdens on clinical and auxiliary staff, who previously managed the physically demanding task of transporting and replacing heavy cylinders throughout the hospital. By streamlining this process, the system enhances staff efficiency and allows them to focus more directly on patient care. The project is also addressing safety concerns that have persisted for several years. Staff injuries related to the manual handling of cylinders have been reported as recently as four years ago. With piped oxygen delivery now being implemented, these risks are being minimized, contributing to a safer working environment. In sterile areas such as the operating theatre, the removal of gas cylinders further supports infection control by maintaining aseptic conditions and reducing unnecessary movement. Moreover, the transition to a piped medical oxygen system is reducing delays in care delivery, especially for critical patients. Waiting times for cylinder replacements and the resulting gaps in oxygen availability are being eliminated, ensuring patients receive uninterrupted access to life-saving oxygen therapy. This has significant implications for patient safety, treatment outcomes, and overall care quality. While the project requires a substantial initial investment, its ongoing implementation is laying the groundwork for long-term financial sustainability, operational efficiency, and enhanced clinical care. By generating oxygen onsite and distributing it through a secure pipeline system, the Princess Alexandra Hospital is reinforcing its resilience and capacity to meet patient needs, particularly in a resource-constrained, small-island context.

E3: CE/HTM LMIC Innovations

Designing a Containerized Public Health Laboratory Solution for the Madagascar Ministry of Health

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Background: The United Nations Office for Project Services has an agreement with the Madagascar Ministry of Health to provide two BSL3 and two BSL2 containerized laboratories. This initiative responds to the COVID-19 emergency and aims to strengthen Madagascar's health system preparedness for pandemic threats. These laboratories will be the most complex in the country and represent a significant effort to enhance local public capacities in preventing and managing transmissible diseases. The containerized laboratories will be equipped with state-of-the-art diagnostic equipment and technologies, including advanced molecular biology capabilities, to support early detection, surveillance, and response to infectious diseases. **Objective:** The overarching aim is to develop a cohesive and effective laboratory framework that guarantees sustainable diagnostic services and robust disease monitoring and response mechanisms within Madagascar. This containerized solution was also designed to mitigate common logistical and infrastructural obstacles found in resource-constrained environments, with a strong emphasis on long-term viability and the strengthening of local expertise. Methodology: Starting from the clinical needs, a list of analysis and the intended productivity, UNOPS Biomedical Engineers experts, working together with National Laboratory experts, elaborated and revised a list of equipment, and consequently a planned amount of lab spaces needed to host the resulting equipment. This process has considered several alternatives of design options before getting to the optimal solution, applying a life cycle cost analysis of the different solutions. The design has primarily considered the installation site as available spaces and the opportunity of interconnecting the containerized labs with an existing building. Structural, electrical, water, and air treatment supplies have been studied, as well as liquid and solid contaminated waste treatment systems. All the equipment has been carefully fitted in the final design through a 3D rendering for each laboratory: BSL3 Molecular Biology, Parasitology, and Bacteriology, and BSL2 Hematology, Immunology, Biochemistry, and Culture. Appropriate space for sample storage has also been included in the design. A specific focus has been considered for the maintenance of the lab and of the equipment in order to allow the long-term use of the new infrastructure even in a context where the experience in maintenance management is generally scarce and almost null for high complexity lab infrastructures, installations, and equipment. **Results:** Given that this was the first high-complexity lab in the country, the approach of starting from the planning phase of the clinical activities and proceeding through the design phase was implemented gradually. A visit to similar containerized solutions in Benin has been organized with the participation of UNOPS and Ministry of Health experts to learn and discuss together the strengths the weaknesses of those installations, and how to enhance their durability. The process of working together to get an optimal design was itself a process of strengthening the capacities of the Ministry of Health to be progressively prepared for the installation, start-up, and running of the new labs. **Conclusion:** Several factors must be considered when planning and designing a BSL3 and BSL2 containerized laboratory solution, beginning with the clinical and epidemiological framework of each analytical process and the installation site. It is also important to consider the limitations of the installation site and the current local expertise in terms of laboratory professionals, particularly the local capacity for managing laboratory equipment. The design focused primarily on in vitro diagnostic devices, aligning analytical needs with workspace requirements as a foundation for infrastructure design.

E3: CE/HTM LMIC Innovations

Pul Alliance and GCEA: Partners in Digital Transformation for the Last Mile

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Our partnership goal is to improve access to quality healthcare, particularly those serving "Last Mile" patients—typically defined as those in small villages in poorer countries lacking adequate access to evidence-based healthcare

services using clinically appropriate medical devices and digital health tools. We call this Strengthening the Last Mile Using Digital Bridges. We have begun to accomplish this through a series of Case Study Clients involving: Capacity Building, Strengthening Clinical & Business Operations, and Digital Transformation.

This Client Study focuses on Gynocare Women's and Fistula Hospital in Kenya, their story told here: https://gynocarefistulacentre.org/. Their mission is to "improve the dignity of women who have suffered from the effects of female genital fistula, and advocate that all expectant women should not get obstetric fistula at the time of giving birth". This is accomplished through surgeries, inpatient care, ambulance, and other surgeries and services, with a developed ICU as a current goal. Located in Eldoret (western Kenya near Uganda), the hospital serves as a referral center for over 10 million people—nearly half of whom are pastoralists across the region.

How are Pul Alliance and GCEA partnering with this Client?

Pul Alliance, led by Dr. Kohli, and his wide network of volunteer healthcare professionals with a focus on digital health, work on comprehensive solutions to challenges presented. GCEA, with its primary expertise in Medical Equipment Management (MEM), operates alongside other outside experts leading the IT and Data Analytics team as well as the Supply Chain team.

A 3-year project, with expected first phase results in 18 months, started in May 2025. Priorities are improving care along the continuum, with a medical equipment focus on upgrading key inpatient clinical and critical equipment, assisting Smart (Community) Care in 10 nearby villages, and creating a two-bed e-ICU capability to assist Remote Care and augment staff capability.

Another method employed to assist workforce development is the Buddy or Mentor programs. For MEM, this began with Tom meeting the 3 biomedical equipment technicians (biomed team) employed at Gynocare (Mike, Calkin, and Erick), the longest serving there for 7 years.

The biomed team provided an initial inventory, for which we started to add greater detail over the following weeks. Tom sought a country-based mentor to join him and was delighted that CE Millicent Alooh (a GCEA member) from Nairobi accepted. Millicent, with global recognition through WHO, Africa East Regional involvement through NGO NEST 360 focused on Maternal Child Health (MCH) in several East African countries, and national leadership roles through AMEK (the Kenyan national CE-BME society and member of GCEA), has access to many CE-BME resources. Millicent is joining Dr. Kohli for a site visit in June, addressing many MEM remaining questions, and considering how to best implement new capabilities, eg, identify training most needed, consider a CMMS.

E3: CE/HTM LMIC Innovations

Indigenous Capacity Building in Healthcare Technologies in Resource-Scarce Countries—Based on Experience Gained from a Four-Decade-Long Endeavour in Bangladesh

By Khondkar Siddique-e Rabbani*

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Imported electro-medical devices fail to sustain in Low- and Middle-Income Countries (LMICs) because of warm and humid weather, power line abnormalities, and inappropriate user interface, resulting in e-waste and a drain on scarce resources. The only envisaged solution is the design, development, and manufacture of essential devices by local engineers. I started my journey into the applications of Physics in Medicine in 1978 in Bangladesh, leaving aside Microelectronics, the field of my PhD research. The first instrument was a successful Pulsed Electromagnetic Field (PEMF) device, which healed bone non-unions. This led to a collaboration with a British group. Knowledge acquired through this collaboration allowed us to develop the first Computerized Electrophysiology equipment in Bangladesh, using which we initiated clinical service for nerve conduction in the country in 1988. The main hardware was used for more than 20 years, albeit with small repairs at a very low cost. Local design allowed us to modify it suitably to introduce a new technique to detect Cervical and Lumbo-sacral Radiculopathy and Myelopathy early, which is useful where MRI machines are not available. This also allowed us to discover a new nerve conduction mechanism, which may turn out to be a breakthrough in neuroscience.

Recently, R&D into a home-use device for pain relief using PEMF resulted in a huge success. We developed a Dynam-

ic Pedograph device for getting foot pressure scans and installed several units in Bangladesh and neighboring countries, where these are being used to design custom-made shoe insoles for diabetic patients, thus restoring blood flow and preventing ulcers and gangrene that often lead to amputation. The recent COVID-19 pandemic led us to disinfection devices, and we successfully developed a UV-C tower with a unique design to cover 360°, not available otherwise. We also developed Negative and Positive pressure canopies-on-bed for isolating infectious patients in hospital beds and for protecting vulnerable ones like burn patients. Both are unique and have proved very useful. We have developed other devices and educational equipment to train Biomedical Engineers.

We faced a major obstacle from the Government's regulatory offices, which blindly follow the regulations of advanced countries. Without the necessary scientific and technical expertise, regulators fail to comprehend special circumstances that may allow some flexibility in the rules. The delegated power sometimes leads to corruption as well. Therefore, I propose a two-level self-declaration modality for small-scale production by local innovators of electro-medical devices in LMICs. Here, the innovator has to declare that s/he has adequate educational qualifications (science, engineering) and expertise on a particular device that is being manufactured and sold. On the other hand, a registered doctor, involved with the purchasing group, will declare that s/he has adequate expertise in the clinical use of the particular equipment being procured and that s/he is satisfied with its performance. Otherwise, locally developed medical devices will never be able to reach the market, and people in the LMICs will remain deprived of modern technology in healthcare.

E3: CE/HTM LMIC Innovations

Pulpi: A Pediatric-Specific ECG Monitoring Innovation to Bridge Gaps in Clinical Engineering Practice in Low-Resource Settings

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Ventricular Septal Defects (VSDs) are one of the most common congenital cardiovascular malformations found in humans, particularly in infants. Diagnosis of VSDs is notoriously difficult in low-resource contexts due to the limitations of traditional Electrocardiogram (ECG) medical equipment, which is mostly designed for the anatomy of adults, not children. This disparity often results in poor signal acquisition, decreased diagnostic accuracy, and patient discomfort.

Congenital heart defects constitute close to 80% of pediatric cardiology consultations in Peru. Mortality is exacerbated by delayed diagnoses of heart defects, high-altitude birthing conditions, and newborns with congenital heart defects. Rural and poor access to diagnostic services further prolongs diagnosis time and increases mortality rates. Together, these conditions emphasize the importance of developing pediatric-adapted technologies to facilitate early detection and equitable care.

As biomedical engineering students collaborating with local clinicians and academic mentors, we identified the need for a pediatric-specific solution and developed Pulpi, a wearable ECG prototype tailored to children aged 0 to 12. The project aimed to address unmet needs in pediatric cardiac monitoring through ergonomic design, motion-resistant signal processing, and low-cost implementation.

Pulpi integrates a three-electrode configuration adapted to pediatric thoracic dimensions, interfaced with an AD8232 analog front end and an ESP32 microcontroller. It employs hardware filtering (0.5–40 Hz), dynamic threshold-based R-peak detection, and real-time wireless data transmission to a mobile app. The ergonomic casing, inspired by octopus-shaped designs, ensures child-safe material use, comfort, and minimal motion interference. Validation was conducted with a ProSim 4 FLUKE simulator, yielding < 1% error across a range of 30–210 BPM. Simulated arrhythmias like ventricular tachycardia and fibrillation were identified with 99.2% and 96.8% accuracy, respectively.

Pulpi's architecture follows a modular block design: acquisition, processing, transmission, and visualization. This approach supports future feature expansion, such as SpO□ monitoring and cloud-based diagnostics. From a health technology management perspective, Pulpi emphasizes the impact of locally engineered innovations that reduce reliance on costly imports and enable decentralized pediatric diagnostics.

Key lessons learned include the importance of interdisciplinary design (engineering + clinical feedback), adherence to safety standards even in prototypes, and the role of simulation for early validation when clinical trials are not immediately feasible. Challenges such as minimizing motion artifacts and ensuring secure yet comfortable electrode contact were addressed iteratively.
In conclusion, Pulpi illustrates how clinical engineering innovation can emerge from academic settings and respond directly to pediatric care challenges in underserved regions. This case contributes to the discourse on frugal medical technology, emphasizing contextual design, cost-conscious prototyping, and user-centered validation. Future work involves clinical pilot deployment and integration with AI for early arrhythmia screening.

E4: CE/HTM Challenges in LMICs

Healthcare Technology Management (HTM) in Kenya, A Case Study: Pumwani Maternity Hospital

By Salome Mwaura*

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Medical devices are developed to solve health problems and improve the quality of life. Health care providers require medical devices for effective and efficient preventive, diagnosis, treatment, and rehabilitation services.
Due to the importance of Medical Devices, the World Health Organization (WHO) expanded its scope and replaced the term with Healthcare Technologies (HT). In Kenya, traditionally, the use of herbal or alternative medicine approaches was widespread, and even today, we still have communities which still practice “herbal medicine”. Kenya also has some religious beliefs that prohibit people from going to the hospital when sick, and this practice is on the rise. Others believe that treatment using electricity can kill someone quickly, and so patient resistance increases.
In Pumwani hospital, we conduct community outreaches every now and then so that we can educate the population on safe deliveries so as to reduce maternal deaths. Unfortunately, the more the device technology advances, the more expensive the treatment becomes, and so pregnant mothers may be unable to afford it.
Again, these newer health technologies are not available in most parts of the country. This could be due to a lack of infrastructure and other important amenities such as electricity. These technologies have the capabilities to:

- Improve the quality of the health delivery service
- Improve efficiency
- Improve effectiveness
- Reduce costs
- Improve accessibility of health services.

HT management (HTM) has a life cycle including Invention (conception), Production, Installation, Commissioning and User Training, Operation/ maintenance and repair, Decommissioning, Disposal, and then Replacement or new technology. Clinical or Biomedical Engineers (CE-BME) are responsible for the management of all health technologies in the hospital and particularly medical equipment for life cycle management noted above, as well as solving health care delivery problems for equipment use and improving the quality of care.
In Pumwani maternity hospital, most of these management/maintenance services are done in-house, but we also outsource some services. We also have partners who assist with donations and required accessories for our equipment, including:

- NEST 360, which deals with Neonatal Care, https://nest360.org/
- Muthaiga Rotary Club, https://rcnairobimuthaiganorth.org/ and,
- AMREF https://amref.org/, which supplies us with oxygen and many other resources.

In most cases, we have so much inoperable equipment due to a lack of one or more of the following:

- Technical skills to repair this equipment
- Inadequate technical knowledge on HT issues
- Technical Documentation / Manuals
- Need spare or repair parts
- Needed repair funds

- Administrative support

In summary, Kenya needs the following to change this narrative repeated in many LMIC countries:

- Clear national HT regulations and standards
- Clear professional ethics and code of CE-BME practitioner procedures
- Health policy and guidelines
- Adequate technical training
- Hospital Management trust and partnership

The way forward: (1) HT Policy and guidelines (at the national level); (2) Teamwork and best management practices within CE-BME; and (3) Encouraging innovation and creativity within CE-BME.

In conclusion, proper use and management of health technologies can bring a revolutionary change in the health sector. For health workers, embracing HT is inevitable. For patients, they are becoming increasingly aware of their health rights and available clinical best practices due to accessible information on the internet and other information sources, and are also aware when these practices are not followed. For health leaders, there is an increasing need for CE-BME to expand and communicate their knowledge of best practices for best quality HTM.

E4: CE/HTM Challenges in LMICs

Relationship Between Quality Defects Identified Through Visual Inspection and Performance Failures in Substandard Medical Devices

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Background: The right to health entails not only high-quality medical assistance and person-centered medical care, but also access to safe and efficient health technologies, where the regulatory system and national governments play a key role. The National Regulatory Authorities, responsible for the authorization and surveillance of sanitary products, face the challenge of strengthening health systems by ensuring access to quality, safe, and efficient products that meet the population's needs. However, these institutions often operate under resource constraints, which hinder effective surveillance and force the prioritization of efforts. An alternative is to adopt a surveillance approach based on risk management, which allows the identification of substandard medical products using low-cost methods, such as visual inspection by attributes. This technique allows for the identification of quality defects with minimal resource investment, unlike performance testing, which requires advanced technology and higher costs. **Objective:** To demonstrate, through laboratory testing, technical and scientific evidence of the relationship between the defects identified by visual inspection and failures observed during performance testing of medical devices. **Method:** This study analyzes the results of quality evaluations conducted as part of market surveillance on different types of medical devices at the Quality Control Laboratory of the Sanitary Regulation Superintendency of El Salvador from 2021 to May 2025. The quality evaluations were led based on methods of international standards declared by the manufacturers during the marketing authorization process; on the other hand, sampling was performed in accordance with the international standard ISO 2859-1:1999. **Results:** There exists a significant relationship between the defects identified through the visual inspection by quality attributes and the performance failures when subjected to laboratory tests; this demonstrates the usefulness of the visual inspection as an efficient tool for the preliminary detection of substandard products, particularly in settings where the technological and financial resources are limited. **Conclusion:** It is possible to optimize the resources available for the regulatory function of market surveillance by using accessible techniques such as visual inspection. This contributes to the efficient use of public resources and supports sustainable development. This approach aligns with regulatory compliance and evidence-based decision-making, ensuring the application of good regulatory practices and the protection of stakeholders' rights, allowing the regulatory authority to fulfill its functions proportionally and effectively, while also strengthening the national health system and the guarantee of public health protection.

E4: CE/HTM Challenges in LMICs

Community-Based Medical Device Management System for Healthcare Facilities in Resource-Constrained Environments: A Case Study from Cameroon

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Background: Medical devices play a critical role in healthcare delivery, yet their effective management remains a significant challenge in low- and middle-income countries (LMICs), including Cameroon. Fragmented systems, manual record-keeping, lack of collaboration, and limited data analytics capabilities hinder optimal equipment performance, resulting in increased downtime, financial inefficiencies, and compromised patient care. **Objective:** This study aims to implement a community-based medical device management system tailored to healthcare facilities in resource-constrained environments. The system will enable structured recording, sharing, and analysis of medical device information across hospitals and community health facilities while integrating contract management, work order management, financial tracking, predictive analytics, and automated notifications. **Methods:** The project adopts a human-centered design approach, beginning with user requirement analysis from Saint Blaise Hospital and Nkwen Baptist Hospital, progressing through database design and prototype development using Figma, followed by full-stack implementation via Laravel, PHP, HTML, CSS, and JavaScript. The system incorporates Internet of Medical Things (IoMT) principles with smart sensors and microcontroller-based nodes for real-time monitoring. Wireless communication protocols (Wi-Fi/LoRa) facilitate seamless data transmission to a centralized management platform. Validation testing will be conducted across multiple healthcare facilities to evaluate real-world effectiveness. **Expected Results:** The system is expected to improve maintenance scheduling accuracy by 40%, reduce equipment downtime by up to 35%, extend average equipment lifespan by 2–3 years, and achieve a 12% reduction in total lifecycle costs through data-driven decision making. Enhanced inter-facility collaboration and knowledge sharing will strengthen biomedical engineering practices across participating healthcare networks. **Conclusion:** This community-based approach represents a significant advancement in medical device management for resource-constrained environments. By leveraging IoMT technology and collaborative frameworks, the system addresses critical gaps in equipment lifecycle management while ensuring transparency, security, and scalability. The solution serves as a replicable model for other developing countries facing similar challenges in healthcare technology management, ultimately contributing to improved patient care outcomes and healthcare system resilience in Cameroon and beyond.

E4: CE/HTM Challenges in LMICs

Clinical Engineering & Health Technology Management in Low-Resource Regions: An Investigation in Bangladesh

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This paper investigates the challenges and opportunities in Clinical Engineering and Health Technology Management (HTM) within low-resource healthcare environments, focusing on Bangladesh. Using a mixed-methods research

approach, the study identifies systemic gaps, analyzes operational inefficiencies, and suggests actionable improvements to enhance the sustainability of health technology services. The study aims to assess the current status of clinical engineering and HTM practices in Bangladesh, identify key challenges affecting the performance and sustainability of biomedical equipment, and propose evidence-based interventions for improved healthcare technology infrastructure in low-resource settings. Bangladesh faces a critical shortage of clinical engineers and lacks a structured HTM system. Hospitals often operate with non-functional or poorly maintained medical equipment, compromising patient care and safety. There is limited coordination between government policy, technical education, and operational hospital practices. A mixed-methods approach was adopted, involving both qualitative and quantitative analysis. The methodology included stakeholder interviews, hospital surveys, equipment audits, and a review of policy documents. Public and private hospitals across urban and rural areas were selected to ensure representativeness. Data were gathered from 15 hospitals across Dhaka, Chattogram, and Khulna divisions. Surveys were administered to 30 clinical engineering staff and 50 hospital administrators. In-depth interviews were conducted with Ministry of Health officials and donor agency representatives. An equipment audit of 750 medical devices was also performed. Survey responses were analyzed using descriptive statistics, and qualitative data were thematically examined. Equipment audit data were categorized based on functionality, maintenance history, and availability of spare parts. Interview transcripts were coded using qualitative analysis software to identify recurring themes and institutional barriers. Results show that 42% of biomedical equipment surveyed was non-functional or only partially operational. Only 10% of hospitals had a full-time biomedical engineer on staff. Additionally, 75% of respondents reported no preventive maintenance system in place. Most institutions relied on third-party or donor-provided equipment without standardized documentation or technical support. The findings highlight a systemic gap in HTM infrastructure, aggravated by the absence of a comprehensive national policy. While donor support provides access to modern equipment, sustainability is undermined by limited training and missing service manuals. There is a critical need for capacity building and policy reform tailored to local conditions. This study underscores the urgent need to strengthen clinical engineering and HTM frameworks in Bangladesh. It recommends integrating HTM into national health policy, developing localized training programs, and establishing a centralized equipment inventory and maintenance system. These actions can significantly improve healthcare outcomes in Bangladesh and other low- and middle-income countries (LMICs).

E4: CE/HTM Challenges in LMICs

The Critical Role of Timely Repair of Medical Equipment in Enhancing Healthcare Delivery in Resource-Limited Settings: A Case Study from Combined Military Hospital (CMH), Bangladesh

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General Motivation: In low- and middle-income countries (LMICs) like Bangladesh, delivering quality healthcare to a large and diverse population remains a persistent challenge. One of the most overlooked yet vital aspects of healthcare infrastructure is the operational status of medical equipment. Accurate diagnosis—which forms the foundation of effective treatment—is critically dependent on the functionality of devices such as X-ray, MRI, CT scan, USG, ventilators, phaco systems, and various forms of diagnostic and therapeutic technologies.
Findings: Despite substantial investments, many healthcare institutions in Bangladesh struggle with equipment downtime due to inadequate repair and maintenance systems. Dhaka Medical Hospital serves as a prominent example. Over the past three fiscal years, the hospital has invested significantly in its operations—135 crores BDT (Bangladeshi Taka) in FY (Fiscal Year) 2022–2023, 90 crores in FY 2023–2024, and 77 crores in FY 2024–2025. However, a large portion of essential medical equipment currently awaits repair: 46 X-ray machines, 79 USG devices, 22 MRIs, 3 CT scanners, 21 phaco systems, 58 ventilators, 38 autoclaves, 246 shortwave therapy units, and many others, including high-value assets like cath labs, mammography units, and endoscopy systems.
The cumulative equipment backlog includes:

- Diagnostic Imaging: 155 devices

- Life Support & Surgical: 147 devices
- Rehabilitation & Therapeutic: 367 devices
- Specialized Tools (e.g., endoscopy, laparoscopy): 58 devices

This critical situation leads to prolonged diagnostic delays, overburdened functional equipment, increased healthcare costs, and reduced patient trust. Furthermore, it limits the return on investment in healthcare infrastructure and affects the broader public health outcomes.

Recommendations:

- Establishment of a Centralized Biomedical Engineering Unit: To ensure consistent repair, calibration, and preventive maintenance across hospitals.
- Development of a National Equipment Maintenance Policy: Integrating scheduled servicing, tracking, and audit systems using digital platforms.
- Training and Deployment of Skilled Technicians: Focused on regional capacity-building through public-private partnerships and vocational training programs.
- Mandatory Reporting and Equipment Downtime Analysis: To inform government policy and resource allocation.

E5: HTM Lifecycle Challenges

Optimizing Medical Equipment Effectiveness and Sustainable Management in Low-Resource Settings

By Andro Atoshvili*

Association of Biomedical and Clinical Engineers of Georgia, Georgia.

Medical equipment, as a material object widely used in hospitals or home care, can significantly influence the environment throughout all stages of its life cycle. In many countries, appropriate regulations have been developed that strictly define specific rules and actions; however, in most developing countries, environmental impacts and sustainability pose significant challenges. The research focused on the use of medical equipment and the influence of personnel on all processes from procurement to disposal, since the design and manufacturing stages are not relevant for such markets. We analyzed personnel actions in all processes at every step of the life cycle between developed and developing countries. Evaluated organizational, structural frameworks for healthcare facilities, export-distribution firms, and government bodies having any relationship with medical equipment management and quality control, alongside national regulations and supervision, leading to actionable conclusions. As a result, personal influence plays a significant role in effectiveness or sustainability, depending on personal knowledge and conscientiousness. Thus, clinical engineers can play the most effective role in safe, effective, and environmentally friendly actions related to different types of medical device use and disposal.

E5: HTM Lifecycle Challenges

Publication of the first edition of a “Handbook of biomedical procedures for low-resource settings”

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Description: Testers and simulators are widely used in high-income countries by biomedical engineering staff to

perform routine quality and performance inspections on medical devices. However, these tools are often unaffordable for Ministries of Health and hospitals in Low- and Middle-Income Countries (LMICs). Not only is their purchase costly, but their calibration requires sending them abroad for extended periods, due to the absence of local metrology services. Where test equipment is unavailable—either temporarily or permanently—it is essential to provide technical staff with low-cost, easy-to-use alternatives that allow them to assess the functionality of electronic medical devices and detect malfunctions that could compromise patient diagnosis or treatment. The French NGO Humatem has brought together a task force of biomedical professionals and healthcare workers from the French biomedical societies AFIB and AAMB, the NGOs Médecins Sans Frontières (France/Switzerland), Horizons Sahel (France), ULB-Coopération, Médecins sans Vacances (Belgium), and biomedical engineering students (Polytech Marseille, ISEN Brest). Together, they have designed, tested, and formatted 33 procedures tailored to resource-limited settings, requiring only simple or no testing equipment.

The resulting Handbook includes:

- 5 instruction sheets for manufacturing homemade low-tech testers and simulators
- 15 maintenance procedures using these testers
- 2 procedures for facility quality control
- 1 procedure for managing biomedical departments
- 10 user protocols for proper care and use of medical devices

The Handbook was officially launched on April 11, 2025, during a dedicated webinar co-organized with GCEA. It attracted 156 participants from 38 countries, with an active 25-minute Q&A session. A biomedical technician from Senegal, who had used the Handbook for several months, shared his positive experience—for example, using the low-tech ultrasound phantom to test elementary image settings or probes.

So far, the Handbook has been shared with over 670 recipients in 52 countries—including biomedical engineers, students, caregivers, hospital managers, NGO staff, and international cooperation stakeholders.

In addition, 290 people in 15 countries have participated in technical training sessions covering the practical use of the low-tech testers and associated preventive maintenance procedures, which proves helpful in using the Handbook correctly.

Conclusion: While conventional test equipment remains the best solution for medical device performance assessment, low-tech alternatives provide a valuable temporary solution in resource-limited contexts. This Handbook should contribute to improving the safety and quality of care delivered in such settings.

The collaborative work around the « Handbook of biomedical procedures for low-resource settings will continue with 3 main goals:

- continuous improvement of existing procedures based on field feedback
- development of new procedures covering a broader range of equipment (maternal and child health, imaging, laboratory, cold chain, sterilization, etc.)
- translation of the Handbook to reach a wider global audience

The ongoing effort of the task force will be supported by new partners such as the University of Lorraine and La Chaîne de l'Espoir, and, let's hope, by the broader international biomedical community.

E5: HTM Lifecycle Challenges

Improving Electrical Safety of Medical Devices in Operating Rooms in Low-Resource Settings: A Case Study from Togo

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Electrical safety of medical devices is a key concern in operating rooms, where any failure can have serious consequences on patient care and staff safety. This thesis focuses on the management of electrical risks within the operating theatre of the Sylvanus Olympio University Hospital, specifically in the visceral surgery department. Using a

methodology that combines field surveys, interviews with biomedical staff, and an analysis of current safety standards, the study identifies several shortcomings: lack of preventive maintenance, inadequate follow-up of electrical safety tests, outdated equipment, and limited staff awareness. However, the study also highlights a genuine willingness to improve practices. Strengthening staff skills, investing in appropriate equipment, and implementing rigorous maintenance protocols are identified as key strategies to enhance technical reliability. While the research is limited to one hospital unit, it opens the door to a broader reflection on electrical safety across all operating theatres of the hospital.

E5: HTM Lifecycle Challenges

Smart Decommissioning: A Circular Economy Approach to Medical Equipment Lifecycle Management in Emerging Health Systems

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Decommissioning is the final stage of the medical equipment life cycle. In low- and middle-income countries (LMICs), particularly Bangladesh, the decommissioning of obsolete medical equipment is often unstructured, resulting in environmental harm, value loss, and storage of non-functional devices. This paper introduces a data-driven, sustainable decommissioning framework grounded in circular economy principles, with a focus on maximizing value recovery and minimizing waste. We develop and implement a Multi-Criteria Decision Analysis (MCDA) tool that integrates clinical condition, environmental risk, and economic salvage value to categorize medical devices for reuse, recycling, or disposal. The framework was applied to 780 devices across five public hospitals in Bangladesh, leading to the redeployment or recycling of 60–65% of equipment. Two hospitals (1) Khulna Medical College Hospital and (2) Barisal Medical College Hospital are used as case studies that theoretically demonstrate quantifiable environmental and economic benefits. Smart decommissioning in Khulna reduced waste by 800 kg (50%) and saved USD 4.0 million through the redeployment of 400 devices. In Barisal, waste reduction reached 1,580 kg (59.8%) with $6.1 million in cost avoidance. Circularity ratios improved from 0 to over 0.64 in both cases. The results validate smart decommissioning as a practical, replicable model for LMICs. The paper concludes by advocating for national-scale policy adoption and enhancing clinical engineering capacity to embed circular economy strategies within health technology management systems.

E5: HTM Lifecycle Challenges

Managing Donated Medical Equipment in LMICs: Towards Sustainable Use, Local Ownership, and Strategic Alignment

By Millicent Alooh*

Association of Medical Engineering of Kenya, AMEK, Kenya.

Description: Donated medical equipment represents a significant portion of the available health technology in many low- and middle-income countries (LMICs), particularly in public and mission-run healthcare facilities. While these donations aim to fill critical equipment gaps, they often arrive misaligned with facility needs, lack user or maintenance training, and are incompatible with local infrastructure or clinical practice. Studies across African health systems reveal that 40–70% of donated equipment becomes non-functional within the first two years of receipt.

This paper presents practical lessons and strategic approaches for managing donated medical equipment, based on real-world experiences from Kenya and other sub-Saharan African countries. It draws on evidence from national health technology assessments, equipment audits, and a number of ongoing technical implementation efforts.

Key challenges identified include the absence of structured needs assessments before donation, non-adherence to national essential medical equipment lists, fragmented communication between donors and host institutions, lack of clinical and technical capacity to integrate new equipment, and poor tracking mechanisms post-installation. Additionally, the absence of regulatory oversight at points of entry and within procurement systems results in the proliferation of obsolete, non-standard, or unsupported equipment.

To address these issues, the paper proposes a practical donation management framework grounded in the principles of health technology management (HTM), lifecycle costing, and systems thinking. The framework includes five key pillars:

1. Needs-Based Donation Planning: Aligning donations with national service delivery priorities and hospital-specific gaps.
2. Technical and Regulatory Pre-Validation: Ensuring all donated equipment meets national standards and operational requirements.
3. Stakeholder Coordination: Involving biomedical engineers, clinicians, procurement teams, and donors in early-stage planning.
4. Capacity Strengthening: Building local technical capacity in installation, use, maintenance, and decommissioning.
5. Monitoring and Traceability: Establishing donation registries and outcome tracking mechanisms to assess impact.

Case studies from county-level hospitals in Kenya illustrate how aligning donated equipment with local context and empowering biomedical engineering units results in higher utilization rates, longer service life, and improved clinical outcomes. Policy-level examples also demonstrate the effectiveness of donation guidelines and health technology assessment tools in improving coordination and accountability.

Conclusion: Effective management of donated medical equipment in LMICs requires more than goodwill. It demands structured processes, national policy support, and local system readiness. By adopting a context-specific, systems-based approach to equipment donations, LMICs can transition from donation dependency to donation optimization, where each donated device contributes meaningfully to patient care, cost-efficiency, and sustainable health system strengthening.

This paper contributes to the global conversation on Medical Engineering and Health Technology Management by offering evidence-based strategies that are scalable, actionable, and locally owned. It calls for stronger partnerships between donors, governments, and technical professionals to ensure that donations are not just generous but transformative.

E6: HTA Challenges in LMICs

Beyond Transaction Procurement: Building Sustainability and Trust Through End-User Engagement in Early Health Technology Sample Inspections

By Smriti Kafle[1,*], Valerio Di Virgilio[2], Emmanuel Tchokodjeu Kouemo[1]

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Background: Some internationally funded health projects in Low- and Middle-Income Countries (LMICs) are managed focusing primarily on cost and delivery timelines rather than on the clinical outcome. Procurement is seen as a "transactional activity", and people who will ultimately use the technology are little involved. Sustainability is focused on the environmental impact of the production process rather than the long-term usability of the procured goods. This often leads to poor alignment between selected products and actual clinical needs, local capacities and infrastructure constraints, resulting in reduced acceptance, underutilization, or, in some cases, equipment being left unused or stored in warehouses. In fact, up to 70% of medical devices, according to WHO findings, lie unused in LMICs. In contrast, the

UNOPS managed two Madagascar health projects focused on strengthening 1,200 Health centers spread all over the country adopted a participatory approach, grounded in continuous engagement with end-users to ensure that procured items were safe, adequate, accepted, and sustainable in their long-term use. **Objective:** Proposing a consistent end-user involvement in the procurement cycle, especially during needs assessment, specification development, product evaluation, and sample inspection, to significantly improve project outcomes in health technology deployment. This paper presents an experience of users' involvement in the sample inspections. **Methodology:** During the procurement, the project team coordinated closely with hospital-based end-users, including anesthesiologists, senior clinicians, and Ministry of Health (MoH) officials. The joint UNOPS and MoH teams organized different forms of inspections depending on the nature of the goods: complexity, weight, transportation constraints, and on the project timelines, such as On-site factory visits to inspect production lines and assess quality; Inspection of the samples shipped to Madagascar; Online inspections were conducted. During these processes, performance and quality of the materials were controlled, and meaningful design changes and personalization that enhanced satisfaction and the perceived value of the product by the end users were possible, without increasing the costs. **Results:** The approach to sample quality control before mass production involving end users resulted in significant benefits: early detection of non-conformities, including in a few cases rejection of the samples; prevention of post-delivery complaints by the users; customization of the goods, especially furniture, to respect local habits and practices and increase users' acceptance; Increased user satisfaction from receiving context-appropriate, high-quality products; Strengthened trust within the stakeholders based on consideration and respect local needs and culture. These improvements collectively enhanced the overall efficiency, sustainability, and impact of the health technology deployed. **Conclusion:** The Madagascar experience illustrates that end-user involvement is essential for effective health technology procurement. Structured engagement at each stage of the procurement cycle leads to better product fit, stronger stakeholder commitment, and long-term success. In particular, this project shows the results of involving the users in sample approval. Development partners and health system leaders should embed end-user participation into procurement frameworks as a standard practice to improve the impact by leveraging users' knowledge of local context and thus to maximize return on investment and improve health outcomes.

E6: HTA Challenges in LMICs

Sustainable Procurement Strategies for Medical Devices

By Valerio Di Virgilio*

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Background and Objectives: This work investigates the meaning of sustainable procurement when applied to the process of purchasing Medical Devices (MDs), considering its impact on health services in low- and middle-income countries (LMICs). This work also proposes a reflection on the concepts of sustainability and quality assurance as guiding principles for technical teams during MD procurement with the aim of describing how sustainability principles and concepts of value-based procurement can be applied by the biomedical/clinical engineers in charge of preparing the technical planning of the procurement process. Material and **Methods:** Sustainability is explored from a macrosystemic perspective, considering the ratio between a procurement project's long-term impact on healthcare services and its investment. Based on the author's experience of more than 25 years in implementing procurement projects and implementation of MDs in LMICS, three main perspectives are investigated, namely: (1) sustainability and alignment with national health priorities, as the needs assessment phase; (2) sustainability and value-based procurement, as the assessment of local conditions and capabilities towards existing commercial solutions; and (3) sustainability and technology life cycle management, as planning of post sales services and MD management. **Results:** The results show how important it is to shift the center from the purchase of a "sustainable MD" to the purchase of an MD that provides a "sustainable clinical benefit" to the population. Focusing on the future use of the MD to be procured means to plan the procurement process and design the good on the base of: (1) the patients to be treated; (2) the capability of the clinical staff; (3) the condition of the infrastructure and the presence of other connected medical technologies; (4) the local capability for MD safe management; (5) the availability of funds for consumables and maintenance; (6) the existence of a strategy for MD life-cycle management and disposal. **Conclusion:** Strengthening the health service in LMICs does not solely depend on possessing new, up-to-date "sustainable" technology, but rather on the capability to establish the conditions for its proper and safe use, and to manage it properly throughout its entire life cycle. International

funded projects should emphasize strengthening local infrastructures and developing the clinical, technical, and managerial capabilities of personnel. This would create the necessary minimal conditions for successful and sustainable procurement that is based on planning and designing Medical Technology solutions tailored to the local context.

E6: HTA Challenges in LMICs

The Role of Needs Assessment in Sustainable Medical Equipment Procurement in LMICs

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Background and Objectives: The procurement of Medical Equipment (ME) within healthcare systems, particularly in low- and middle-income countries (LMICS), is a multifaceted process fraught with challenges that can significantly impact the quality and accessibility of healthcare services. Internationally funded projects in LMICS to procure medical equipment are often implemented by third-party agents. This is due to local governments' lack of technical and managerial capacities, as well as funding agents' requirements for a highly transparent procurement process and to avoid the bureaucratic complexities of government procurement.
Relevant literature shows that a significant percentage of ME in LMICs is not used due to several factors, including lack of adequate planning, lack of appropriateness, poor infrastructure, lack of clinical, technical, and managerial capabilities, and lack of funds for maintenance and consumables. The article analyzes the link between the unused equipment with weak procurement processes and investigates the relevance of an adequate needs assessment in the procurement of sustainable technological solutions for healthcare. Where sustainable means accessible and available in the long term. Methodology: A model for ME procurement is presented based on 20+ years of experience of the authors in international cooperation projects, in technological transfer projects, and in managing healthcare technologies. The model is based on the assumption that in an LMIC country, adequate funds are available during a procurement process as capital investment, usually time-limited, while the funds available for running costs are scarce and usually invested in salaries and pharmaceuticals more than in maintenance and management of ME.
Results: The model highlights the critical role of the needs assessment phase, which should consider not only the clinical needs but also the total cost of ownership, the infrastructural requirements, the training requirements, and the disposal strategies. Needs assessment should be a foundational pillar upon which sustainable medical equipment procurement is built. It means that adequate time and resources shall be dedicated to this procurement phase, which includes the analysis of:

- Demographics, Epidemiology, and Disease Burden of the reference population;
- Existing clinical service demands, patient volume;
- The existing healthcare infrastructure and resources, including equipment inventory;
- Staffing levels and capabilities;
- Service availability, cost, utilization, and organization.

The types of medical services identified in the needs assessment should drive the selection of equipment that aligns with the local capabilities and helps achieve the specific healthcare goals required by the population.
Conclusion: A robust needs assessment framework is crucial to ensure that medical equipment procurement aligns with the actual healthcare demands, infrastructural capabilities, and financial constraints of the LMIC setting, fostering long-term sustainability and improved healthcare outcomes. Technical professionals like Clinical/Biomedical Engineers with equipment support experience are critical to forecast the necessary tasks, their timing, and the resources required to implement them. Their participation and technical contributions in the needs assessment process are fundamental to determining the challenges of strengthening or creating local Clinical Engineering departments that can appropriately manage the purchased medical equipment, and stress the importance of covering maintenance and consumable costs throughout the equipment's life-cycle.

E6: HTA Challenges in LMICs

Enhancing Health Technology Access, Equity and Sustainability through Patient and Community Involvement

By Debjani Mueller*, Mladen Poluta

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Introduction: Low-resource settings (LRS) continue to face considerable challenges in ensuring equitable access to affordable healthcare services. Deep-rooted disparities, often shaped by socioeconomic, geographic, and systemic factors, have resulted in uneven healthcare outcomes across and within these regions. These inequalities are further compounded by growing demands for universal health coverage and the limited capacity of health systems in many of these countries to generate and apply context-relevant, evidence-informed decision-making frameworks. Communities in LRS also face ongoing challenges with respect to public/community, occupational, and environmental health due to shortcomings in health-related interventions, such as the provision of clean water, sanitation, and waste management, and related technologies. Variations in contextual factors—such as health system readiness, workforce availability, population groups, supply chains, patient behavior, and their cultural norms—can all impact availability, cost-effectiveness, and utilization outcomes of health technologies.
Suggested Approach: To address these challenges and to better inform equitable and sustainable health system resource allocation in LRS, active involvement of patients and communities in decision-making related to health technology access, deployment, and utilization is proposed. Patient and community engagement can offer critical insights into contextual realities, social values, health-seeking behaviors, and lived experiences that are often overlooked by traditional, top-down allocation methodologies. The growing trend towards digital health and home-based solutions reinforces the need for such engagement. Community participation contributes to more equitable health systems by amplifying the voices of marginalized or underserved communities and promoting greater accountability in the allocation of limited healthcare resources. When patients and communities are co-producers of knowledge and decision-making—even co-implementers of community-based interventions—rather than passive recipients of care, they are more likely to support and sustain the resulting health policies and interventions. Incorporating patient and community voices into resource allocation methodologies such as Health Technology Assessment (HTA) and implementation and ongoing support processes associated with Engineering Asset Management (EAM) underpins health system sustainability and improved community wellness, thereby realizing tangible benefits as envisaged by the Alma-Ata Declaration and related frameworks. It encourages transparent deliberative processes, builds trust in healthcare institutions, and increases the likelihood of uptake and compliance with recommended technologies or practices. This is especially critical in LRS, where trust in the health system may be fragile and where implementation challenges are common.
Conclusion: Strengthening HT-related decision making in LRS through inclusive, participatory approaches that engage patients and communities is not merely a technical enhancement—it is a strategic imperative. By embedding equity and contextual relevance into HTA and EAM processes, LRS stakeholders can make more informed, acceptable, and sustainable health technology decisions. This, in turn, can help close equity gaps, optimize the use of scarce resources, and advance the goal of resilient, people-centered health systems.

E7: Quality of Care Strategies

Bridging the Gap of Health Diagnosis Services in Low- and Middle-Income Countries Through Telemedicine

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Clinical Background: Health diagnosis services are scarce and limited in low- and middle-income countries (LMIC).

The challenge for clinical and biomedical engineers is to develop a bridging system to maintain the basic health services for chronic pathologies in LMIC. Populations living in low-income countries did not have access to basic health diagnosis services countrywide and thus depended on the scarce resources of their central health system. There were also equity issues between urban and rural populations. In this context, telemedicine tools should be directed towards maintaining the basic health diagnosis services for chronic pathologies. This study has evaluated the results of a telemedicine system in remote public hospitals in Paraguay, aiming to demonstrate how health diagnosis services for chronic pathologies have been enhanced by providing access to tertiary-level diagnostic services from specialists. **Methodology:** Descriptive study, where the results using telemedicine for diagnosis in remote public hospitals were evaluated as a tool to bridge the gap of basic health diagnosis services for chronic pathologies between 2014 and 2025. For these purposes, the type and frequency of diagnosis performed were determined. **Objective:** This study aims to evaluate the utility of telemedicine as a tool to bridge the gap in basic health diagnosis services for chronic pathologies in LMIC. **Results:** A total of 940,943 telediagnoses were performed in 80 hospitals countrywide. The 622,303 ECG diagnoses performed were mainly normal (64.0%), sinus bradycardia (11.8%), and sinus tachycardia (4.0%). 286,050 teletomography tests were performed, where 55.6% corresponded to head as a consequence of accidents (motorcycles) and cerebrovascular diseases, 14.6% chest, and the rest the other anatomical regions. Regarding the 20,718 EEG tests performed, antecedents of seizure (26.2%), evolutionary controls (14.0%), and headache (8.5%) were mainly diagnosed. The 8,509 remote mammography studies performed were normal (60%), cysts, fibroadenoma, and macrocalcifications (33%), and carcinoma (7%). The most frequent diagnoses of the 2,094 Tele-Holter studies were supraventricular extrasystoles (34%), normal (25%), supraventricular and ventricular extrasystoles (23%), and ventricular extrasystoles (9%). Regarding the 1,269 remote ABPM studies, the most frequent diagnoses were pathological 24-h systolic blood pressure (21.0%), pathological 24-h diastolic blood pressure (23.0%), pathological daytime systolic blood pressure (20.9%), pathological daytime diastolic blood pressure (22.2%), pathological nocturnal systolic blood pressure (28.0%), pathological nocturnal diastolic blood pressure (34.7%), dipper (43.8%), no-dipper (31.4%), extreme dipper (3.2%) and riser pattern (13.6%). **Conclusion:** despite the promising results of the telemedicine tool implemented in public health to bridge the gap of basic health diagnosis services for chronic pathologies in remote locations of LMIC, a widespread use assessment should be analyzed before this tool is adopted.

E7: Quality of Care Strategies

Development of a Low-Cost Quality Assurance Platform for Diagnostic Ultrasound Probes

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Background: Ultrasound is one of the most widely used diagnostic imaging techniques, valued for its real-time capabilities, non-invasive nature, and portability. The quality of ultrasound imaging, however, depends heavily on the condition of the probe. Degradation of probes over time, such as element dropouts, cable faults, and reduced sensitivity, can lead to image artifacts and diagnostic inaccuracies. Regular quality assurance (QA) is essential to maintain imaging reliability and patient safety. While high-income countries often have better access to biomedical engineering resources and testing equipment, routine QA of ultrasound probes remains inconsistently implemented even in well-funded hospitals. In low- and middle-income countries, the situation is more challenging due to a lack of trained personnel, limited access to phantom models or probe testers, and no system in place to monitor probe condition longitudinally. This project aims to develop a low-cost, user-friendly, and scalable platform that enables healthcare facilities to assess and track the quality of ultrasound probes over time using in-air images. System Design and Concept: A probe image quality assessment method was developed earlier using in-air ultrasound pictures taken at fixed ultrasound machine settings. The image is processed in Python using computer vision techniques to detect common signs of probe degradation: element dropout patterns, noise, and resolution loss. The processed images are analyzed by an embedded engine that produces simple, quantitative scores: A Quality Index (QI) from 0 to 100, summarizing the image integrity, and a fault risk score ranging from 0 to 100, quantifying the risk.

A platform is being built around this ultrasound probe quality assessment approach. The platform will be designed for both offline and cloud-based use, depending on the facility's infrastructure. Hospitals and clinical engineering teams around the world can define and add their ultrasound machines and probes to their collection on the platform, and upload in-air images each time quality assessment is being done. These images will be analyzed, and the various probe quality scores can be displayed on a centralized dashboard, visualizing trends in probe image quality. These trends can be used to identify probe hardware issues and help to plan the timely replacement of probes. The platform will support shared usage across staff, with logs and alerts for declining probe performance.
Discussion: The platform is currently being developed. On completion, the platform will allow scalable, consistent, low-cost QA in any low to high-income context. It can reduce reliance on expensive testing equipment and provide real-time insight into equipment quality. The platform will help ensure high diagnostic standards, reduce the risk of misdiagnosis due to faulty equipment, and optimize hospital resource management. The ability to monitor probe conditions using easily collected images and automated analysis enables access to QA practices across healthcare systems globally.
Conclusion: This project presents a practical, low-cost approach to ultrasound probe quality assurance that can be implemented across diverse healthcare environments. By enabling multiple users to collect images and visualize degradation trends over time, the platform not only supports safe clinical practice but also builds a data-driven foundation for equipment lifecycle management.

E7: Quality of Care Strategies

Clinical Engineering's Emerging Role in LMIC Digital Health Transformation

By Thomas Judd[1,*], Manish Kohli[2]

[1] Global Clinical Engineering Alliance (GCEA), Mercer Island, WA 98040, USA.
[2] Pul Alliance DHE, London, UK.

Partners: The Global Clinical Engineering Alliance (GCEA) was created foremost to empower and recognize the Clinical/Biomedical Engineering (CE-BME) profession for its unique contribution to improving healthcare delivery outcomes. Two other key goals are: (1) to combine strengths and leverage national and regional CE-BME associations to address healthcare challenges; and (2) to provide international professional networking between and across healthcare stakeholders, associations, policy makers, global agencies, academia, government, and industry interested in in managing Health Technologies as prescribed by the World Health Organization (WHO). One emerging great partner is Pul Alliance, whose vision is to help create empowered and resilient communities through "digital bridges" that lead to more equitable pathways for access to quality healthcare, educational opportunities, and better livelihoods.
Last Mile: GCEA and Pul Alliance have begun to work together to improve access to quality healthcare, particularly those serving "Last Mile" patients—typically defined as those in small villages in poorer countries lacking adequate access to evidence-based healthcare services using clinically appropriate medical devices and digital health tools. We call this Strengthening the Last Mile Using Digital Bridges. We have begun to accomplish this through a series of Case Study Clients where improved Medical Equipment Management is a key feature, but also ensuring other CE-BME skillsets are developed.
Goals of Partnership:

- The right medical equipment/health technologies are used
- Clinical appropriateness and adherence to global standards
- Save money
- Deal with and limit bad donations and unsustainable purchases
- Create sustainability and resilience
- Client doesn't need assistance after the change is managed and assisted; leverage what they already have

Emerging Skillsets—see the CE-BME Capacity Building Framework developed by GCEA & IFMBE CED in recent years. Clinical Engineers (CEs) are Biomedical Engineers (BMEs) who serve at the Point of Care, typically in healthcare facilities, as designated by World Health Organization (WHO) Resolution 60.29 (2007) for Health Technologies Management-HTM. The WHO World Health Assemblies in 2020 and 2021 called out the global need for CE-BME practitioners (engineers, technicians, technologists & managers) to further manage Health Technologies, defined by WHO as traditional Medical Devices, PPE, Oxygen Sources and Delivery devices, & Digital Health Tools.

Clinical Engineers and CE practitioners then have the following skillsets and alliances:

- Manage Health Technologies (HT) through their lifecycle, according to WHO methodologies
- Innovate to create new models and tools for healthcare delivery, including Digital Health
- Ensure Appropriate HT selection and deployment initially
- Ensure device sustainability throughout use until obsolescence
- National CE-BME Societies to assist Capacity Building at local, country, and regional levels
- Demonstrate measurable improvement for healthcare Safety, Quality & Clinical Outcomes

E7: Quality of Care Strategies

Health Technology and Digital Health in Kyrgyzstan

By Thomas Judd[1,*], Manish Kohli[2], Talant Sultanov[3]

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Background

Mr. Sultanov has previously held leadership roles in government and NGOs, including serving as Policy & Advocacy Lead for the Global Digital Inclusion Partnership.

He describes his background as being in the government Digital and Finance sectors.

In February 2025, Dr. Erkin Checheybaev, MD, MPH, was appointed as the new Minister of Health (MOH) of Kyrgyzstan.

Talant has been a LinkedIn connection of Tom's for several years due to his government digital efforts.

Assessment

1. Relevant Networks & Opportunities for Assistance

We discussed the following potential avenues where Judd and Kohli could provide support:

GCEA—Health Technology Management (HTM).
WHO—both HQ and in-country leaders; Talant is also connecting us to the US Embassy in Kyrgyzstan.
Kaiser Permanente—Digital Health and HTM global best practices.
Pul Alliance—partnerships with GCEA and many countries in Digital Health Transformation.
HIMSS—global leadership in Digital Health issues.
AMTZ—Digital Health and HTM resources, with relationships across MOHs in the region.
Uzbekistan—GCEA 2023 draft MOU with their MOH as a model for education, training, and HT policy.
MOH Kyrgyzstan—Tom previously served here as a WHO consultant (2001–2005) for iHTP.

2. Request for ZAP-X Connection

Talant asked Tom for contact with Stanford University (USA, California-based) ZAP-X for brain cancer treatment.

The contact was made, and follow-up is ongoing between Talant and the company.

3. Examples of Digital Health Integration

Two specific case examples were shared, illustrating the integration of Digital Health into both Primary Care and Secondary Care:

a. Primary Care (Theoretical Example)

Based on an actual request in Xi'an, China, several years ago.
Proposed use of digital and evidence-based medicine (EBM) tools (clinical practice guidelines with medical devices and pharma) to double pediatric practice access.
Built upon methods perfected by Kaiser Permanente (USA) in recent years.
(Attachment was originally produced in 2016.)

b. Secondary Care (Actual Example)

Presented in 2021 by clinical engineer colleague Ms. Xiaomin Lou at the 1100-bed Red Cross Hospital in Hangzhou, China.
Demonstrated use of digital tools to optimize care flow and delivery.

c. Reference Video

https://youtu.be/Sj3n2EXNJpI?si=PMIQ_-YMU2GHE5W1—watch from 27:10 to 36:20.

E7: Quality of Care Strategies

Software-Related Failures in PC-Based Medical Devices: A Multidisciplinary Study from Bangladesh

By Md. Saiful Islam[1,*], Alve Yeasin Bin Anwar[2], Md. Anwar Hossain[3], Tom Judd[4]

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PC-based medical devices are widely used in healthcare for their affordability and flexibility. However, in countries like Bangladesh, these devices often experience software-related failures due to inadequate user training and a lack of technical support. This study investigates these failures using a mixed-method approach involving 300 participants, including engineers from NEMEMW & TC, ICU nurses, and local vendor engineers. Findings show a 38% software failure rate, primarily due to poor training, software incompatibility, and weak maintenance practices. The study recommends structured training, improved IT-biomedical coordination, and health technology management policies to address these issues.

E7: Quality of Care Strategies

Transcription of Medical Corpus with West African Accents

By Houessouvo C. Roland[1,2], Keke Mahuvivi Turibio[3], Jossou R. Thierry[1,2], Medenou Daton[1,2]

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In a rapidly evolving medical context, integrating artificial intelligence (AI) into patient consultations offers substantial opportunities to optimize time management, reduce administrative burdens, and enhance the overall quality of medical documentation. However, despite their growing adoption, most existing speech-to-text models—including both open-source and proprietary solutions—are predominantly trained on Western-accented speech, leading to a marked decline in performance when applied to non-standard accents such as those commonly spoken in West Africa. This disparity stems largely from the underrepresentation of African speech data in training corpora, resulting in low transcription accuracy, high latency, and poor robustness to environmental variability. To address this gap, this research project proposes the creation of a dedicated medical audio corpus representative of West African accents. The dataset will be constructed by recording diverse African participants (men and women) reading a uniform medical script at various times of the day to capture natural intra-speaker and inter-speaker variations in speech patterns. This corpus will be used to fine-tune or retrain speech recognition models, particularly Whisper (an open-source model by OpenAI) and Dragon (a commercial solution by Nuance), with a focus on improving recognition accuracy, minimizing word error rates (WER), and enabling real-time, edge-compatible deployments in clinical environments. Preliminary evaluations will benchmark model performance in terms of transcription accuracy, latency, and robustness to noise, comparing adapted models to their respective baselines. Beyond its technical impact, this work advocates for linguistic justice and technological inclusiveness by enabling more equitable access to intelligent medical systems. It also lays the groundwork for the development of standardized multilingual medical speech corpora, fostering innovation in inclusive and culturally aware healthcare technologies.

F1: Digital Health & Connected Devices

Serving the Last Mile Patients with Digital Health

By Tom Judd[1,*], Mahesh Shirke[2]

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By invitation, Mahesh Shirke, MD, MBA (Chief Digital Officer at AMTZ https://www.amtz.in/ India) and I (GCEA Liaison Director) met an Indian community hospital CEO (physician), his IT Director, and the hospital CE-BME Director in December 2024, touring their 450-bed 50-year-old facility that is planning a new addition of 120 more beds in 2025. This facility, together with nearby hospitals, serves a metropolitan population of approximately 2 million, with an additional 1 million residents living up to 100 km away. We found the following Clinical-Biomedical Engineering (CE-BME) Digital Health opportunities:

First Mile—at the Hospital

Need for greater access to high-level clinical skills, in specialty areas with not enough 24/7 providers, e.g., Tele-ICU, Tele-Radiology

Need for an Electronic Medical Record (EMR) Advisory group, e.g., for new module/feature/workflow development with CE-BME, medical device interoperability software with EMR integration, and laboratory information system (LIS) interfacing with 3rd party lab reports, point of care & homecare devices, etc.

New clinical service planning group, e.g., what medical devices and digital health tools are needed, based on disease patterns in the coverage area and hospital data analysis.

Need for a Maintenance Advisory group, e.g., IoT for hospital facility and medical device maintenance, along with remote assistance?

Digital Pathology, e.g., cost-effectively developing this new capability, from onsite fully automated screening & basic diagnostics devices to advanced pathology outsourcing/investigations referral.

Last Mile—Remote Patients

"Last Mile" monitoring of high-risk (remote) patients; e.g., what devices and systems can best serve these patients, for example, via enabling community health workers who live near the patients and can help monitor and assist timely interventions for various non-communicable diseases (NCDs).

The hospital IT Director had previously studied Cellular Connectivity for the 100 km patients, determining that Satellite was the most cost-effective solution so far, as the current 5G coverage was highly variable due to topology.

On the second day, Dr. Shirke and I met with the following:

The hospital's affiliated hospice, which serves 3,500 villages, providing quality care for end-of-life cancer patients; and

An affiliated Primary Health Center (PHC), led by 2 physicians, serving 50–70 patients per day, and providing several mobile clinics. A suggestion was made for CCTV in patient areas, including rooms and wards, for better supervision/nursing care and any emergency handling.

We ended by interviewing the physician, Community Health Medical Director, who clarified and identified the following highest priority needs to best and affordably serve Last Mile patients:

Decision Support for first contact—for Community Health Workers as they assist by reaching out to high-risk patients.

Predictive symptomatic diagnostic health IT application for primary care and referral.

A hybrid AI model for access to Primary and Specialty Care providers for timely intervention, either face-to-face or online.

The hospital CEO and IT Director then attended the 2nd World Health Innovation Forum at AMTZ with us to further explore possible solutions for their Digital Health First and Last Mile challenges. Results are a work in progress.

F1: Digital Health & Connected Devices

Health Wearable Devices as Foundational Technology for Healthcare

By Nestor Gonzalez[*]

University of Denver, Colorado, USA.

This research study explores how health wearable devices are key technologies to revolutionize the healthcare system and its outcomes. Benefits from the use and adoption of health wearable devices include promoting a healthier lifestyle, leading to a preventive medicine approach, continuous health monitoring and chronic disease management, and reduction of financial strain for individuals and organizations. Challenges for these health wearables include data privacy and data security, review of the regulatory landscape, and overcoming the new digital divide that leads to data absenteeism, where underserved demographics are systemically excluded from the development and benefits of health wearable devices. The study explores some recommendations on data unification, data regulations, and the development of health wearable devices. The study concludes, emphasizing the importance of collaboration between academia, government, and organizations, as well as the importance of a human-centric approach to the research and development of health wearable devices.

F1: Digital Health & Connected Devices

Barriers and Breakthrough Paths in the Promotion of Home Nursing Technologies

By Yuan Liao*

Obstetrics and Gynecology Hospital of Tongji University, Shanghai, China.

This paper conducts a systematic analysis of the multifaceted barriers potentially hindering the promotion of home nursing technologies, proposing a comprehensive framework for breakthrough paths. Drawing from hypothetical modelling and cross-industry scenario analysis, the study identifies potential technical adaptation challenges, cost transmission bottlenecks, trust ecosystem dilemmas, and service ecology coordination gaps as primary obstacles. Corresponding solutions integrating technological innovation blueprints, proposed economic models, ethical framework designs, and inter-industry collaboration roadmaps are presented, offering a prospective roadmap to facilitate the widespread adoption of home nursing technologies.

F1: Digital Health & Connected Devices

Connected Devices: Usefulness, Complexity & Challenges

By KaMan Liu[1,*], Ted Cohen[2]

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The rapid growth in medical device technologies has enabled tremendous and expanding opportunities for devices and systems to be interconnected in various ways and to different degrees, but it is not always clear how much clinical usage and benefit that connectivity brings, along with the associated technical complexities and challenges. This summary shares UC Davis Health's experience and insights in connecting various devices and systems in various ways for the past 20 years in order to increase the benefits from EMR Integration in various care areas, as well as from OR (Operating Room) Integration.

Background: UCD Health is a teaching hospital where devices are connected in a myriad of ways/formats encompassing:

- •Care Areas: ORs, Cath Labs, ICUs, ER
- •Data/Contents Integrated: EMR charting, HD/4K images and video streams, OR audio, waveforms (ventilator/physiological)
- •Devices Integrated: Patient monitors, Anesthesia, Perfusion, Surgical/Endo cameras, various OR video sources (Imaging/Navigation, Robotic), Ventilators, VSM
- •Middleware Infrastructure/Technologies: Philips PiiC, Capsule Tech, Masimo Iris, InterSystems Ensemble, Stryker

SPI/CoreHub, Steris|BDV IDSS/HexaVue

Conclusion: There is a large variance in how often data/contents are utilized to benefit patient care, but the importance/significance depends on the use case outcome that clinicians desire. When resources are limited, it is imperative to assess the TCO (total cost of ownership) and complexities vs. the clinical benefits. Clinical effectiveness will be illustrated by example use case narratives offered in this presentation. Some challenges include: streamlining workflow, guiding users toward "Next Clinical Decision", cybersecurity protocols/measures, networking constraints/implications, clinician acceptance, adapting AI, and immaturity of middleware technologies.

F2: AI, IoT & Future of HTM

Artificial Intelligence in Medical Imaging Technology Research in China: An Evolutionary Trend and Frontier Analysis—A Scientific Knowledge Mapping Study Using CiteSpace

By Junhao Dai*

The Affiliated Panyu Central Hospital of Guangzhou Medical University Equipment Department, Guangzhou, Guangdong Province, China.

Objective: Investigating the Developmental Landscape of Artificial Intelligence in Medical Imaging Technology Research in China (2001–Present): An Evolutionary Trajectory Analysis and Frontier Exploration with Evidence-Based Strategic Recommendations. **Methods:** Visualization Analysis of Artificial Intelligence Research in Medical Imaging Based on Knowledge Graph: A Scientific Measurement Study. This study conducted a professional search on the Chinese National Knowledge Infrastructure (CNKI) database for relevant literature, followed by manual screening to establish the research database. CiteSpace was employed to perform scientific measurement and visualization analysis, including annual publication volume analysis, author publication analysis, research institution analysis, keyword co-occurrence, keyword clustering, and burst detection analysis. These visualization processes systematically explore the evolutionary trends and research frontiers of this paradigm. **Results:** Through visual analysis of 3,205 valid documents included in the database, it was found that since 2001, the annual number of research literature on artificial intelligence in medical imaging diagnosis in China has been increasing year by year, and the academic attention has also been rising, which can be divided into two stages: the budding stage and the explosive stage. The research topics cover multiple medical and artificial intelligence fields. The study on the formation of core author teams found that a clear core team has been formed in this field. However, at the same time, the distribution of research institutions in China is scattered, and the overall cooperation tendency is relatively low. The keywords "image segmentation", "artificial intelligence", "radiomics", and "deep learning" have high frequency and centrality. The top 10 clusters with the largest co-occurrence are #0 prediction, #1 radiomics, #2 image segmentation, #3 artificial intelligence, #4 transfer learning, #5 hepatocellular carcinoma, #6 surgery, #7 discrimination, #8 neural network, and #9 feature fusion. In the analysis of emergent words, it was found that with the development of this field, artificial intelligence technology and disease imaging diagnosis have been well integrated. **Conclusion:** China's AI-based medical imaging diagnosis research will continue to advance towards higher precision and diversified application scenarios.

F2: AI, IoT & Future of HTM

Future-Proofing Connected Devices for a Connected Health Ecosystem, with Standards-Based Interoperability

By Ricardo Silva[1,*], Lloyd Williams[2], Aditya Ayyagari[2]

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In today's rapidly evolving healthcare environment, ensuring that connected medical devices can seamlessly and securely exchange data is not just a technical requirement; it is a foundational necessity. As health systems become increasingly digitized, the demand for standards-based interoperability has never been more urgent. At the heart of this transformation lies a powerful principle: medical devices, regardless of manufacturer, function, or location, must speak a common language to deliver safe, efficient, and data-driven care. Medical devices generate a wealth of critical data—from physiological measurements and diagnostic results to operational metadata such as calibration status, usage patterns, error logs, and maintenance cycles. When this data is locked in proprietary systems or inaccessible due to interoperability gaps, clinical and operational risks rise. Decisions may be made with incomplete information, preventive maintenance may be delayed, and device failures may go undetected. A standardized approach to data exchange enhances clinical decision-making, strengthens patient safety, and supports effective device lifecycle management. To meet this challenge, the industry must move beyond piecemeal adoption of isolated standards and embrace a Comprehensive Medical Device Interoperability Framework. While individual standards like HL7® FHIR®, IEEE 11073, ISO 14971, and IEC 62304 each serve essential purposes, they often function independently. This creates complexity for manufacturers and providers, increases regulatory burden, and slows innovation. The Carefluence platform directly addresses these challenges by delivering a unified, Office of the National Coordinator for Health Information Technology (ONC)-certified open Application Programming Interface (API) environment purpose-built for medical device and healthcare Information Technology (IT) interoperability. In the pre-market phase, Carefluence accelerates readiness by simplifying Fast Healthcare Interoperability Resources (FHIR) conformance, integration testing, and certification processes. In the post-market phase, it provides robust data interoperability, real-time observability of device performance metrics, and seamless connectivity to clinical systems, assuring continuous monitoring, proactive maintenance, and operational transparency. By enabling secure, standards-based data exchange of both clinical and device-specific metadata, Carefluence supports observability of key device metrics, such as time between failures, calibration integrity, and operational status, helping manufacturers and care teams maintain optimal performance. At the same time, it enhances patient safety by integrating real-time clinical monitoring data into care pathways, enabling early interventions and coordinated responses in both acute and remote settings. Rather than reinventing standards, Carefluence harmonizes and operationalizes them, embedding cybersecurity and safety by design. It creates a foundation on which manufacturers, providers, and regulators can align. Regulatory guidance, such as the U.S. Food and Drug Administration (FDA)'s interoperability recommendations and the European Union (EU)'s Medical Device Regulation (MDR) requirements, underscores the importance of such frameworks in reducing ambiguity and encouraging innovation. Ultimately, standards-based interoperability is the backbone of a connected health ecosystem. It powers AI-driven decision support, enables scalable integration, supports remote diagnostics, and ensures reliability throughout the product lifecycle. Futureproofing connected devices demands not only advanced technology, but regulatory foresight and implementation discipline. With the Carefluence platform, the industry has a proven, standards-ready foundation for building a more adaptive, resilient, and patient-centered healthcare system.

F2: AI, IoT & Future of HTM

Real-Time IoT (Internet of Things) Monitoring in Medical Equipment

By Jihan Aleid*

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The integration of Internet of Things (IoT) technology in healthcare has revolutionized the monitoring and maintenance of medical equipment. Real-time IoT monitoring leverages interconnected devices and sensors to communicate data, enhancing the efficiency, safety, and reliability of medical equipment management. This study explores the benefits, challenges, and future directions of IoT-based real-time monitoring systems in healthcare settings. Key benefits identified include predictive maintenance, remote diagnostics, and improved operational efficiency, which contribute to enhanced patient care and reduced equipment downtime. However, challenges such as high initial costs, data privacy concerns, and lack of interoperability among devices remain significant barriers to adoption. The research employs a quantitative methodology to analyze the perceptions of healthcare professionals regarding the implementation of IoT

in their facilities. Findings suggest a positive outlook for the future expansion of IoT, particularly with advancements in artificial intelligence (AI) and blockchain technologies, which promise to address current limitations related to data security and integration. The study concludes that while IoT technology offers substantial opportunities for optimizing healthcare delivery, strategic efforts are necessary to overcome the challenges associated with its deployment.

F2: AI, IoT & Future of HTM

IoT-Enabled Virtual Sharing Framework for Medical Equipment in Multi-Campus Hospitals: Survey-Based Design

By He Zhang*, Haicheng Zu, Hailin Shan, Jingru Zhong, Yuan Xue

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The sharing economy has become a global trend. With the penetration of the sharing economy concept in the medical field, the sharing of medical equipment resources has emerged as a crucial approach to enhance asset utilization efficiency. This study addresses the critical limitations of traditional physical equipment-sharing centers in hospitals, including excessive space requirements, high labor costs, and inefficient cross-campus coordination. An innovative IoT-based virtual sharing model is proposed to overcome these challenges. A rigorously designed survey encompassing 294 healthcare professionals across 23 Chinese provinces, including physicians (10.54%), nurses (61.56%), and administrators (20.75%), systematically identified and analyzed the critical barriers to effective equipment sharing. The research reveals three primary categories of implementation challenges: First, operational concerns emerged as significant barriers, with 77.55% of respondents expressing apprehension about potential equipment damage during sharing processes. Second, systemic deficiencies were prominently noted, as 74.49% of participants highlighted the absence of standardized management protocols as a major constraint. Third, resource limitations were frequently cited, with 70.41% of professionals indicating staffing shortages as a substantial obstacle to effective sharing implementation. The study demonstrates considerable potential for adoption under appropriate conditions. Notably, when establishing standardized management systems that include organizational structures, billing rules, incentive mechanisms, disinfection protocols, and maintenance safeguards, 78.91% of surveyed professionals expressed willingness to participate in equipment sharing programs. This positive disposition was particularly strong for specific equipment types, with 87.41% of respondents favoring the sharing of mobile devices and 79.93% supporting the sharing of easy-to-operate equipment. Building upon these empirical findings, the proposed IoT-enabled virtual sharing framework effectively eliminates the need for physical sharing centers while addressing their inherent limitations. The framework comprises four key components: (1) real-time equipment monitoring through advanced sensor technology, (2) intelligent scheduling algorithms designed to optimize resource utilization across multiple campuses, (3) automated billing systems incorporating time-based accounting (supported by 88.44% of respondents), with 55.1% favoring a 70-30 revenue sharing model between equipment-owning and borrowing departments, and (4) standardized operational protocols addressing critical maintenance requirements (87.41% concern) and disinfection standards (63.61% requirement). This study makes three principal contributions to the field of healthcare management: First, it provides large-scale empirical evidence regarding equipment sharing barriers in developing healthcare systems. Second, it introduces a novel virtual sharing paradigm that circumvents the spatial and staffing limitations of traditional physical sharing centers. Third, it delivers practical, policy-ready implementation guidelines encompassing equipment selection criteria, incentive mechanisms, and risk mitigation protocols. These evidence-based findings offer healthcare administrators actionable insights for optimizing equipment utilization through IoT-enabled sharing systems, presenting particular relevance for resource-constrained multi-campus hospitals seeking to enhance operational efficiency without substantial capital investments.

F2: AI, IoT & Future of HTM

Application of IoT Technology in Medical Equipment Quality Control and Risk Management

By Yunhao Zhou, Xin Huang, Jing Li, and Nan Zhang*

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The increasing intelligence and connectivity of medical devices enhance diagnostic and therapeutic capabilities but also introduce greater clinical risks. Consequently, quality control of medical equipment has become a critical factor in ensuring patient safety and healthcare quality. This paper describes the current applications of Internet of Things (IoT) technology in the field of medical equipment quality control, focusing on how its synergistic integration across the perception layer, transmission layer, and application layer enables full lifecycle management, optimizes risk control strategies, and facilitates the intelligent advancement of medical safety systems. At the perception layer, various sensors (e.g., RFID tags, environmental monitors) collect real-time medical data, operational parameters, and location information. The transmission layer leverages Wi-Fi, 5G, and other network technologies to achieve low-latency, high-stability data transfer. The application layer employs algorithms such as frequent itemset mining, convolutional neural networks (CNNs), and particle optimization filtering to perform fault prediction, early warning, and preventive maintenance, enabling remote monitoring, automated inspections, and condition-based repairs.
In terms of quality and risk management, IoT systems significantly reduce equipment failure rates, improve operational efficiency, and ensure operational safety through real-time data analytics and intelligent decision-making, thereby mitigating medical risks. For instance, case studies involving MRI systems and ventilators demonstrate that IoT-based quality control platforms enhance the precision of preventive maintenance, support full lifecycle management, and provide objective data for hospital performance evaluations. However, challenges remain, including data security, privacy protection, system compatibility, and big data processing. Future advancements will rely on deeper integration of IoT with artificial intelligence (AI), along with the refinement of standardized frameworks, to propel medical equipment quality control toward comprehensive intelligence and full lifecycle optimization, thereby strengthening risk management and promoting high-quality hospital development. IoT technology has been successfully applied in medical equipment quality control, enabling intelligent and precise supervision while substantially improving quality and risk management. Through real-time monitoring, fault prediction, and preventive maintenance, IoT systems effectively mitigate operational risks, optimize resource allocation, and reinforce medical safety. Despite technical challenges, the continued convergence of IoT with AI and the development of standardized protocols will unlock greater potential in the medical IoT domain, driving quality control toward a more efficient and intelligent, fully integrated management model.

F2: AI, IoT & Future of HTM

IoT-based Intelligent Management System for Operating Room Medical Equipment: A Practical Study

By He Zhang*, Haicheng Zu, Jingru Zhong, Yuan Xue

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The operating room serves as a central platform within hospitals, housing the largest and most concentrated inventory of medical equipment. Effective management of these resources is critical to ensuring healthcare service quality and operational efficiency. However, many hospitals face common challenges in optimizing equipment utilization, obtaining real-time status updates, and implementing efficient management practices.
This study addresses three key pain points in traditional operating room equipment management: (1) lack of transparency in equipment status, (2) inefficiencies in manual recording and allocation processes, and (3) absence of comprehensive lifecycle data. To overcome these challenges, an intelligent management system for operating room medical equipment based on Internet of Things (IoT) technology is proposed.
Employing a combined approach of theoretical framework development and practical implementation, this research first established a three-tier system architecture comprising perception, network, and application layers through collaboration with network technology specialists. Subsequently, conducted empirical research in a tertiary hospital's operating room, deploying 122 WiFi-based dynamic energy-efficiency tags (current-sensing monitoring terminals) on critical medical de-

vices. These IoT-enabled sensors collected comprehensive operational data, including equipment location, power-on duration, standby time, usage periods, and idle intervals, enabling real-time visual monitoring and dynamic efficiency analysis. The implementation demonstrates that the IoT-based intelligent management system provides valuable data support for the entire lifecycle management of operating room equipment, including procurement decisions, maintenance strategies, and decommissioning evaluations. The system significantly enhances equipment management effectiveness through data-driven insights.

Key contributions of this study include: (1) development of a specialized IoT management framework for operating room environments, (2) validation of real-time monitoring data's decision-support value in equipment lifecycle management, and (3) creation of a replicable, refined equipment management solution that offers practical implementation guidance for similar healthcare institutions.

F3: AI for Improved & Safer Patient Care

An Ethical Framework for AI-CDSS

By Ricardo Silva[1,*], Razi Iqbal[2]

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Recent advancements in Artificial Intelligence (AI) have enabled its deep integration into Clinical Decision Support Systems (CDSS), profoundly transforming healthcare decision-making while introducing complex ethical considerations. This paper proposes a foundational ethical framework for AI-enabled CDSS (AI-CDSS), addressing the urgent need to embed ethical principles directly into system architecture. The framework aligns AI-driven decisions with core tenets of patient-centered care, drawing from medical ethics—autonomy, beneficence, non-maleficence, and justice—and regulatory standards like HIPAA and GDPR.

The analysis is structured around the Internet of Medical Things (IoMT), which underpins many modern CDSS applications. A three-layer model—Sensing, Network, and Application—guides the ethical assessment of data from acquisition to clinical insight. In the Sensing Layer, we apply the PACPAC framework (Privacy, Accuracy, Compliance, Property, Accessibility, Contextual Awareness) to ensure ethically sound data collection. The Network Layer emphasizes transparency, consent, and compliance during data transmission. The Application Layer focuses on personalization, cultural sensitivity, and shared decision-making, ensuring AI-generated outputs remain actionable, interpretable, and respectful of patient values.

To operationalize ethical guidance, we introduce two novel constructs: Patient Ethical Value (PEV) and Utilitarian Force (UF). PEV captures the ethical weight of a clinical intervention for an individual, considering prognosis, autonomy, and quality of life. UF, calculated as PEV multiplied by a Medical Safety Rating (MSR), estimates the net ethical impact—potential harm or benefit—of an AI recommendation. These metrics enable a dynamic, quantifiable layer of ethical reasoning in real-time clinical decisions.

A case scenario in lung cancer treatment demonstrates the application of PEV and UF in guiding AI-CDSS output. While promising, we acknowledge that quantifying ethics introduces risks such as oversimplification and algorithmic bias. To mitigate these, the integration of Explainable AI (XAI) is recommended to improve transparency, accountability, and patient trust. The framework also addresses the importance of cultural and socioeconomic context in validating ethical AI across diverse populations.

This framework is envisioned not as a final solution but as a living ethical engine, requiring iterative development through collaboration among clinicians, ethicists, AI developers, and policymakers. As AI continues to advance toward higher levels of autonomy—and potentially, sentience—ethical infrastructure must evolve in parallel.

In conclusion, we offer a practical foundation for embedding ethics into AI-CDSS by introducing actionable metrics like PEV and UF. This model serves as a stepping stone toward building trustworthy, equitable, and transparent AI systems for the future of healthcare.

F3: AI for Improved & Safer Patient Care

Development of a Low-Cost Telehealth Monitoring System for Bedridden Patients

By Mas Sahidayana Mohktar[1,2,*], Nur Farhana Suhaimi[3], Ahmad Hisyam Ahmad Shukri[3], Nur Rasyidah Hasan Basri[2]

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Healthcare practitioners, including physicians and nurses, frequently face the demanding and time-intensive responsibility of doing regular home assessments for bedridden patients, which entails the manual measurement and documentation of vital signs such as blood pressure, heart rate, temperature, and oxygen saturation levels. The manual nature of this operation increases the likelihood of human mistakes. A cost-effective telehealth monitoring device has been developed for patients to utilize at home for the regular measurement of their vital signs. This adaptability facilitates diverse health monitoring protocols without necessitating constant operation. Healthcare practitioners, including physicians and nurses, can retrieve patients' health data via ThingSpeak's web interface. ThingSpeak is accessible from multiple devices, including computers, tablets, and smartphones, allowing both patients and healthcare providers to effortlessly view data from any location. The system employs cost-effective, commercially available sensors and microcontrollers that deliver dependable performance while maintaining low expenses, ensuring the device's base price stays accessible for both patients and healthcare professionals. The prototype demonstrated overall strong consistency with the standard clinical equipment. The prototype's heart rate readings exhibited an average inaccuracy of 4.73%. The SpO2 readings exhibited high accuracy, with a mean error of merely 0.76%. The average inaccuracy of body temperature readings was 1.56%, signifying dependable functioning. Electrical safety is definitely a fundamental feature and crucial for medical devices that engage in direct contact with the patient through the patient interface. IEC 60601-1 specifies that the prototype must be completely separated from mains electricity to mitigate the risk of electrical shock. To mitigate such risk, the prototype employs a power bank to provide energy to the circuit, which is intrinsically safer due to its low voltage operation. The factors considered when utilizing a power bank include the quality of the device and the routine examination of its exterior to ensure it is not compromised or swollen as a result of overcharging. Another critical aspect of patient safety is the sensors' adherence to relevant standards, such as ISO 10993 for biocompatibility, and the sanitary practice of repeatedly using a medical device on various individuals. Adhering to proper sterilizing protocols is essential for ensuring patient safety during every testing session. It is imperative to establish stringent processes for cleaning and disinfecting the device after each use, ensuring that all components of the prototype that contact the patient are meticulously cleansed with sanitizing wipes. This procedure is particularly vital when measuring bedridden people afflicted with any form of infection. Consequently, by adequately cleaning the prototype, patient safety is enhanced, thereby promoting trust and adherence to the testing protocol. The prototype uploads measurement data to the web database ThingSpeak, making patient data security and privacy vital. Maintaining the confidentiality of patient data safeguards against unauthorized access to sensitive personal and health information, hence mitigating risks of identity theft, fraud, and other nefarious actions. When patients are assured of the security of their personal information and the respect for their privacy, they are more inclined to participate in the testing session, resulting in improved testing outcomes.

F3: AI for Improved & Safer Patient Care

A Next-Generation Integrated Digital Health Ecosystem Empowered by AI, Cybersecurity, and IoT for Strengthening Healthcare Delivery in Resource-Constrained Settings

By Rohith Jampani*

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The accelerating digital transformation of global healthcare is creating new paradigms for accessibility, efficiency, and patient-centric care. This paper presents the development of a comprehensive, modular, and scalable digital health ecosystem designed to integrate Electronic Health Records (EHR), Point-of-Care (POC) diagnostics, AI-driven decision support, and mobile health hubs with strong cybersecurity and interoperability foundations. The platform is purpose-built to address healthcare disparities, especially in underserved rural areas and low-resource environments. Key innovations include AI-based clinical intelligence, blockchain-backed consent management, federated architecture for interoperability, and real-time data synchronization from Internet of Things (IoT)-enabled diagnostic devices. Emphasizing clinical engineering's vital role, the system also aligns with regulatory and privacy frameworks like HIPAA, GDPR, and India's DPDP Act. This paper underscores the transformative potential of a unified, AI-enabled, cyber-resilient digital health system in reshaping global health delivery, improving continuity of care, and enabling evidence-based policymaking.

F3: AI for Improved & Safer Patient Care

AI-Enhanced Digital Transformation in Elderly Care: A Practical Implementation Plan and Societal Impact in Rural Japan

By Ichiko Watanabe*

Japan Association for Clinical Engineers, Tokyo, Japan.

Background and Objectives: Japan faces an unprecedented demographic crisis: rapid aging and depopulation, particularly in rural areas like Akagi-machi, Gunma. This leads to "genkai shuraku" (critical villages) with over 50% elderly, threatening community survival and exacerbating caregiver shortages and burdens. This study addresses these urgent issues by implementing advanced AI-powered care technologies—an exoskeleton and an AI-equipped smart intercom—at Akagien elderly health care facility. Our goal is to enhance operational efficiency, reduce caregiver burden, facilitate communication for foreign staff, and develop a sustainable care business model.

Implementation Plan (Methods): Starting September 2025, this project at Akagien will introduce:

- Exoskeleton: Features AI for real-time learning, adaptive lift control, and fatigue detection/adjustment, providing optimal support and safety warnings. Cloud connectivity and OTA updates ensure continuous improvement, with an app for data visualization. This aims to reduce physical strain, prevent MSDs, and improve staff retention.
- AI-equipped Smart Intercom: Leverages AI for optimized translation, hands-free communication, and integrated record keeping. This facilitates seamless communication, especially for foreign staff, and enhances documentation efficiency.

Evaluation Items:

- Care staff's physical burden reduction (using exoskeleton AI data on risk movements and subjective reports).
- Care staff's mental burden reduction (questionnaires, interviews).
- Operational efficiency improvement (reduction in care time, documentation time, and travel time. This also includes streamlining device attachment/detachment workflows and optimizing staffing arrangements to mitigate the current widespread challenge of time-consuming attachment/detachment of wearable devices, thereby streamlining overall operational flow).
- Improvement in communication with foreign care staff.
- User satisfaction and changes in Quality of Life (QOL).
- Economic impact on the facility's management (human resource cost reduction, increased revenue from additional service fees, cost-benefit analysis of technology introduction).
- Ripple effects on the local economy (collaboration with local businesses, creation of new employment opportunities, and the potential for Tokyo-based technology companies to expand into rural markets and establish local bases through the success of this demonstration).

Expected Outcomes and Future Prospects:

This project anticipates groundbreaking outcomes:

- Revolutionizing Workforce: AI-driven exoskeletons will drastically reduce physical strain, improving staff

retention and attracting new talent. AI intercoms will eliminate language barriers, fostering a more inclusive and stable foreign workforce.

• Enhancing Care Efficiency and Quality: AI features in both technologies will optimize care safety and efficiency, reducing documentation time and enabling efficient care delivery even with limited staff, crucial for depopulated areas. Addressing the challenge of device usability will accelerate wider adoption.

• Driving Regional Innovation: Seamless AI-enabled communication will strengthen collaboration with local medical and administrative bodies. The established DX model will offer a blueprint for optimizing care operations, attracting external investment, and stimulating local economies.

• Global Model: This project will serve as an advanced solution for super-aging societies and depopulation, offering a replicable model for other nations, particularly in Southeast Asia, facing similar demographic challenges.

This project represents the convergence of clinical engineering, nursing science expertise, and cutting-edge AI technology, poised to accelerate the digital transformation of the entire care industry and set a new international benchmark for sustainable elderly care.

F3: AI for Improved & Safer Patient Care

Investigation Methods when Intelligent Devices or AI are Involved in Patient Injury or Death

By Elliot Sloane[1,*], Ricardo Silva[2,3], Yadin David[3]

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Investigating patient harm or death involving intelligent or AI-based devices and systems requires specialized approaches. These "smart" technologies form a complex System of Systems, where devices, software, and firmware interact in dynamic and often unpredictable ways. Asynchronous system and device configurations, updates, and application settings can all lead to unexpected patient harm. Emerging semi- and fully autonomous systems, such as those emerging in robotic surgery, will further complicate causality assessments. Effective investigation demands rapid, skilled system analysis and documentation to determine root causes and implement timely remediation.

A key challenge is preserving the "as-was" state of all involved technologies, as well as the incident environment and clinical participants, before potential reconfiguration or automatic updates occur. Investigators must act very quickly to document and secure relevant component and configuration details for all components and subsystems. This might include smart infusion pump systems, computerized order entry systems, clinical decision support systems, surgical robots, or multi-departmental integrated EHRs and EMRs. These devices and systems, along with their human operators, can be highly interdependent and subject to asynchronous changes from multiple vendors and users.

The healthcare environment where the incident occurred also often plays a critical role. Wired and wireless networks, data servers, data gateways, and links to shared cloud resources such as drug information must all be fully documented in sufficient detail to ensure the investigation can recreate the failure mode(s) and allow effective root cause analysis. Only then can the appropriate corrective actions be identified and implemented.

This presentation outlines essential steps and success factors for conducting thorough, timely accident, incident, and forensic investigations in today's AI-driven healthcare environment.

6th ICEHTMC Posters

A: CE/HTM Interventions, Services & Systems

Research on the Health Evaluation Method of Medical Devices Based on Multiple Electrical Performance Parameters

By Xiaoyu Chen*, Haitao Guo, Xin Song, Xiaohua Yu, Zihong Wang*

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Objective: This paper aims to develop a digital evaluation method based on Multiple Electrical Performance Parameters (MEPP) to assess the health of medical devices objectively. **Methods:** Firstly, the circuit characteristics of the medical devices were analyzed to establish the theoretical basis and evaluation index for the evaluation system. Then, based on the experience with the health status of medical devices throughout their entire life cycle, this paper correlates the health status of medical devices with their electrical performance parameters. Finally, this paper selected 4 different brands of monitors. The maintenance records of our hospital, as a result, were used to determine the stability of each brand and calculate the stability value of four devices based on their electrical performance. The health status is scored and evaluated at last. **Results:** The experimental results show that the scores of the four devices are 83.9, 88.1, 89.5, and 81, respectively. After checking and comparing the maintenance frequency, it is found that it conforms to the order of stability. And the experiment results of the same brand monitor also show that the stability is consistent. **Conclusion:** This study aims to evaluate the electrical performance parameters of the monitors, providing a scientific assessment of their health status and that of similar medical devices. It serves as a basis for new computer technology applications in traditional circuit detection.

A: CE/HTM Interventions, Services & Systems

Research Progress on the Application of Intelligent Operation and Maintenance Models in Medical Equipment Management

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Medical equipment management plays a pivotal role in enhancing healthcare service quality and operational efficiency. However, traditional management approaches, often reliant on manual or fragmented electronic systems, struggle to address growing demands due to challenges such as poor data interoperability, high maintenance costs, and unpredictable equipment failures. Recent advancements in intelligent operation and maintenance (O&M) models, underpinned by big data analytics, the Internet of Things (IoT), and artificial intelligence (AI), offer transformative solutions for proactive and data-driven management. This paper systematically reviews the technological foundations of intelligent O&M models, evaluates their practical applications in medical equipment management, and identifies critical challenges and future research directions.

The technical framework of intelligent O&M encompasses five core components: data acquisition (via IoT-enabled sensors and interfaces), data processing (cleaning, normalization, and feature extraction), predictive maintenance (leveraging machine learning for fault prediction), decision support (prioritizing tasks through visualization tools), and executive feedback (automated task execution and model optimization). Case studies demonstrate diverse applications: IoT-based systems enable real-time monitoring of critical devices like CT scanners and anesthesia machines, while deep learning models achieve high-precision fault detection by analyzing multi-source heterogeneous data. Big data platforms further enhance operational efficiency by integrating equipment logs with hospital information systems (HIS/RIS/HRP) to optimize resource allocation and lifecycle management.

Despite these advancements, significant challenges remain. Energy consumption of IoT sensors and wireless devices poses sustainability concerns, necessitating energy-harvesting technologies. Data heterogeneity and legacy system incompatibility hinder seamless integration, requiring standardized protocols (e.g., IEEE 11073, HL7) and middleware solutions. Cybersecurity risks, including data breaches and unauthorized access, demand robust encryption and multi-

factor authentication mechanisms. Additionally, the "black-box" nature of deep learning models limits interpretability in maintenance decision-making, highlighting the need for explainable AI frameworks.
In conclusion, intelligent O&M models hold immense potential to revolutionize medical equipment management by reducing downtime, lowering costs, and improving service reliability. Future efforts should focus on enhancing energy efficiency, strengthening data governance, and developing transparent algorithms to address existing limitations. The successful implementation of these models will not only streamline healthcare operations but also contribute to the broader digital transformation of the medical industry.

A: CE/HTM Interventions, Services & Systems

Exploring the Optimization Path of Medical Equipment Management from the Perspective of Nurses

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In the modern medical environment, effective management of medical equipment is crucial for improving the quality of healthcare services. This study explores optimization paths for medical equipment management from a nurse's perspective. By analyzing issues such as untimely equipment maintenance, insufficient training on equipment uses, and unreasonable allocation of equipment, the study proposes corresponding optimization paths. These include establishing a comprehensive equipment maintenance monitoring system to ensure that equipment is always in optimal working condition; enhancing the nurse training system for equipment use to improve operational accuracy and efficiency; and building a scientific equipment allocation platform to achieve efficient utilization of equipment resources. These optimization paths help enhance the management level of medical equipment, thereby providing safer and more efficient medical services to patients.

A: CE/HTM Interventions, Services & Systems

An Oral Diagnosis and Treatment System with Cross-Level Data Interaction and Intelligent Supervision Based on Hardware-Data-Control Architecture

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The present study proposes an innovative intelligent diagnostic and therapeutic management system that facilitates cross-level data interaction and intelligent supervision. This novel system has two key features: first, it digitally reconstructs diagnostic procedures and, secondly, it facilitates intelligent upgrading of supervision through the collaborative interconnection of dental equipment. The system utilizes a three-layer "hardware-data-control"

architecture: The hardware layer is responsible for the construction of physical interaction terminals, which comprise dental comprehensive treatment units, multimodal anomaly warning modules, and underlying control systems. The purpose of these systems is to enable state perception and basic control of diagnostic equipment. The data layer integrates equipment operation data and patient diagnostic information via a backend management subsystem. It uses data coupling algorithms to establish bidirectional mapping models between equipment status and business processes, and to form a standardized data asset pool. The control layer is responsible for the development of intelligent control modules. Examples of these modules include doctor identity authentication, patient information visualization, and remote dental chair manipulation. These modules are based on two-way communication technology, which enables automated coordination of diagnostic procedures. The establishment of cross-unit data sharing mechanisms and a hierarchical permission system for supervision is realized through the collaborative operation of the three layers. This enables transparent supervision of diagnostic processes via dynamic data interaction. This research provides an innovative solution for the oral diagnosis and treatment field by integrating device interconnection, data integration, and intelligent supervision, thereby enhancing the efficiency of diagnostic procedures and supervision effectiveness.

A: CE/HTM Interventions, Services & Systems

Research on Cold Chain Monitoring System and Equipment Fault Prediction Model Based on Internet of Things

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Purpose: Enhance the management level of the hospital cold chain to ensure the quality and safety of medical supplies. **Methods:** reduce manual intervention through intelligent monitoring and enable intelligent prediction for early warning and timely response. The system integrates IoT, big data, and cloud computing technologies, utilizing temperature and humidity sensors to establish a browser/server architecture-based cold chain monitoring platform. Three predictive modeling approaches were sequentially implemented: a standard BP neural network, a genetic algorithm-optimized BP neural network, and an improved genetic algorithm-enhanced BP neural network. These models were trained using complete 2022–2023 temperature monitoring datasets from a 2–8°C medical refrigerator, subsequently generating three distinct sets of temperature predictions for January 2024. **Results:** Establish a cold chain monitoring system to achieve comprehensive temperature and humidity monitoring of equipment and develop a predictive model for equipment failures. Compared to pre-implementation, the system significantly reduced equipment alarm response time, repair time, and spare parts application time. The variance of the error values in the equipment failure prediction model was significantly reduced compared to the pre-improvement version, while improving clinical satisfaction. These differences were statistically significant ($p < 0.05$). **Conclusion:** The IoT-based cold chain monitoring system enables comprehensive, continuous, and intelligent surveillance of the cold chain environment, significantly enhancing the storage quality and safety of pharmaceuticals and biological agents. By employing an improved genetic algorithm to optimize the BP neural network, the system establishes an equipment failure prediction model capable of forecasting malfunctions and issuing early warnings, thereby preventing large-scale drug spoilage caused by temperature deviations. This approach provides a developmental roadmap for sustainable cold chain monitoring systems, with profound implications for hospital operations, patient safety, and public health.

A: CE/HTM Interventions, Services & Systems

Malfunction Analyses and Management Strategies of Medical Electronic Linear Accelerators with Different Brands

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Background: Medical electronic linear accelerators (LINACs) are essential and important medical equipment in radiation therapy, but have a high frequency and diverse types of malfunctions. Previous studies mostly focused on some specific malfunctions of a certain brand of LINAC. However, the comparisons regarding different brands or different service years of LINACs were rarely reported. It is necessary to analyze and explore the management strategies of LINACs in different working conditions. **Methods:** Three in-use LINACs of a tertiary hospital in Xinjiang were selected in this study, namely: Varian CX, launched in 2012; Varian True Beam, launched in 2023; and Elekta Synergy, launched in 2012. The brands, types, malfunction classifications, specific causes, and disposal methods of malfunctions from January 2023 to December 2024 were recorded and investigated by using SPSS 21.0. **Results:** A total of 209 malfunctions of three LAs occurred from January 2023 to December 2024, including 52 cases (24.90%) of Varian CX, 112 cases (53.60%) of Varian True Beam, and 45 cases (21.50%) of Elekta Synergy. The number of malfunctions of Varian True Beam was significantly higher than the other two LAs ($\chi^2 = 67.756$, $p < 0.001$). There was no statistical difference in the number of malfunctions between Varian and Elekta under the same service life ($p > 0.05$). The malfunction classifications included malfunctions of the multi-leaf collimator (MLC), electron accelerator system, treatment couch, motion system of gantry and treatment head, control system software, workstation, cooling system, accelerator console hardware, and others. The frequencies of MLC malfunctions (84 cases, 40.20%) and electron accelerator system malfunctions (82cases, 39.20%) were significantly higher than others $\chi^2 = 405.713$, $p < 0.001$). The disposal methods of malfunctions included reboot, parameter adjustment, and component replacement. Component replacements (107 cases, 51.96%) were significantly more frequent than the other two disposal methods ($\chi^2 = 31.416$, $p < 0.001$), especially in MLC malfunctions and electron accelerator system malfunctions. There was a significant difference in the distribution of malfunction types between two LAs in the same brand with different service lives ($\chi^2 = 23.598$, $p = 0.003$), but no significant differences in the disposal methods. The malfunction distributions ($\chi^2 = 14.077$, p = 0.029) and disposal methods ($\chi^2 = 18.734$, $p = 0.000$) of LAs with the same service life between Varian and Elekta were significantly different, respectively. **Conclusion:** LA in the run-in period had the highest malfunction rate. LAs with a long service life require the replacement of components to be restored. Purchasing warranty services increased the dependence of clinical engineers on manufacturer engineers. Clinical engineers still need to have daily maintenance and repair judgment abilities to directly solve simple problems or diagnose complex malfunctions, thereby saving maintenance time.

A: CE/HTM Interventions, Services & Systems

Discussion on the Maintenance and Preventive Maintenance Management of Emergency Equipment in Tertiary Hospitals

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This paper explores the importance, current status, and specific improvement strategies for the maintenance and preventive maintenance management of emergency equipment in tertiary hospitals. Emergency equipment, such as ventilators, defibrillators, and cardiac compression pumps, plays a critical role in medical treatment. To ensure their efficient and safe operation, preventive maintenance has emerged as an effective management approach. The core of preventive maintenance lies in its "preventive" nature, which involves establishing specific plans and implementation methods to ensure high reliability in medical equipment usage. Unlike traditional post-failure repair models, preventive maintenance proactively identifies and resolves potential issues, thereby reducing failure rates. This paper proposes improvements in areas such as the scope, principles, methods, division of responsibilities, personnel training, inspection and evaluation, informatization management, cost control, risk management, and continuous enhancement of emergency equipment maintenance and preventive maintenance. It provides comprehensive guidance for tertiary hospitals. In practice, hospitals should establish long-term management mechanisms for preventive maintenance, formulate relevant regulations,

standardize operational procedures from procurement to usage and maintenance, and implement full-process quality monitoring. Additionally, the costs of equipment procurement, usage, and maintenance should be linked to the economic performance of the respective departments, with a clear responsibility management system in place. Furthermore, healthcare professionals, as the primary users of medical equipment, play a key role in the successful implementation of preventive maintenance. Strengthening their technical training and fostering communication between clinical staff and equipment management departments can enhance the effectiveness of this approach. A scientific and rational maintenance and preventive maintenance system not only extends equipment lifespan and improves healthcare service quality but also reduces failure risks, ensuring a better diagnostic and treatment experience for patients. Therefore, tertiary hospitals should prioritize the maintenance and preventive maintenance management of emergency equipment to guarantee their safe and efficient operation, thereby supporting clinical rescue efforts.

A: CE/HTM Interventions, Services & Systems

Kidney Tumor Segmentation Using Swin-Unet Enhanced with Skip-Convolution Blocks

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Accurate segmentation of renal tumors in computed tomography (CT) images is critical for diagnosis, treatment planning, and surgical navigation. Recent advances in deep learning, particularly convolutional neural networks (CNNs), have greatly improved medical image segmentation performance. However, CNNs are inherently limited in capturing long-range dependencies due to their localized receptive fields. To address this, Transformer-based architectures have been introduced into vision tasks, demonstrating superior capability in modeling global contextual information. In this work, we propose a novel Swin-Unet with Skip-Convolution Blocks, an architecture that fully leverages the hierarchical design of the Swin Transformer while enhancing feature fusion through dense skip connections and convolutional refinement. The encoder extracts multi-scale features using shifted window attention mechanisms, while the decoder progressively restores spatial resolution via patch expanding layers. Skip-convolution blocks further bridge the semantic gap between encoder and decoder by refining high-resolution feature maps before fusion. We evaluate our method on the KiTS2019 dataset for renal tumor segmentation. Experimental results show that the proposed model achieves a mean Intersection over Union (M-IoU) of 93.79%, outperforming both the original Swin-Unet and other state-of-the-art CNN-based approaches. Notably, our method demonstrates superior boundary segmentation accuracy, reflected by a lower Hausdorff Distance compared to baseline models. These findings highlight the potential of Transformer-based models for medical image segmentation and suggest that further improvements may be achieved with domain-specific pretraining on large-scale medical datasets.

A: CE/HTM Interventions, Services & Systems

Construction and Application Practice of POCT Information Management System

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This study focuses on the design and practical application of the device management module in the Point of Care Testing (POCT) information management system. In response to the problems of dispersed spatial distribution of POCT equipment, data islands, difficulties in data management, and insufficient quality control, a modular architecture design was adopted to meet the centralized and unified management needs of POCT equipment and its application data. Combined with Internet of Things technology, a POCT information management system was built, which has functions such as user management, device management, device operation status monitoring, device parameter setting,

device fault prompts, and data statistical reports. The system was deployed and applied in the First Affiliated Hospital of Zhejiang University School of Medicine, achieving real-time collection of POCT equipment application data and providing a data foundation for the reliability evaluation model of POCT equipment. It is effective. Support the implementation of POCT. The project objective of equipment reliability evaluation research.

A: CE/HTM Interventions, Services & Systems

Construction Practice of the Municipal Regional Medical Equipment Sharing Management Platform

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Objective: To establish a municipal regional medical equipment sharing management platform, activate idle medical equipment in regional medical institutions, reduce the total expenditure on medical equipment procurement within Yangzhou City, and explore the balanced allocation of medical equipment within the region. Method: By leveraging Internet of Things (IoT) technology and through multiple status collection tags, the physical status values of medical equipment operation are collected. The data is transmitted to the background via IoT to achieve real-time collection and calculation of equipment status. Idle equipment in the "not in operation" or "off" state within each medical institution can be discovered in real time, which can be manually or automatically added to the pool for allocation and management. **Result:** From January 1, 2024, to December 31, 2024, the inter-hospital equipment allocation frequency of the completed municipal regional medical equipment sharing management platform was 29, the total allocation duration was 51,258 h, and the charge was 706,570 Chinese Yuan (CNY). The number of equipment allocations within the hospital (Hospital B) was 8,681, with a total allocation duration of 1,235,908 h and a charge of 6,253,873 CNY. **Conclusion:** A municipal regional medical equipment sharing management platform has been initially established, and a sharing and allocation mechanism among medical institutions within the region has been formulated. This provides a feasible solution for the improvement of medical services in the entire region. Meanwhile, this mechanism helps optimize the utilization efficiency of medical equipment, improve the overall utilization efficiency of resources, and achieve balanced development of medical services within the region.

A: CE/HTM Interventions, Services & Systems

Research on Maintenance Strategy Formulation Based on Criticality and Previous Maintenance Data for Medical Equipment

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Objective: To explore a medical equipment maintenance evaluation system to provide quantifiable reference for the formulation of a medical equipment maintenance strategy, optimize the maintenance selection evaluation process, and reduce hospital operating costs. **Methods:** Based on the medical equipment's criticality, a maintenance evaluation system is established based on previous maintenance data. Taking existing equipment as an example, the maintenance evaluation system is used to calculate scores for the equipment, and the scores are used as an important basis for formulating maintenance strategies. **Result:** The scores are calculated through the maintenance evaluation system to formulate the best maintenance strategy for the equipment. Compared with previous maintenance strategies, equipment operating costs are significantly reduced, and equipment operating reliability is improved. **Conclusion:** The maintenance evaluation system in this study is of great significance to the formulation of maintenance selection strategies, and maintenance strategies can be flexibly selected according to equipment conditions, ensuring the safe and

reliable operation of equipment, and helping hospitals reduce costs and increase efficiency.

A: CE/HTM Interventions, Services & Systems

Intelligent Assistant for CT X-Ray Tube Troubleshooting: A Knowledge Graph and Large Language Model Approach

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Description: Computed Tomography (CT) X-ray tubes are critical medical components, yet their fault diagnosis is traditionally reliant on expert experience and can be time-consuming. This study addresses these challenges by leveraging Artificial Intelligence (AI), specifically Knowledge Graphs (KG) and Large Language Models (LLMs), to enhance troubleshooting efficiency in clinical engineering. We have developed and presented an innovative intelligent question-answering (Q&A) system, the "Intelligent Fault Diagnosis System for CT X-ray Tubes". This system is designed to assist clinical engineers and technicians in rapidly diagnosing, understanding, and resolving CT X-ray tube failures, thereby improving equipment uptime and patient safety. The system's core is a comprehensive knowledge graph constructed using Neo4j. This KG is populated with structured data derived from CSV files, encompassing CT tube components (e.g., anode, cathode), operational parameters, diverse fault types (e.g., arcing, oil leakage), their potential causes, interrelationships, and subsequent effects. A Large Language Model (ZhipuAI GLM-4-Flash) is integrated to perform several key functions: (1) Natural Language Understanding (NLU) of user queries posed in colloquial language; (2) automatic generation of Cypher query statements for efficient information retrieval from the KG; and (3) Natural Language Generation (NLG) to formulate coherent, human-readable answers. The system architecture features a user-friendly interface built with Gradio, a central Q&A engine orchestrating the workflow, and the Neo4j knowledge base. The intelligent assistant successfully interprets a wide range of natural language questions about CT X-ray tube faults. It accurately retrieves relevant information, such as specific fault etiologies, affected sub-components, potential cascading failures, and detailed attributes of components or parameters. Answers are delivered to the user not only in clear textual format but also through an intuitive visualization of the pertinent sub-graph from the knowledge graph, significantly enhancing user comprehension and diagnostic insight. The system demonstrates robust performance in handling diverse queries, for instance, "What are the common causes of frequent arcing in a CT tube?" or "Which faults are typically associated with the anode assembly and what are their subsequent impacts?" This work presents professional experiences in developing such a system, lessons learned during its implementation, and best practices for integrating AI into clinical engineering workflows for medical device troubleshooting. **Conclusions:** This AI-powered intelligent assistant shows considerable promise in streamlining CT X-ray tube troubleshooting processes, thereby reducing equipment downtime and fostering knowledge dissemination among clinical engineering personnel. It represents a practical and innovative application of AI and knowledge graph technologies within Health Technology Management (HTM). The system contributes to the advancement of medical device maintenance strategies and operational safety. The presented approach offers a scalable and adaptable framework for developing similar intelligent support systems for other complex medical equipment.

A: CE/HTM Interventions, Services & Systems

AI-Driven Medical Equipment Retirement Decision Model Construction and Empirical Research

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As a core asset of hospitals, the management of medical equipment directly affects patient safety and hospital operating costs. The traditional equipment obsolescence decision-making relies on manual experience, which suffers from subjective, inefficient, and inconsistent results from time to time, so intelligent solutions are urgently needed. In this study, an artificial intelligence (AI)-based medical equipment obsolescence decision-making system is constructed, and the obsolescence decision-making model is built by integrating hospital medical equipment maintenance records, third-party repair data, and manufacturers' maintenance information, and structurally extracting key parameters such as the age of the equipment, acquisition cost, maintenance history and cost, and historical failure characteristics, and establishing a multidimensional decision matrix. Taking the patient monitor and ventilator as representative validation case objects, the experimental results demonstrate that the model's accuracy is significantly enhanced in comparison to manual judgment, thereby effectively minimizing the hospital's non-essential maintenance expenditures. The innovation of this system is primarily manifested in two aspects. First, the system introduces a dynamic adjustment mechanism, which can automatically optimize the decision threshold according to the different types and characteristics of the equipment. Second, the system has a risk warning function, which can identify high-risk equipment in advance through failure mode analysis to reduce the risk of clinical use. This study verifies that the AI model has significant advantages in reducing subjective bias and optimizing cost control through real hospital data, and provides a practical technical solution for the digital transformation of medical equipment management, which has important clinical application value and economic significance.

A: CE/HTM Interventions, Services & Systems

An Intelligent Maintenance Assistant System for Medical Devices Based on a Large Language Model

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Description: With the increasing complexity and variety of medical devices, clinical engineering departments face significant challenges in maintenance efficiency, knowledge inheritance, and data security. To address these issues, we have developed an Intelligent Maintenance Assistant System based on the Qwen-32B large language model, utilizing a private, on-premise deployment to ensure full data security. The system is built upon a Retrieval-Augmented Generation (RAG) architecture. It first retrieves information from a comprehensive, locally-hosted professional knowledge base that integrates historical maintenance records, device manuals, expert experience, and industry standards. If local knowledge is insufficient, the system then leverages external web search capabilities, ensuring that responses are both professionally accurate and comprehensive. The system's core functions include an intelligent fault diagnosis engine, a smart search and recommendation system, a precise maintenance guidance system for generating step-by-step instructions, and an interactive Q&A module. **Conclusions:** The system has been successfully implemented at the Medical Engineering Department of Nanfang Hospital. It has significantly improved the efficiency of fault diagnosis, reduced equipment downtime, and enhanced the quality and standardization of maintenance work. The system also serves as an effective tool for training new engineers and preserving expert knowledge within the department. This project provides a secure, replicable, and scalable solution, demonstrating the immense potential of privately deployed large language models to advance the intelligence and standardization of clinical engineering and health technology management.

A: CE/HTM Interventions, Services & Systems

Construction and Application of Quality Evaluation and Management Platform for Digital Use of Large Medical Equipment

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Objectives: By building a digital management platform for medical equipment IoT, real-time monitoring of equipment operation status, fault warning, remote operation and maintenance monitoring, and single machine benefit evaluation can be achieved. Mainly serving hospital equipment management departments, clinical use departments, and operation management departments, solving problems such as low equipment utilization, delayed fault response, and high operation and maintenance costs. To achieve the construction goals of improving equipment utilization, reducing operation and maintenance costs, and enhancing the level of precision in equipment management. **Methods:** The platform realizes real-time collection of medical equipment data based on Internet of Things technology (edge computing based on hospital Internet of Things system), including equipment operation log, fault log, operating system log, etc. The collected data is encrypted and transmitted to the local server to build a digital operation database for medical equipment. The data preprocessing system completes the preliminary cleaning and processing of the data, and the data is transmitted to the subsequent fault log analysis, operation log analysis, and key parameter analysis modules. The processing results are displayed by the result display module. By comprehensively utilizing artificial intelligence algorithms and statistical learning models, based on historical data trends, state prediction and analysis are carried out to assist management personnel in making advanced decisions and optimizing maintenance plans. Abnormal pattern recognition and fault trend prediction of equipment data are automatically performed, as well as single-machine benefit analysis of equipment. **Results:** Through the application of intelligent analysis algorithms, the platform can effectively reduce equipment failure response time, improve warning accuracy, significantly reduce the frequency of unplanned equipment downtime events, significantly improve equipment operation stability, and reduce operation and maintenance costs by more than 3%. By intelligently analyzing the cost, efficiency, and return on investment of medical equipment through the system, hospitals can more accurately understand the operational status of various types of equipment. This helps hospitals make more informed decisions in resource allocation, optimize equipment procurement and maintenance budgets, and identify and improve inefficient or problematic equipment. The equipment procurement budget is reduced by more than 10%, and equipment utilization and economic benefits are significantly improved. **Conclusions:** Through the accumulation and analysis of equipment operation data, a standardized knowledge base for equipment operation and maintenance has been gradually established, which helps improve the level of hospital refined management.

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Design and Implementation of Maintenance Expert Decision-Making System for Medical Linear Accelerator

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Objective: To construct a maintenance expert decision-making system for medical linear accelerators to achieve maintenance and management with a full life circle for them. **Methods:** The C#.NET + SQL Server 2008. The database was adopted as a development environment. The maintenance expert decision-making system of the medical linear accelerator was established by adopting a network station structure, applying the Active Server Pages (ASP) technique, and combining Hypertext Markup Language (HTML), ASP commands and objects, Active X components, and SQL Server database. The reliability-centered maintenance (RCM) was used as an analysis mode to analyze 560 maintenance cases of used precise medical linear accelerator during 2009–2018 to establish the mode of maintenance expert decision-making system and to calculate the operation rate and the total operation cost of the medical linear accelerator in 10 years by statistical method. **Results:** The schemes of preventive maintenance and corrective maintenance were formulated. The operation rate of the medical linear accelerator of the hospital was increased from 96.7% in 2013 to 98.6% in 2018 after the maintenance expert decision-making system of the medical linear accelerator was combined with a network technique and was operated. And the total cost of operation in 10 years was decreased by 77.5% as compared to the warranty expense of manufacturers. **Conclusion:** The medical maintenance expert decision-making system can guide the maintenance of the equipment of a hospital, determine the time point of preventive maintenance and the content of maintenance, optimize the maintenance strategy of the system, and obtain higher equipment availability and operation rate.

A: CE/HTM Interventions, Services & Systems

Integrated Platform for Analysis and Decision-Making of Testing Reagents

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Objectives: To improve the management efficiency of reagents and consumables, ensure the accuracy and timeliness of test results, and enhance emergency support capabilities. **Methods:** By utilizing an intelligent IVD management system, the procurement requirements for reagents and consumables are seamlessly integrated with the supplier database, achieving automatic generation and one-click submission of procurement plans. Developed the 'inventory warning' function. This function monitors inventory status in real time. When the inventory level is below the preset safety threshold, an automatic warning mechanism will be triggered to remind management personnel to replenish promptly.
The "New Batch Number Reminder" function has been introduced, which effectively avoids inspection errors caused by batch changes and improves the stability and reliability of inspection results. In response to the actual situation of multi-hospital management, we have developed a "hospital allocation" function, which optimizes resource allocation, improves resource utilization efficiency, and significantly enhances emergency response speed, ensuring the smooth progress of clinical laboratory work. We have adopted a closed-loop management model for the management of hazardous materials, reagents, and consumables. From procurement, warehousing, storage, and use to scrapping, every step is strictly recorded and monitored. For reagents and consumables that require refrigeration or freezing storage, we have implemented "full cold chain management", which strictly monitors and records temperature at every step from supplier shipment to warehousing, storage, and use. To achieve full chain traceability of reagents and consumables, we have assigned a unique QR code or barcode to each batch of reagents and consumables, achieving "one-to-one coding of reagents" management. In order to achieve comprehensive and systematic management of reagent and consumable certificate instructions, we have integrated key information such as certificate information, instruction content, and expiration date of reagent and consumable materials, realizing centralized storage and unified management of data. **Results:** The Clinical Laboratory Center has successfully solved many problems in traditional management methods by implementing a systematic IVD management and emergency support system for reagents and consumables. **Conclusions:** The introduction of innovative points such as one-click procurement, new batch number reminder, inventory warning, campus allocation, closed-loop management of dangerous goods, one-to-one coding of reagents, and full process cold chain management not only improves management efficiency and quality safety level, but also reduces operating costs, providing strong support for clinical laboratory work.

A: CE/HTM Interventions, Services & Systems

Empirical Study on the Benefit Analysis and Evaluation of Large Medical Equipment Procurement

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With the increasing aging of the population, the development of the national economy, and the increase in the income of residents, the demand for health care of our residents is also increasing, which puts forward the requirements of operation and management of medical equipment configured in hospitals. Therefore, how hospitals effectively manage the use of medical equipment, especially the management of large medical equipment, is directly related to the effective allocation of social resources. This paper combines the data related to the investment and operation of MRI equipment in S Hospital, and analyzes the comprehensive benefits of MRI equipment in large-scale medical equipment in S Hospital by using the payback period method and the return on investment method, etc., and discusses the results of the analysis. The results are discussed. On this basis, relevant policy recommendations are proposed for the management of large-scale medical equipment in hospitals.

Conclusion: Although at present, for public hospitals, public welfare is still their most important feature, with the reform of the medical system, hospitals need to be self-financing, and profitability in the development of hospitals on the road also needs to be highlighted. Hospitals in medical equipment acquisition decisions, in addition to social benefits, must also consider the economic benefits of equipment acquisition.

Hospitals in the specific equipment acquisition decision-making, in addition to the above cost-benefit analysis, also require a comprehensive evaluation of various aspects, such as housing reconstruction, the price of equipment, payback period, return on investment, different brands of similar equipment, after-sales service, and other aspects of the quantitative analysis.

A: CE/HTM Interventions, Services & Systems

Research and Application of Intraocular Lens Acceptance Equipment Based on Intelligent Visual Recognition

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Objective: To improve the management level of ophthalmic intraocular lenses, optimize management efficiency, reduce management costs, respond to national policy requirements, and incorporate the Unique Device Identifier (UDI) into the business flow. This study proposed a set of development and application schemes of an intraocular lens acceptance table based on visual recognition technology. **Methods:** A visual recognition model suitable for intraocular lenses was developed through computer vision recognition technology, and batch automatic recognition, intraocular lenses' UDI parsing, and automatic entering were realized. Lightweight hardware devices are designed to be used in a wide range of work environments. Make up for the shortcomings of RFID technology through visual recognition technology, and use UDI as a tandem field to optimize the existing medical consumables management process. **Results:** The intraocular lenses acceptance device, which can identify intraocular lenses in batches and enter UDI into the logistics acceptance system, makes up for the defects of the existing management methods, improves the management efficiency and accuracy, shortens the time required for the acceptance phase, realizes process reengineering, reduces the supplier's time stay in the hospital, reduces the management cost, and improves the satisfaction both of the supplier and the medical institution. **Conclusion:** This device can significantly improve the efficiency and accuracy of ophthalmic intraocular lenses management, has a good application prospect, and promotion value. It creates a prospect of linking the supply chain through information technology. In the future, this technology can be applied in more parts of the supply chain. Promoting the intelligent and refined development of medical consumables management.

A: CE/HTM Interventions, Services & Systems

Machine Learning-Driven Quality Risk Prediction for Critical Care Equipment: A Clinical Data Analysis Framework

By Hongwei Wang*

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Background: The reliability of critical care equipment (such as defibrillators and ventilators) is crucial to patient safety. The traditional risk management methods rely on passive maintenance and manual inspection, which not only wastes resources but also lacks the ability to predict and evaluate. This study proposes a machine learning (ML) framework to actively identify the quality risks of critical care equipment using real clinical data from hospitals. Method: We collected the operation data of 328 intensive care unit (ICU) devices from 5 hospitals for 24 months, including 12,500 cases of device error logs, preventive maintenance records, clinical accident reports related to device failures, and environmental sensor data. Based on the construction of the database, an integrated ML model combining Extreme Gradient Boosting (XGBoost) and a Long Short-Term Memory (LSTM) network was developed, which can predict the failure probability 72 h in advance, analyze the feature importance for the identification of high-risk units, and finally quantify the clinical impact through the severity-weighted risk score. **Result:** The model achieved an accuracy of 89.3% in predicting critical faults (F-1 score = 0.87), and the equipment downtime for maintenance was reduced by 41%. The main risk factors predicted by the model include unstable battery voltage, repeated self-check errors before mechanical failures, and accelerated electrode degradation when the humidity is too high (OR > 6, $p < 0.001$). Meanwhile, the probability of treatment delay in patients caused by high-risk equipment increased by 3.7 times ($p = 0.002$). **Conclusion:** The machine learning-driven quality risk prediction model transforms passive maintenance into predictive risk management, significantly improving the reliability of equipment in the intensive care environment.

B: Health Technology Innovation & Assessment

Research on the Construction of an Evaluation Index System for Hospital CT Equipment Configuration Based on Health Technology Assessment

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Objective: This study proposes a methodological framework for optimizing medical equipment allocation in a hospital by Health Technology Assessment (HTA) principles. Focusing on computerized tomography (CT) in a tertiary hospital, using real-world operational data with structured assessment criteria to address persistent challenges in strategic medical resource management. To provide a basis for decision-making in CT equipment allocation. **Methods:** This study utilizes literature review and expert in-depth interviews to develop an evaluation index system for CT equipment configuration from clinical, engineering, and hospital perspectives. Using a hospital information platform and questionnaire surveys to support the quantity and device type in medical equipment allocation. **Results:** Result indicated that the evaluation index system for CT allocation consists of 5 primary and 12 secondary indicators. The appropriateness indicators include 4 secondary indicators: patient volume to be examined, appointment waiting time, clinical examination demand, and actual examination volume. The technical indicators include 2 secondary indicators, spatial resolution and density

resolution of the equipment. The safety indicators include 2 secondary indicators: equipment failure rate and maintenance service quality. The social indicators include 2 secondary indicators: equipment usage satisfaction and research contributions. The economic indicators include 3 secondary indicators: cost, revenue, and the ratio of revenue-to-cost. Data shows that CT examination appointment waiting time is 19.32 days, and the proportion of enhanced scanning in the past year is 18%. Configuring a medium-or low-range CT based on an existing high-range CT is reasonable. Comparison of indicators between the medium/low range CT indicates that, in terms of economic indicators, the low-range CT has a clear advantage. However, the medium-range CT demonstrates a more significant performance in technical indicators such as spatial resolution and density resolution, social indicators like research contribution, and safety indicators such as the failure rate. These differences are statistically significant, and the scores of the spatial resolution and density resolution indicators for the low-range CT are 7.6 and 7.7, respectively (with a maximum score of 10). In terms of usage satisfaction for social indicators and manufacturer's service quality for safety indicators, there is no significant difference between them. Therefore, based on the scores on these indicators of the medium/low-range CT, the hospital should configure an additional low-range CT. **Conclusion:** This study employs an HTA framework to resolve implementation barriers such as insufficient clinician involvement and real-world evidence gaps, proposing a multidimensional evaluation system that strengthens methodological precision while guiding healthcare organizations in strategic resource allocation optimization.

B: Health Technology Innovation & Assessment

Research on the Development of China's Innovative Magnetocardiography Based on Maturity Evaluation Model

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Aims: In order to cultivate and develop the magnetocardiography technology industry, fully grasp the industrial maturity law and predict the development trend, correctly formulate the industrial development plan, and put forward relevant technological development decision-making suggestions. **Methods:** Conduct an industry maturity evaluation based on questionnaires, and invite experts in the field to evaluate the maturity of magnetocardiograph by comparing the 9-level measurement of technology maturity, the 10-level measurement of manufacturing maturity, the 3-level measurement of market maturity, and the 4-level measurement of industry maturity, to determine the maturity development stage of magnetocardiograph. Then, the patent index evaluation method and technology life cycle S-curve evaluation method were used to objectively analyze the patent literature data of the magnetocardiograph and confirm the maturity stage of the magnetocardiograph. **Results:** Based on the questionnaire scale, experts in the field determined that the maturity of domestic magnetocardiograph products is in the fourth stage, that is, the market product stage, which means that the system-level products of magnetocardiograph have passed the low-rate production and use environment demonstration verification. It is determined that the market maturity of the magnetocardiograph is in the first stage, that is, the engineered products of the magnetocardiograph are put on the market to form a new market. It is judged that the industry maturity of magnetocardiograph is in the second stage, that is, competitive magnetocardiograph products are introduced into the market, and market expectations are high. The expert authority coefficient Cr of the questionnaire survey was

0.8785, and the results were credible. **Conclusion:** Magnetocardiograph products are still in the growth period and have not yet entered maturity, and its industry is in the cultivation stage, requiring relevant cultivation policies.

B: Health Technology Innovation & Assessment

Clinical Evaluation of Implantable Cardioverter-Defibrillator (ICD) Based on Real World Evidence from a Tertiary Hospital in Xinjiang, China

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Background: Implantable cardioverter-defibrillators (ICDs) have been widely used for primary and secondary prevention of sudden cardiogenic death. This study aimed to objectively evaluate the effectiveness, safety, and economy of ICD in clinical applications. **Methods:** 1,542 patients undergoing ICD implantation surgery from 2019 to 2024 were collected from a tertiary hospital in Xinjiang, China. The factors of age, gender, occupation, education, surgery time, hospitalization expenses, ICD brands, and ICD procurement prices were discussed in detail. Then, 230 patients were selected using systematic sampling, and their quality after surgery was assessed using questionnaires or on-site interviews. The Short-Form Six-Dimension inventory (SF-6D) and the Florida Shock Anxiety Scale (FSAS) were used to evaluate the health status and anxiety of ICD electric shocks, respectively. 171 valid questionnaires were finally collected. **Results:** The majority of respondents were those aged 60 and above (64.07%), male (75.29%), retirees (45.85%), and with a high school or secondary school educational background (44.42%). Medtronic was the most commonly used brand of ICD. The average hospitalization cost of ICD implantation surgery was approximately 160,600 RMB. The procurement price of ICD and the ratio of consumable materials cost in medical revenue showed a decreasing trend from 2019 to 2024, respectively ($p < 0.001$). 96 respondents (6.22%) were undergoing secondary surgery in the past three years, mainly due to programmed prompts for battery depletion (83.33%), electrode abnormalities (7.29%), defibrillator upgrades (5.21%) and cystic hematoma (4%), and the number of programmed prompts for battery depletion was significantly higher than other reasons ($p < 0.001$). The utility value of SF-6D among 171 patients was 0.73 ± 0.06, which was significantly lower than that in the health status ($p < 0.001$). The health status of the ICD patients declined with the increase in monthly rehabilitation cost ($p = 0.001$). The average self-rating score was 26.13 ± 5.13. The patients who suffered from ICD electric shocks showed a significantly higher anxiety than those who had not ($p = 0.001$), and the anxiety symptoms aggravated with increasing times of ICD electric shocks ($p = 0.013$). **Conclusion:** The health status of patients had no significant improvement and presented deficiencies in physical function, social role, and mental health after ICD implantation surgery in this study. Electrical storms of ICD not only accelerated the consumption of ICD batteries but also had an impact on patient survival rates. The popularity of ICD in clinical application was currently insufficient to match the actual medical needs in Xinjiang. The centralized bulk-buying with quantity of ICDs still needs to be continuously advanced for reasonable cost control, medical insurance payment optimization, and medical resource utilization promotion, thereby enhancing a wider and more reasonable application of ICD in China.

B: Health Technology Innovation & Assessment

Real-Time Monitoring and Analysis of Tissue Impedance Variations During Ultrasound Scalpel Application Based on Transducer Impedance Matching

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Ultrasonic scalpels are widely used in surgery due to their precision and efficiency, yet real-time monitoring of tissue

characteristics during operation remains a challenge. Tissue impedance is a critical parameter that reflects tissue composition and cutting state, but existing ultrasonic scalpels lack an effective mechanism for dynamically sensing and adjusting to tissue variations, limiting surgical precision and safety. To address this limitation, this study proposes a novel real-time tissue impedance monitoring and analysis method based on an ultrasonic transducer impedance matching algorithm. By measuring the impedance at the cutter head's contact point, signals were acquired and processed to fit tissue parameters, construct tissue models, and derive impedance curves for different tissue types. This approach enables continuous tracking of tissue properties during surgical procedures. Experimental results demonstrated distinct cutting phases—initiation, denaturation, and separation, and completion—with significant variations in impedance curves across tissue types under identical energy outputs. A fitted impedance change curve obtained from ex vivo porcine tissue cutting experiments validated the feasibility of the proposed method. This study provides critical data support for optimizing ultrasonic scalpel design, improving surgical outcomes, and advancing adaptive surgical technology.

B: Health Technology Innovation & Assessment

Exploration of Low-Viscosity Liquid Substitution Method in the Performance Evaluation of Heparin Pumps in Hemodialysis Machines

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The heparin pump is a critical component in hemodialysis (HD) therapy, and its infusion accuracy directly affects anticoagulation efficacy and patient safety. Traditional evaluation methods predominantly use high-viscosity heparin solutions, which suffer from low testing efficiency, high costs, and susceptibility to environmental interference. This study proposes an evaluation method using low-viscosity liquids (e.g., saline or deionized water) as substitutes for high-viscosity heparin solutions, aiming to enhance the convenience and reliability of heparin pump performance testing. The research begins with a theoretical analysis to explore the differences in hydrodynamic properties between low-viscosity liquids and heparin solutions, establishing a viscosity-flow correction model. Subsequently, a controlled experimental design was employed, using saline (viscosity ≈ 1 mPa·s) and standard heparin solution (viscosity ≈ 3 mPa·s) as testing media under identical conditions, to evaluate the heparin pump's flow accuracy and long-term infusion deviation. Experimental data indicated that low-viscosity liquids exhibit superior linearity during pumping ($R^2 > 0.99$), with flow rate errors controlled within ± 2%, though viscosity-dependent velocity deviations require compensation via correction coefficients. Clinical simulation tests further validated that the corrected low-viscosity liquid method showed no significant difference from traditional heparin solution-based evaluations ($p > 0.05$). This study provides a novel approach for the maintenance and calibration of hemodialysis equipment.

B: Health Technology Innovation & Assessment

Design and Implementation of Contactless Gesture Interaction System Based on Machine Vision in Ward Environment

By Yao Chen*

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The rapid development of the computer and semiconductor industries has propelled the performance of computer platforms to unprecedented heights, making operation and usage increasingly simple. As a result, users are becoming younger. Smartphones, tablet computers, desktops (laptops), and other electronic products have been widely accepted by the general public. In today's intelligent era, human-computer interaction is a popular technology that urgently needs to be made more accessible to bring convenience, especially in hospital ward environments, where it can provide better assistance to patients and medical workers. Gesture recognition is one of the most intuitive forms of human-computer interaction. By using hand

gestures as input for computers with the help of Google's Mediapipe hand model, generated by OpenCV + Mediapipe and trained by Teachable Machine model trainer, we can improve the success rate of hand motion recognition.
This paper discusses and explores gesture recognition and application systems in ward environments based on machine vision using an ordinary laptop computer as hardware. Patients in ward environments should have natural and effective gesture interactions with their surroundings through a computer camera without being constrained by input equipment or environmental limitations. The paper is divided into three main tasks: building a hand model based on artificial neural network methods; studying Chinese sign language to create suitable gestures for patients; and training the hand model along with adding a speech module. The system design includes creating an interactive program page for applying predictive models from training parts. Future optimization will focus on continuously improving gesture recognition success rates.

B: Health Technology Innovation & Assessment

Research on Gastric Cancer Detection Technology Using CNN Integrated with Attention Mechanism Combined with Surface-Enhanced Raman Spectroscopy

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Objective: Gastric cancer is the most common malignant tumor of the digestive tract, ranking fourth among all malignant tumors, after lung cancer, breast cancer, and prostate cancer. Early non-invasive diagnosis is of great significance for improving the survival rate. Raman spectroscopy technology can reveal the vibrational energy level information of molecules and form unique spectral fingerprints by analyzing the frequency changes of inelastically scattered light generated after the interaction between incident light and molecules. Surface-enhanced Raman spectroscopy (SERS) can detect molecular fingerprint characteristics in serum with high sensitivity. However, traditional analysis methods are faced with challenges such as difficult feature extraction, high spectral complexity, and large individual differences. This study proposes a convolutional neural network (CNN) integrated with an attention mechanism, aiming to achieve the goal of early diagnosis of gastric cancer. **Methods:** Data Collection: Serum samples from 20 gastric cancer patients and 10 healthy volunteers from the China-Japan Union Hospital of Jilin University were collected. Raman spectroscopy data were obtained through enhancement with gold nanoparticle substrates. Each sample was scanned 100 times, and finally, a dataset containing 3,000 spectra (wavelength range 200 - 2600 cm□¹) was constructed. Attention Mechanism CNN Model: A 3-3-layer 1D convolution kernel was used to extract spectral features. The self-attention block was activated by Softmax to dynamically weigh the features of important bands, so as to realize the classification and diagnosis of normal and gastric cancer. Validation Scheme: Stratified five - fold cross - validation was carried out. The random forest (RF), support vector machine (SVM), linear discriminant analysis (LDA), K-nearest neighbors (KNN), extreme learning machine (ELM), and baseline CNN models were compared. The evaluation indicators included confusion matrix, AUC, classification accuracy, and F1-score. **Results:** Classification and Diagnosis: The accuracy of distinguishing cancer from health reached 87.0%, which was significantly higher than that of traditional models (RF: 75.8% ± 1.2%, SVM: 67.2% ± 0.4%, ELM: 70.3% ± 16%, LDA: 66.2 ± 2.3%). Feature Interpretability: From the feature weights, it was known that 400 cm□¹ (vibration related to lipids) and 655 cm□¹ (vibration related to disulfide bonds) had prominent weights. **Conclusion:** The CNN model with an attention mechanism can achieve early diagnosis of gastric cancer, and its classification performance is significantly better than that of traditional machine learning methods. It lays a foundation for the development of a bedside rapid diagnosis system based on portable Raman equipment.

B: Health Technology Innovation & Assessment

Real-World Study on Coronary Intravascular Lithotripsy for Calcified Coronary Lesions

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Objective: To compare the safety, effectiveness, and cost-effectiveness of shockwave catheter technology versus traditional rotational atherectomy in treating coronary artery calcification lesions in real-world clinical settings. **Methods:** Data from 110 patients with coronary artery calcification admitted to the sample hospital between April 2023 and December 2024 were collected. Comparative analysis of patient outcomes was performed using t-tests and chi-square tests. **Results:** Shockwave catheter technology demonstrated comparable effectiveness to traditional rotational atherectomy. However, it exhibited significantly shorter procedure durations and greater cost-effectiveness compared to rotational atherectomy. Its shorter learning curve also facilitates adoption in primary hospitals, promoting the implementation of hierarchical medical systems.

B: Health Technology Innovation & Assessment

Design and Implementation of the MRI Equipment Monitoring and Early Warning System

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Objective: To improve the efficiency of Magnetic Resonance Imaging (MRI) equipment inspection and to promptly detect and address equipment anomalies, an MRI equipment monitoring and early warning system was designed. **Methods:** The system hardware includes cameras, monitoring and early warning terminals, and cloud servers. It utilizes image processing and artificial intelligence technologies based on OpenCV and EasyOCR. The system is composed of two parts: the monitoring and early warning module and the data-sharing cloud platform module. **Results:** The system enables remote monitoring of MRI equipment's operational status, automatically performs power supply status detection, liquid nitrogen pressure detection, and environmental temperature detection, and provides early warning notifications. Practical application of the system shows that it significantly increases the frequency of MRI equipment inspections, from once every few days to once a day. The power supply status detection accuracy is 100%, the liquid nitrogen pressure detection error is within ± 0.1, the alarm light status detection accuracy for environmental temperature is 100%, and the temperature reading detection accuracy is 95%. **Conclusion:** The application of this system not only effectively reduces the workload of manual inspections and increases the inspection frequency, but also enhances the speed of fault response, ensuring the stable operation of MRI equipment. It provides an intelligent and automated solution for equipment management in hospitals.

B: Health Technology Innovation & Assessment

Single Crystal High Frequency Ultrasound Transducer and Medical Imaging for Skin Cysts via Arc-Scanning Mode

By Jiewen Zhou*

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High-frequency ultrasound technology with arc B-scanning mode is the optimized choice in ultrasound imaging for many skin cysts with a convex surface. A 32 MHz ultrasonic transducer was fabricated based on the high-performance $Pb(Mg_{1/3}Nb_{2/3})O_3$-$xPbTiO_3$ (PMN-xPT) single crystal, and the performance of the transducer was investigated by using the pulse echo method. Then, a new arc-scanning technology was proposed for the convex skin cyst imaging. The ultrasound signals were collected via a novel mechanical rotating system in the scanning range of 0–120, and a new signal processing method was also developed for ultrasound imaging. It provides an effective way based on the PMN-xPT single crystal to get the high-frequency ultrasound images for skin cysts with a convex surface.

B: Health Technology Innovation & Assessment

Design and Implementation of Speech Recognition and Medical Equipment Information Inquiry Functions Based on Deep Learning

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This study introduces a novel mobile medical equipment information inquiry system that harnesses deep learning techniques in speech recognition and natural language processing (NLP). The system is engineered to retrieve equipment details through voice commands, significantly enhancing the efficiency of traditional manual search methods. The architecture integrates a speech recognition module using the Vosk toolkit, an NLP module leveraging CNNs with attention mechanisms, and a large language model module. Preliminary testing at Shanghai First Maternity and Infant Hospital demonstrated a remarkable increase in query efficiency, user satisfaction, and response speed, achieving a query accuracy rate of 96.6%. User feedback surveys indicated that the system excels in convenience and functionality, suggesting its potential for broader application in clinical settings. This research underscores the importance of integrating AI technologies into medical equipment management to streamline healthcare operations and improve the management efficiency of medical equipment. Future work will focus on optimizing system performance and expanding functionalities, including real-time fault detection and cross-hospital management capabilities, to further the development of intelligent medical equipment management.

B: Health Technology Innovation & Assessment

Construction and Application of an Intelligent Management Platform for Infant Incubators

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Aims: To ensure the safety and reliability of infant incubators during clinical use, achieve real-time monitoring and early warning for incubators of different brands and models, and establish an intelligent management platform to provide maternal and child healthcare institutions with smart incubator management and maintenance services. **Methods:** By collaborating with infant incubator manufacturers to obtain communication protocols, a data acquisition module was designed to collect operational parameters (including set/displayed temperature/humidity, alarm information) via interfaces such as RS232, RS422, and RJ45. The acquired data were uploaded to the platform through Wi-Fi, LoRa, NB-IoT, and other communication technologies. **Results:** The platform enables 24/7 remote monitoring of temperature, humidity, and other critical parameters. Administrators can view real-time data, historical records, temperature/humidity curves, and alarm logs through web terminals, with options to export data. Emergency alerts are automatically sent to users or technicians via SMS or WeChat. **Conclusions:** The platform simultaneously supports PC and mobile interfaces, offering remote status monitoring, fault alerts, device management, and data analysis services for both clinical users and technical staff, thereby enabling intelligent management of infant incubators.

B: Health Technology Innovation & Assessment

Research on Usability Assessment Indicator System for Magnetocardiographic Recording System from Hospitals' Perspective

By Xiu Xu[1], Da He[2], Jinjuan Yu[1], Yunxin Zheng[3]

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As a typical innovative large-scale medical device, the technical route, product form, and usage environment of the magnetocardiographic recording system (MCG) are still in the exploratory stage, and there is no consensus within the industry. Significant differences still exist in those aspects among products from different enterprises, and even among different series or generations of products from the same enterprise. At present, the usability assessment of medical devices (1) is mainly conducted from the perspectives of industry regulation departments and producers, (2) and is primarily applied in the design and pre-market verification stages of medical devices, (3) and is with the premise of a defined usage environment, (4) and focuses on the use process and user interface. In view of the industrial status of the MCG, the usage environments for devices of different models are significantly different. The usability assessment carried out by hospitals during equipment configuration should be based on the user's perspective and cover the entire lifecycle of the medical device in the hospital, which considers not only the use process and user interface but also multiple stages such as environmental preparation, installation, maintenance, repair, and disposal. That means the current usability assessment standards cannot fully meet the needs of hospitals for usability assessment of MCG. To address the above issues, this study explores the development of a usability assessment indicator system for innovative medical devices covering the full lifecycle, based on existing standards and research. This system is applied to establish the usability assessment indicator system for MCG, providing basic assistance for medical institutions to select MCG and other innovative medical devices. The study adopts a technical route of deductive reasoning, which is also called "from the general to the specific". First, methods such as literature analysis, brainstorming, and expert consultation are used to establish a usability assessment indicator system for innovative medical devices, comprising 4 first-level indicators, 10 second-level indicators, and 40 third-level indicators. Then, based on the characteristics of the MCG, methods such as on-site research, systematic analysis, and modified Delphi expert consultation are used to screen and refine the general indicator system, forming the usability assessment indicator system for MCG, including 6 first-level indicators and 20 second-level indicators.

Usability assessment indicators and weight coefficients for MCG

1. Environmental Fitness
- (1) Electromagnetic shielding method, 9.72
- (2) Liquid helium consumption, 8.59
- (3) Occupied area, 5.81

2. Safety
- (4) Adverse events and usage safety incidents, 7.04

3. Effectivity
- (5) Inspection success rate, 7.56

4. Efficiency
- (6) Inspection time, 6.38
- (7) Report generation time, 2.26

5. Ease of Use
- (8) Training time or number of cases required for inspectors, 2.26
- (9) Training time or number of cases required for report personnel, 2.42
- (10) Conformity between the identification of user interfaces and common sense, 2.47
- (11) Whether a foolproof design is available and reasonable, 13.21
- (12) Boot-up preparation time and difficulty, 2.47
- (13) Pre-inspection preparation time and difficulty, 2.67
- (14) Operational difficulty for inspectors, 3.19
- (15) Operational difficulty for report personnel, 2.88
- (16) Cooperation difficulty for examinees, 2.57
- (17) Maintenance difficulty for biomedical engineers, 2.57

6. Satisfaction
- (18) Satisfaction of technicians, 5.60
- (19) Satisfaction of doctors, 5.96

(20) Satisfaction of clinical engineers, 4.37

In the Delphi expert consultation for the assessment indicator system, the authority coefficient (Ca) is ≥ 0.95, and the coefficient of variation (Cv) is ≤ 0.17, indicating that the usability assessment indicator system for MCG proposed in this study is scientific, authoritative, and feasible to a certain degree. In developing strategies to generate the necessary actions, the following critical challenges arise and will be addressed throughout the process:

Data integration, normalization, and cleansing of fragmented information.

The need for the formation and training of multidisciplinary teams.

Harmonization with the Federal Law on Personal Data Protection for the storage of sensitive data.

Ensuring compatibility with the current infrastructure.

The adoption of the Big Data framework in healthcare subsystems will enable a transformation that fosters improved quality healthcare based on real-time data, sustainability through resource optimization and long-term cost control, and innovation through research accelerated by the availability of data and analysis and synthesis tools.

B: Health Technology Innovation & Assessment

Development and Validation of a Double-Claw Extrusion Type Calf Rehabilitation Device for Deep Vein Thrombosis Based on Ankle Pump Exercise Principle

By Hong Zhang*

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Objective: To address the limitations of existing deep vein thrombosis (DVT) rehabilitation devices (such as compression stockings, pneumatic compression devices, and ankle pump exercise assistants), including complex operation, poor comfort, lack of specificity, or potential risks, this study aimed to develop a user-friendly, broadly adaptable DVT rehabilitation device based on the ankle pump exercise (APE) principle, specifically targeting calf muscle stimulation. The goal was to promote venous blood return in the lower limbs through physical rehabilitation, thereby enhancing DVT recovery outcomes and patient comfort. **Methods:** The core design of the device focused on simulating the muscle contraction state of the calf (soleus and lateral gastrocnemius muscles) during ankle pump exercise. The hardware system integrated several key modules: a drive module comprising a 110BYG25C stepper motor and power supply; a main control module utilizing a DKY-110 controller and DM542 driver; a double-claw extrusion type ankle pump simulation module (the core innovative component, designed in SolidWorks), which employed a belt-gear transmission to drive two profiled massage claws in opposing reciprocating motion within an alloy frame featuring resin contact surfaces; and a multi-segment adjustable alloy bracket leg support module. Software control, based on an STM32 microcontroller, implemented preset key operational parameters: a massage claw force of 20-22N, a reciprocating motion cycle of 2 s (0.5 Hz), and a single treatment duration of 3 min. Structural optimization of the massage claws was performed via finite element analysis (ANSYS) to ensure safety and reliability. The effectiveness of the device in promoting venous blood flow was validated by measuring changes in posterior tibial venous blood flow velocity using color Doppler ultrasound in three volunteers before and after device use. **Results:** Finite element analysis led to structural optimization of the massage claws, enhancing device safety. Ultrasound test results demonstrated a significant increase in posterior tibial venous blood flow velocity after 3 minutes of device use (e.g., Subject 1: increased from 8.11 cm/s to 19.17 cm/s; Subject 2: from 9.19 cm/s to 16.76 cm/s; Subject 3: from 9.19 cm/s to 17.30 cm/s). The average increase was substantial, confirming that the device effectively simulated the ankle pump exercise and accelerated deep venous blood return in the lower limbs. **Conclusion:** A double-claw extrusion-type calf DVT rehabilitation device based on the ankle pump exercise principle was successfully developed. The device features a reasonable structural design, simple operation, and controllable parameters. Experimental validation confirmed its ability to precisely target the calf muscle groups and effectively simulate the muscle contraction pumping effect, significantly increasing lower limb deep venous blood flow velocity. This device provides a safe, effective, and comfortable physical rehabilitation method for DVT patients, demonstrating promising clinical application value and potential for home-based rehabilitation.

B: Health Technology Innovation & Assessment

Ultrasound Image-based Intratumoral and Peritumoral Radiomics Nomogram for the Preoperative Prediction of Lymph Node Metastasis in Papillary Thyroid Carcinoma

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Objectives: To evaluate the predictive value of ultrasound image-based intratumoral and peritumoral radiomics nomogram for preoperative lymph node metastasis (LNM) status in patients with papillary thyroid carcinoma (PTC). **Methods:** In total, 200 PTC patients were randomly divided into the training cohort (n = 140) and validation cohort (n = 60) with a ratio of 7:3. We extracted 863 ultrasound image-based radiomics features across various region of interest (ROI) scales (ROI−2mm, ROI entire, ROI+2mm, and ROI+4mm). The diagnostic performance was assessed using receiver operating characteristic (ROC) curves and their corresponding area under the curve (AUC) values. A radiomics nomogram based on optimal radiomic and clinical models was constructed. **Results:** Compared with the ROI entire, ROI−2mm, and ROI+4mm radiomics models, the ROI+2mm radiomics model exhibited better prediction performance with an AUC of 0.858. The area under the AUC of the clinical model was 0.771. The nomogram incorporating clinical predictors and ROI+2mm- radiomics model surpassed the individual clinical and radiomics models, exhibiting a superior AUC of 0.862. **Conclusions:** Ultrasound image-based radiomics nomogram integrating clinical data and radiomics models based on the multiscale tumor ROI (+2 mm) can predict LNM in patients with PTC. This may help in making personalized treatment strategies before surgery.

B: Health Technology Innovation & Assessment

Research on Performance Evaluation Metrics for Medical Ultrasound Probes Based on Real-World Data

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Description: As a critical component of medical ultrasound equipment, the performance testing of ultrasound probes plays a pivotal role in ensuring the reliability and fault localization of the entire ultrasound system. However, the absence of standardized performance evaluation metrics for ultrasound probes has hindered the establishment of acceptance and quality control standards for these devices. This study investigates a quantitative approach to evaluating the performance of medical ultrasound probes by leveraging advanced probe measurement technologies and real-world evidence. It provides a foundational reference for analyzing the development of medical ultrasound probe-related standards. In this study, the ProbeHunter Lite portable testing equipment was utilized to evaluate ultrasound probes. A total of 198 ultrasound probe tests were conducted, covering 13 brands and 76 models. The number of elements in the ultrasonic probes varied across brands and models, including 64, 80, 128, 192, and 256 elements. The ProbeHunter Lite test reports provided detailed performance metrics for each element, including: (1) Sensitivity; (2) Cable Integrity; (3) Pulse Width; (4) Center Frequency; and (5) Fractional Bandwidth. Among these, reduced sensitivity of individual elements was identified as a critical factor contributing to diminished image quality and reduced blood flow or Doppler sensitivity. Consequently, sensitivity was selected as a key parameter for analysis in this study due to its significant impact on the overall performance of ultrasound probes. Firstly, this study employed the ProbeHunter Lite portable testing equipment to evaluate ultrasonic probes from various brands and models, thereby establishing comprehensive ultrasonic probe test datasets. Subsequently, descriptive statistical analysis was conducted on all ultrasonic probe data to identify the characteristics and trends of performance test data. The quartile was utilized to analyze fault/normal

ultrasonic probe data, and quantitative parameters for ultrasonic probe performance evaluation indices were derived through statistical analysis. Specifically, the threshold value distinguishing an acceptable element from a weak element was determined to be 0.6, while the partition value between weak and dead elements was set at 0.12. These performance evaluation index parameters were subsequently applied to assess 25 cases of faulty ultrasound probes and 27 cases of normal ultrasound probes, with comparative verification achieved through clinical application of the ultrasound probes. The findings indicate that the performance evaluation index proposed in this study can accurately differentiate between ultrasonic probes in a normal state versus those in a fault state, thus demonstrating the utility of appropriate performance test indices for probe fault localization and maintenance guidance.

Conclusion: Through systematic testing and analysis of the performance parameters of ultrasonic probes across various brands and models, this study preliminarily explores a quantitative method for evaluating ultrasonic probe performance indicators. This approach can serve as an initial reference for research on medical ultrasonic probe quality control and fault maintenance.

B: Health Technology Innovation & Assessment

Research on the Influence of the Nutrient Pump's Set Infusion Rate and Heater Clamping Position on Nutrient Solution Temperature

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Objective: To explore the influence of the nutrient pump's infusion rate and heater clamping position on nutrient solution temperature, so as to provide a basis for clinical parameter setting. **Methods:** At a room temperature of 26 °C, experiments were conducted by fixing the heating temperature (35–37°C) and changing the infusion rate (20–200 mL/h), and by fixing the infusion rate (100 mL/h) and changing the heater clamping position (0–50 cm from the output end). The temperature at the output end was measured and statistically analyzed. **Results:** The nutrient solution temperature was negatively correlated with both the infusion rate and the clamping position distance ($p < 0.001$). The faster the infusion rate or the farther the clamping position, the more obvious the temperature drop, and the temperature drop trend slowed down when the distance was longer. **Conclusion:** Infusion rate and heater clamping position significantly affect the nutrient solution temperature. In clinical use, the infusion temperature can be optimized by adjusting both.

B: Health Technology Innovation & Assessment

Research on Improving Low-Dose Imaging Performance of High-Resolution Flat-Panel Detectors via Self-Supervised Domain Adaptation Learning

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Objective: In the field of medical imaging, how to ensure high-quality imaging performance while reducing X-ray radiation dose is a crucial goal in the development of X-ray imaging technology. When operating in low-dose X-ray acquisition mode, high-resolution flat-panel detectors suffer from significant imaging quality degradation due to in-

creased photon noise and weakened signal intensity, which restricts their clinical applications in low-dose imaging scenarios. To address this challenge, this study proposes a self-supervised domain adaptation method to enhance the imaging performance of flat-panel detectors in low-dose imaging applications. **Methods:** First, a large-scale dataset of animal joint images was acquired using flat-panel detectors, based on which the pre-training of the source domain model was completed to construct an initial image analysis framework. Then, an innovative method combining iterative knowledge transfer and style generalization learning was adopted to break through the limitations of traditional data dependence. Only a small amount of unlabeled human joint data was required to achieve efficient transfer training of the source domain model to the target domain. Finally, clinical experiments were conducted to comprehensively verify the improvement effect of the proposed method on the image quality of 2D projection imaging and cone-beam CT (CBCT) 3D reconstruction of flat-panel detectors. **Results:** After denoising the low-dose data acquired by large-scale flat-panel detectors using the self-supervised domain adaptation method, the imaging performance was significantly improved. In terms of 2D projection imaging, the signal-to-noise ratio (SNR) of projection images in the low-dose exposure mode increased by 6.66 dB and 9.95 dB on the two test sets, respectively. The reconstruction quality of cone-beam CT (CBCT) was also significantly optimized: both noise and artifacts in the reconstructed images were effectively suppressed, and the standard deviation of CT values in low-density regions decreased from the baseline of 327 HU to 60 HU, representing a reduction of 81.7%. **Conclusion:** The self-supervised domain adaptation learning method proposed in this paper can effectively improve the imaging performance of flat-panel detectors under low-dose acquisition conditions, providing a feasible solution for reducing patient radiation dose and expanding the applicability of flat-panel detectors in low-dose clinical application scenarios.

B: Health Technology Innovation & Assessment

Clinical Test & Search on Medical Linear Accelerator by Monitoring the PTW QuickCheck

By Jun Li*

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Purpose: Give the test in cases of changing the conditions of measurement and changing reference value, compare the test results, and detect the capacity of QuickCheck to offer a reference for the daily morning check of the accelerator and the evaluation of test results. **Method:** After acquiring the reference value, we change the output dose, field size, SSD, angle of collimator, and gantry angle of the accelerator, and then evaluate QuickCheck's capacity of monitoring the accelerator accordingly. We utilize a 3D water tank, semiconductor detector, and other tools to measure the flatness, symmetry, and dose rate in the field of 10 × 10 cm, and compare the measured results with the outcomes acquired by QuickCheck. **Results:** When the output dose was 1 cGy higher than the reference value or 6 cGy lower than it, the field size expanded or contracted more than 2 cm simutaneouly, SSD was 2 cm higher or 1 cm lower than reference value, the collimator rotated more than 2°clockwise or anticlockwise, the gantry angle rotated more than 6°, then the test results of QuickCheck surpassed the threshold. Comparing the measuring results of QuickCheck with the 3D water tank, the difference between the flatness of the two was 3.84%, symmetry (G/T) 0.67%, symmetry (L/R) 0.47% and dose rate 1.2 MU/min. **Conclusion:** QuickCheck is rather accurate in testing the output dose, field size, angle of collimator, flatness, symmetry, and dose rate, so it could meet the requirements of the accelerator's daily QA. However, its capability is poor in examining SSD and the deviation of the gantry angle.

B: Health Technology Innovation & Assessment

Influence of Pelvic Area of Carbon Fiber Tabletop and Baseplate on Absorbed Dose of Rotating Arc and Fixed Field

By Jun Li*

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Objective: To investigate the influence of the pelvic area of the carbon fiber tabletop and baseplate on the absorbed dose of rotating arc and fixed field. **Methods:** 6 MV X-ray was used, and 100 MU for each field. The distance of the source to the ionization chamber was 100 cm (SCD = 100 cm). The length of the treatment couch was moved to 150 cm, and the solid water phantom was fixed at the center of the treatment tabletop and baseplate. The FC65-G ionization chamber was used to measure the absorbed dose. The gantry angle was changed to let 6 MV X-ray penetrate the treatment tabletop and baseplate from different incident angles of the beam. The penetration factors (F) were calculated and compared. Rotating arc and fixed field irradiations were implemented, respectively. In the rotating arc experiment, a 360° rotating arc was uniformly divided into 4 arcs, 8 arcs, and 12 arcs, respectively, which were denoted as ARC4, ARC8, and ARC12. In the fixed field experiment, the absorbed dose was measured every 10o clockwise degrees from 190° to 180°, which was denoted as Fixed36. **Results:** In the experiments of ARC4, ARC8, and ARC12, the penetration factor was higher when the field area was larger. In the fixed field experiment, the penetration factor reached the minimum at the angle of 120° (symmetry direction of 240°), the values were 92.21% and 92.96%, respectively (10cm × 10cm and 20cm × 20cm in the field area). **Conclusions:** The dose attenuation of the treatment tabletop and baseplate in the IMRT and VMAT is significant. Based on the effects of treatment, tabletop and baseplate on the absorbed dose of fixed field irradiation, this study compares and analyzes the conditions of rotating arc irradiation, and it provides a useful reference for physicists in making plans.

B: Health Technology Innovation & Assessment

Diagnosis of Focal Liver Lesions with Intravoxel Incoherent Motion Diffusion-Weighted Imaging

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Objective: To assess quantitatively the parameters of intravoxel incoherent motion diffusion-weighted imaging (IVIM-DWI) for the diagnosis of benign and malignant focal liver lesions. **Methods:** The imaging data of 75 patients with focal liver lesions (a total of 96 lesions, including 48 malignant lesions: 24 hepatocellular carcinomas, 22 intrahepatic metastases, 2 intrahepatic cholangiocarcinomas, and 48 benign lesions: 27 hepatic hemangiomas, 18 liver cysts, and 3 hepatic abscesses) were retrospectively analyzed. All patients underwent abdominal MRI at 3.0 T (GE Discovery MR 750w HD), including routine plain, IVIM-DWI (with 11 b-values of 0, 30, 50, 80, 100, 200, 400, 600, 800, 1000, and 1200 s/mm^2), and dynamic contrast enhancement (3D-LAVA) examinations. Apparent diffusion coefficient (ADC), true diffusion coefficient (Dslow), pseudo-diffusion coefficient (Dfast), and perfusion fraction (f) values of the lesions were measured through the post-processing operation. The receiver operating characteristic (ROC) curve was used to evaluate the diagnostic value of the parameters, and the cut-off value was calculated according to the Youden index. Comparison of the parameters and their diagnostic performance was determined using the nonparametric Mann-Whitney U test, respectively. **Results:** The group of benign lesions had higher Dslow and ADC values than malignant lesions, and Dslow had the highest diagnostic value (AUC = 0.964, cut-off value = 1.24×10^{-3} mm^2/s), while Dfast and f had no statistical significance ($p > 0.05$). When the lesions were analyzed separately, ADC in the diagnosis of hemangiomas and hepatocellular carcinomas was higher than other parameters (AUC = 0.954, cut-off value = 1.39×10^{-3} mm^2/s). There was no significant difference between hepatocellular carcinomas and liver metastases ($p > 0.05$). **Conclusion:** IVIM-DWI was useful and reliable to distinguish benign and malignant focal liver lesions, and the diagnostic value of Dslow is higher than other parameter values.

B: Health Technology Innovation & Assessment

Research on Collision Detection Methods for Radiotherapy Simulation

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Technology, Wuhan, Hubei Province, China.

To address the issues of resource consumption and detection efficiency in collision checking during the simulation of radiotherapy processes, this paper proposes a novel approach for bounding box generation and validates it through practical instances. This scheme innovatively incorporates the mechanical safety workspace into the collision detection process, and designs a hybrid hierarchical bounding box algorithm that combines static and dynamic elements: First, the safety workspace is utilized for rapid static prediction to identify potential collision regions; subsequently, only within these predicted regions, it employs refined k-dop or OBB bounding boxes for dynamic detection to accurately calculate collision points and equipment status, providing data support for subsequent adjustments. This method integrates the kinematic characteristics of the equipment with the theory of hierarchical collision detection and, through parameterized safety distance design, flexibly adapts to the needs of different equipment, providing a more efficient virtual verification tool for clinical operation safety. Experimental verification shows that, under a detection angle error of 1°, this approach results in a nearly 69% reduction in resource consumption and an approximate 81% improvement in average detection time, effectively enhancing detection efficiency. This method successfully resolves the key bottleneck of collision detection in radiotherapy virtual simulation, providing efficient and reliable technical support for optimizing the safe execution of radiotherapy plans and equipment operation training.

B: Health Technology Innovation & Assessment

Establishment and Application of Data Quality Evaluation Index System for SPD System of Medical Consumables in a Tertiary General Hospital

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Objective: To establish a data quality evaluation index system for the medical consumables Supply, Processing, and Distribution (SPD) system and carry out an evaluation in a tertiary general hospital. **Methods:** A combination of research methods, including literature analysis, questionnaire surveys, and expert consultations, was utilized to construct a data quality evaluation index system. Additionally, practical knowledge of the SPD system was incorporated to ensure the reliability and applicability of the evaluation index system. The constructed index system was then applied in a tertiary general hospital to assess the data quality of its SPD system. **Results:** A systematic evaluation index was developed, comprising four evaluation dimensions, six key business items, 73 evaluation contents, and 875 specific items. The evaluation results indicated that the data quality of the SPD system in the tertiary general hospital was rated as excellent, good, qualified, and unqualified at proportions of 93.15%, 4.11%, 0.00%, and 2.74%, respectively. Although most data within the system met high-quality standards, some deficiencies were identified that need improvement. **Conclusion:** The evaluation index system developed in this study integrates both theoretical frameworks and practical applications, ensuring a scientific and systematic approach to assessing data quality.

B: Health Technology Innovation & Assessment

Advances in Bone Repair Products: A Multifaceted Review from Material Innovations to Clinical Applications

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This review comprehensively examines the current research status and advances in bone repair products. Initially, it introduces the challenge of bone defects and the limitations of traditional bone grafting methods, highlighting the significance and imperative for developing novel bone repair products. Subsequently, it provides a detailed elucidation of the material classifications for bone repair products. This encompasses both natural bone repair materials (including allografts, xenografts, and acellular matrix materials) and synthetic bone repair materials (e.g., bioinert, bioactive, and smart materials), analyzing the characteristics and application prospects of each category. The review further traces the evolution of core technologies underpinning bone repair products, demonstrating continuous technological progress from the early use of conventional materials to the contemporary integration of personalized manufacturing and cell/gene therapy techniques. Finally, it summarizes the current clinical application landscape of bone repair products across various fields, including orthopedics, spinal surgery, joint surgery, oral and maxillofacial surgery, and neurosurgery, delineating the advantages and limitations of different materials in practical use. Overall, while the research, development, and application of bone repair products are continuously advancing, persisting challenges remain. These include the immune rejection risks associated with natural bone materials and the need for performance optimization of synthetic bone materials. Future progress necessitates interdisciplinary collaboration to achieve broader clinical translation, ultimately delivering superior therapeutic solutions for patients with bone defects.

B: Health Technology Innovation & Assessment

A Clinical Engineer's Story: Stroke, Aphasia, and a Game He Developed

By Anderson Alberto Ramos*

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This is a CE living with aphasia who, despite the significant challenges imposed by his condition, found innovative ways to communicate and express his ideas effectively. Using voice typing tools such as Google Drive and Google Docs, he writes and shares thoughts, circumventing the traditional barriers that aphasia places. As of 2025, the CE has not yet fully resumed conventional writing methods, but has adapted to digital technologies, demonstrating remarkable resilience and determination.

Aphasia, a neurological disorder affecting language skills, often severely limits an individual's capacity to communicate through speech and writing and can be profoundly isolating, impacting both personal and professional life. However, the CE's experience highlights the transformative potential of modern digital tools in providing alternative communication pathways. Voice typing technology, powered by advances in artificial intelligence, allows him to overcome many linguistic obstacles, enabling him to maintain his intellectual output and continue engaging with his work and community.

This study emphasizes the importance of understanding aphasia not only as a medical condition but as a lived experience that requires comprehensive support. The CE's journey underscores the need to learn about aphasia's various stages and the efforts of researchers dedicated to studying and improving the lives of those affected. His use of the AI tool Perplexity further illustrates how technology can assist in daily communication, especially when traditional reading and writing remain difficult or impossible.

Central to this narrative is the development of a discourse-oriented game, a project that spanned four years under the expert guidance of Professor Maria Irma Hadler Coudry from UNICAMP. This game was conceived during the CE's Master's program in Discourse Analysis and represents a practical application of academic and personal experiences. The game aims to facilitate communication and learning for individuals facing similar challenges, blending theoretical knowledge with innovative practice.

The methodology behind the project involved a collaborative process where the CE composed texts using voice typing tools, while Professor Coudry meticulously reviewed and refined content. This partnership ensured that the author's original voice and intentions were preserved while enhancing the clarity and linguistic accuracy of the final material.

Such a process highlights the delicate balance between authenticity and precision in academic and therapeutic contexts, ensuring that the discourse remains genuine and accessible.

This case study not only sheds light on the struggles and adaptations of a person with aphasia but also serves as an example of how technology, education, and human support can converge to create meaningful solutions, inviting readers to reconsider the possibilities for communication and rehabilitation in the digital age, encouraging further research and development in assistive technologies.

In conclusion, this article contributes valuable insights into the intersection of language disorders, technology, and education, demonstrating that while aphasia presents significant challenges, it is possible to find new ways to express oneself and remain intellectually active. The ongoing efforts of the CE, supported by academic mentorship and cutting-edge tools, provide hope and guidance for others facing similar obstacles, highlighting the vital role of empathy, creativity, and technological advancement in overcoming communication barriers.

C: Healthcare Facilities & Service Delivery

A Survey and Analysis of the Current Medical Equipment Configuration in 103 Tertiary Public Hospitals Across Different Geographical Regions of China

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Objective: With the rapid iteration of medical devices, the scientific configuration of medical devices has become an evaluation method for hospital refined development. The study overcomes issues of insufficient sample size based on geographic regions and correlation analysis found in previous studies to investigate medical device configuration in 103 tertiary hospitals across different regions in China. The correlation between medical device quantity, domestic device proportion, and hospital region/ bed capacity was analyzed. **Methods:** A questionnaire survey was designed using literature research and expert consultations, and conducted through the Best CE APP platform. **Results:** Data analysis informed a questionnaire designed with 6 primary and 30 secondary indicators. Of the 139 questionnaires, 103 valid ones were retained after cleaning, representing 18 provinces and 7 geographical regions. Three regions with the largest sample proportions were chosen as representative regions: East China (37%), South China (19%), and North China (18%). The overall distribution of medical equipment showed that the average number of medical devices per hospital was 9,003 units, with a total value of 828 million yuan, and the average number of beds was 1,507. Data analysis indicated that the number of beds was a significant factor influencing the quantity and value of medical equipment configuration in hospitals. In terms of equipment distribution across different regions, the average number of medical devices per hospital in North China, South China, and East China was 9,785, 9,245, and 8,153, respectively. Data analysis revealed no statistically significant difference in the overall number of devices, bed count, or the number of devices per 100 beds between North China and South China. However, there was a statistically significant difference between North China and East China in terms of overall equipment numbers, bed count, and other indicators. Large medical devices were found to be less configured and did not correlate with the number of beds. For life-support equipment, the average configuration per hospital included 123 ventilators, 490 bedside monitors, 60 defibrillators, and 255 infusion pumps. No statistical difference was found in device distribution, and device numbers were significantly correlated with the number of beds. The proportion of domestically produced life-support devices has increased. **Conclusion:** The scientific configuration

of large medical devices should consider regional factors such as population size and economic development, as well as the hospital's scale and functional orientation. The configuration of other medical devices, especially commonly used and life-support devices, should align with regional development and hospital bed numbers. This study offers data for analyzing regional medical equipment distribution equity, aiding in enhancing the scientific and equitable allocation of medical devices.

C: Healthcare Facilities & Service Delivery

Clinical Evaluation of Intelligent Occlusion Alarm Function in Intravenous Infusion for Critically Ill Pediatric Patients

By Caixian Zhang, Zhongkuan Lin, Han Cheng, Kun Zheng*

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Objective: To evaluate the clinical efficacy of an intelligent occlusion alarm function in intravenous infusion for critically ill pediatric patients. **Methods:** Compared with the general occlusion alarm, the intelligent occlusion alarm has advantages such as multi-level adjustment of alarm thresholds, real-time display of pipeline pressure, intelligent early warning, occlusion restart, and automatic release of pipeline pressure. Using the Delphi method to establish an evaluation index system, a randomized controlled trial was conducted to compare general occlusion alarm and the intelligent occlusion alarm. **Results:** In terms of safety, both groups of devices had zero occurrences of adverse events and safety incidents ($p > 0.05$). Regarding reliability, neither group of devices experienced any functional blockage failures during the experiment ($p > 0.05$). The intelligent occlusion alarm significantly outperformed the general occlusion alarm in all usability dimensions: visibility (4.33 ± 0.48 vs. 2.63 ± 0.71), interactivity (3.96 ± 0.81 vs. 2.33 ± 0.64), accessibility (4.33 ± 0.64 vs. 1.79 ± 0.51), and response speed (4.25 ± 0.68 vs. 2.54 ± 0.66), all with $p < 0.05$. In terms of clinical efficacy, the intelligent occlusion alarm reduced daily alarm frequency by 25.69% for each device (2.95 ± 0.37 vs. 3.97 ± 0.48 times/day) and, due to its auto-reset capability, decreased manual interventions by 88.66% for each device every day (0.45 ± 0.06 vs. 3.97 ± 0.48 times/day, $p < 0.05$). Enabled automatic resolution of device occlusion alarms for each device every day (2.47 ± 0.37 times vs. 0 times, $p < 0.05$). Additionally, episodes of hemodynamic instability were reduced by 43.59% for each device every day (0.44 ± 0.17 vs. 0.78 ± 0.18 times, $p < 0.05$). **Conclusion:** While matching conventional pumps in safety and reliability, the intelligent occlusion alarm function demonstrated superior usability and clinical efficacy, making it a recommended option for critically ill pediatric patients.

C: Healthcare Facilities & Service Delivery

Study on the Clinical Application Effect of Low-Field Infant MRI

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Objective: Evaluate the clinical application effect of low-field infant MRI. **Methods:** Using literature review, expert consultation, and two rounds of Delphi to determine the evaluation index system. Then retrospectively analyze and compare the data of low-field infant MRI and high-field MRI from January 2022 to December 2024. **Results:** There is a certain gap between low-field infant MRI and high-field MRI in terms of signal-to-noise ratio, image uniformity, scan time, user-friendly interface, image result consistency, and software system reliability. However, there was no difference in terms of spatial resolution and image quality. Hardware system reliability, mean time between failures, noise, and the examination rate completed without sedatives are better than that of the high-field MRI.**Conclusion:** Low-field infant MRI meets the needs of clinical diagnostic and has stable performance.It can be used as a routine screening tool for brain diseases near

bed.

C: Healthcare Facilities & Service Delivery

Empowering with Digital Intelligence for Lean Governance: Innovative Practices and Performance Advancement in Medical Consumables Management at Fuwai Hospital of the Chinese Academy of Medical Sciences

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Background: With current policies promoting high-quality development of public hospitals, the management of medical consumables is undergoing a profound transformation. The management model is shifting from an extensive approach to refined management. Problem: With the comprehensive implementation of diagnosis-related groups payment reforms, zero markup policies for medical consumables, and centralized volume-based procurement, the management of medical consumables has become a key player in high-quality healthcare development. Traditional extensive management models are increasingly challenged by issues such as inventory backlog, uncontrollable costs, and difficulty in traceability. In contrast, refined management of medical consumables through informatization, institutionalization, and standardization enables full lifecycle management. **Methods:** This study takes Fuwai Hospital of the Chinese Academy of Medical Sciences as a case study to examine the impact of refined medical consumables management on cost reduction, efficiency improvement, and medical quality enhancement. **Results:** By integrating the strategies that promote standardization, optimize management, and support development with Fuwai Hospital's institutional characteristics, the hospital achieved bi-directional traceability of medical consumables via an informationalized management system. This approach has standardized consumable usage, reduced the proportion of healthcare materials in overall costs, continually optimized the medical income structure, effectively curbed the irrational growth of healthcare expenses, and alleviated patients' financial burdens. **Conclusion:** This empirical study of the refined medical consumables management at Fuwai Hospital demonstrates how the Fuwai model can drive high-quality hospital development, providing a replicable model for other institutions.

C: Healthcare Facilities & Service Delivery

Reliability Research of Fetal Monitor Based on the Weibull Distribution of Component Lifespan

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A fetal monitor is a fundamental life-support device for fetuses in pregnant women's abdomens. To enhance its refined management, ensure the safe and effective operation of the device, transform the traditional "post-event" passive maintenance into "pre-event" active maintenance, slow down the speed of device deterioration and reduce the risk of failure, cut down the device maintenance cost, and improve the device's performance and operational reliability. We use the Weibull distribution and the maximum likelihood method to statistically organize the maintenance data of fetal monitor probes and conduct reliability analysis. We assess the reliability distribution of the service life of probe components, grasp the operation status of probe components, and statistically analyze the differences by department. Through the Weibull distribution fitting results of the probes, we obtain probe risk intervals and recommended replacement cycles for each department. The service life of fetal heart monitoring probes is longer than that of uterine contraction pressure

probes. The service life of probes is not only negatively correlated with the usage duration but also related to the probe management mode. The reliability analysis of fetal monitors based on the Weibull distribution of component service life can improve the preventive maintenance strategy of fetal monitors, provide a basis for the centralized management of "reusable" components, and achieve the goals of cost reduction, quality improvement, and efficiency enhancement in device operation and management.

C: Healthcare Facilities & Service Delivery

Innovative SPD Self-Managed Model for Medical Consumables in Public Hospitals: A Cost-Effective Approach to Refined Supply Chain Management

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This study explores the implementation and outcomes of a self-managed Supply-Processing-Distribution (SPD) model for medical consumables at a tertiary public hospital in Guangxi, China, against the backdrop of nationwide healthcare reforms that transformed consumables from profit centers to cost centers. Facing annual procurement costs exceeding 400 million Chinese Yuan (CNY) and inefficiencies in manual inventory management, the hospital developed an autonomous SPD system by integrating a customized third-party software platform with its Hospital Information System (HIS). Key innovations included Radio Frequency Identification (RFID)-enabled smart cabinets, cold chain integration for reagents, and a 24-member in-house operational team.

The model achieved full coverage across 255 secondary storage units in three hospital campuses, reducing inventory costs by 94% (from 18 million to 1.02 million CNY) and saving 5 million CNY annually compared to third-party operator fees. Operational efficiency improved significantly, with distribution accuracy rising from 85.62% to 90.48% and nursing workload decreasing by 2.5 h daily. The system enhanced compliance through real-time traceability, reducing surgical hemostatic consumable usage by 61% and registration errors by 97%. Crucially, it mitigated corruption and data security risks inherent in outsourced SPD models while complying with Guangxi's strict anti-outsourcing policies.

This case demonstrates that hospital-led SPD systems are not only operationally feasible but financially advantageous, offering sustainable solutions for supply chain optimization in resource-constrained public healthcare settings. Future directions include integrating Unique Device Identification (UDI) systems and expanding predictive analytics capabilities.

C: Healthcare Facilities & Service Delivery

Research on Progress Management of a Hospital's Reverse Osmosis Water Treatment System Engineering Project Based on Critical Chain Technology

By Zhen Li*, Qin Zhang, Xianli Ma, Jian Liang, Su Tao, Pengcheng Su, Tianxiang Zhao

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Objective: to make the installation project of the reverse osmosis water treatment system in the hospital can be reasonably planned, with real-time monitoring and effective adjustment, so as to prevent project delay. **Methods:** The status of the construction and management of the reverse osmosis water treatment system in Hospital A was fully recognized, and the responsibilities and working steps of the personnel were sorted out. Find out the key chain of the project by using the key chain technology, calculate the project buffer, and get a reasonable project time. Use Monte Carlo simulation to fully simulate the project progress; Use a dynamic monitoring mechanism, a correction chart, and a Gantt chart to monitor project progress and buffer consumption, timely intervention, and adjustment. **Results:** The

project was expected to be completed in 138 days by calculation. The average value of the Monte Carlo simulation was 131.88, the probability of completion within 138 days was 80%, and the final project was completed in 133 days. The project buffer of the critical chain is 20 d, the buffer on the non-critical chain is 5 days, and the consumption of the buffer returns to the green safety zone after experiencing the yellow anxiety zone and the red alarm zone in the medium term, and finally consumes 15 days, 5 days ahead of schedule. **Conclusion:** The critical chain technology can overcome the resource constraint in the project, make a reasonable plan, timely monitor the project progress, and effectively intervene, so that the project can be completed on time and efficiently.

C: Healthcare Facilities & Service Delivery

Influence of Implanted and Interventional Medical Devices on Cardiac Magnetic Signal Acquisition Using MagnetoCardioGraphy (MCG)

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Background and Purpose: Magnetocardiography (MCG) offers unparalleled sensitivity (up to 10 fT/Hz) for detecting extremely weak biomagnetic fields generated by the heart (about 100 pT). However, this high sensitivity makes MCG susceptible to environmental magnetic noise and potential interference from ferromagnetic materials. Patients with implanted or interventional medical devices often raise concerns about compromised signal quality during MCG examinations. This study aims to experimentally quantify the magnetic interference caused by a representative range of commonly used implanted medical devices on MCG signal acquisition, assessing whether they exceed clinically relevant thresholds and potentially necessitate modifications to existing MCG protocols. **Methods:** A controlled laboratory study using a commercial Superconducting Quantum Interference Device (SQUID)-based MCG system assessed the magnetic interference from ten commonly encountered implanted/interventional devices (e.g., infusion ports, dental implants, bone plates, joint prostheses, spinal fixators). Device materials included various titanium alloys (Ti6Al4V, TC4, TC4ELI, TA3), Cobalt-Chromium-Molybdenum alloy, stainless steel, medical resin, and Ultra-High Molecular Weight Polyethylene UHMWPE). The experimental protocol involved:

Baseline Measurement: Recording ambient magnetic field noise without any device present.

Static Measurement: Placing each device stationary on a non-magnetic platform 10–20 mm below the MCG sensor for 60 s. Devices causing signal variations ≥ ± 1 pT were flagged.

Dynamic Measurement: Devices not exceeding the ± 1 pT static threshold were fixed onto a respiratory motion simulator (balloon device) positioned 10–20 mm below the sensor. Data was acquired for 40 s at each of four standard MCG positions. The ± 1 pT threshold was reapplied.

Signal Fidelity Assessment: An ECG simulator signal was recorded both without (Signal A) and with (Signal B) each device present on the motion simulator at 10–20 mm. Signal correlation coefficients between A and B were calculated. A coefficient ≥ 0.99 indicated minimal/no interference.

Robustness: The entire procedure was repeated three times for each device under identical conditions to ensure reliability. Data analysis included calculating average amplitude variations and standard deviations.

Results: The ambient noise floor was measured at ± 0.08 pT. All ten devices exhibited magnetic interference levels significantly below the predefined ± 1 pT threshold in both static and dynamic measurement scenarios:

Maximum Static Variation: ± 0.14 pT (Chest/Rib Fixation System, Ti6Al4V).

Maximum Dynamic Variation: ± 0.16 pT (Central Screw System, 23Mn-21Cr-1Mo Stainless Steel).

All other devices showed variations between ± 0.06 pT and ± 0.12 pT in static and dynamic tests.

Signal correlation coefficients (Signal A vs. Signal B) for all devices met or exceeded 0.99, confirming high signal fidelity even in the presence of the implants during simulated physiological motion.

Conclusion: Systematic assessment confirms magnetic interference from common implants (medical resin, UHMWPE, Ti alloys, Cobalt-Chromium-Molybdenum alloy, stainless steel) is clinically insignificant (< ± 1 pT) during MCG, both statically and under simulated motion. These devices should not contraindicate MCG. Results provide evidence to update clinical guidelines, facilitating MCG use in patients with such hardware. Future studies should target devices with higher ferromagnetic content under stronger fields.

C: Healthcare Facilities & Service Delivery

Clinical Evaluation of a Single-Use Powered Endoscopic Linear Stapler in Resections for Lung, Colorectal, and Gastric Cancers: A Prospective, Pragmatic Randomized Controlled Trial

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Aims: This prospective, single-center, open-label, pragmatic randomized controlled trial (ChiCTR2400092552) aimed to evaluate the clinical efficacy and safety of the new Mindray Powered Endoscopic Linear Stapler (test group) compared to the Ethicon Powered Endoscopic Linear Stapler (control group) in resections for lung, colorectal, and gastric cancers.
Methods: From July 28 to December 25, 2024, 319 patients undergoing laparoscopic resections for lung, colorectal, or gastric cancer at the First Affiliated Hospital of Zhejiang University School of Medicine were randomized to the test (n = 159) or control (n = 160) group. The primary outcome was anastomotic success rate. Secondary outcomes included efficacy (vascular transection success rate, number of additional sutures, device-related conversion rate, anastomotic healing, drainage duration, intraoperative blood loss, hospital stay) and safety (intraoperative transfusion, anastomotic bleeding/leak/stricture/rupture, grade 3–4 complications, 30-day readmission/reoperation rates). Non-inferiority was predefined as a lower 95% confidence interval (CI) limit for anastomotic success rate difference ≥ −10%.
Results: Anastomotic success rates were comparable between groups across all procedures:

1. Lung cancer: 98.1% (52/53) vs. 98.1% (52/53), difference 0.0% (95% CI: −8.2–8.2, $p > 0.999$),
2. Colorectal cancer: 100% (53/53) vs. 96.3% (52/54), difference 3.7% (95% CI: −3.6–12.5, $p = 0.150$),
3. Gastric cancer: 100% (53/53) vs. 100% (53/53), difference 0.0% (95% CI: −6.8–6.8).

Non-inferiority criteria were met for all procedures. No significant differences were observed in secondary efficacy or safety outcomes. Both devices demonstrated excellent usability and satisfaction in clinical practice.
Conclusion: The new Mindray Electric Stapler achieved non-inferior anastomotic success rates and comparable clinical performance to the Ethicon device in minimally invasive radical resections for lung, colorectal, and gastric cancers, with equivalent safety profiles. These findings support its clinical adoption as a cost-effective alternative.

C: Healthcare Facilities & Service Delivery

Construction of a Fast-kV Switching Dual-Energy CT Radiation Model Based on Monte Carlo Methods

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Background: Despite the clinical advantages of dual-energy CT (DECT), radiation risks associated with scanning have garnered attention. Existing CT radiation models and methods are limited in accuracy and applicability for fast-kV switching DECT due to its complexity and lack of specific parameters from manufacturers. **Methods:** To address this gap, this study focuses on fast-kV switching DECT and proposes a novel single-source instantaneous cut dual-energy CT radiation model. This model is developed by integrating and refining international single-energy CT radiation modeling techniques, incorporating dual-energy scanning technology and the Monte Carlo (MC) method. To validate the model's accuracy, we not only employ conventional methods such as equivalent energy spectrum and

dose verification of the CTDI standard model (dynamic scanning) but also introduce a static dose attenuation curve (static scanning) and dual-energy scanning mode validation. **Results:** The experimental measurements and simulation results for the static dose attenuation curve, CTDI standard model dose distribution, and dual-energy scanning mode validation exhibit high consistency, thereby confirming the model's validity. **Conclusions:** The findings of this study have practical implications for clinical applications, particularly in the realms of radiation protection and patient dose optimization. The proposed model offers a more reliable tool for understanding and minimizing radiation exposure in DECT scans.

C: Healthcare Facilities & Service Delivery

Effects of Centralized Intraocular Lens Procurement on Patient Cost Burden and Consumables Consumption in Cataract Surgery

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Objective: To analyze the impact of the Volume-Based Procurement (VBP) of intraocular lenses (IOLs) on patient hospitalization costs and the utilization of medical consumables. **Methods:** Based on Diagnosis-Related Groups (DRG), medical insurance settlement data for 4,303 inpatients within the CB35 lens surgery (with or without general complications or comorbidities) at the Army Medical Center of PLA were collected from January to December 2024. Patients were divided into a pre-VBP group (n = 2,174) and a post-VBP group (n = 2,129), using the VBP implementation date as the cutoff. A comparative analysis was performed on total hospitalization costs, medical consumables costs, and average length of stay (ALOS) between the two groups. Particular emphasis was placed on analyzing structural changes in the quantity and value proportions of IOL products classified under the three-level classification of consumables under medical insurance. **Results:** Following the implementation of the IOL VBP policy, total hospitalization costs for CB35 DRG patients decreased by 9.22%. Medical consumables costs saw a significant reduction of 16.53%, while ALOS experienced a slight increase of 0.90%. Marked structural changes occurred in IOL utilization under the three-level classification of consumables under medical insurance. The proportion of premium-feature IOLs increased significantly. Specifically, the quantity proportions of Extended Depth of Focus IOLs, multifocal non-toric IOLs, and multifocal toric IOLs increased significantly by 22.81 percentage points (pp), 23.80 pp, and 3.27 pp, respectively. Their value proportions also increased significantly by 20.78 pp, 16.89 pp, and 11.42 pp, respectively. Conversely, the proportion of monofocal IOLs decreased substantially. The quantity proportions of monofocal non-toric and monofocal toric IOLs declined by 49.77 pp and 0.12 pp, respectively, while their value proportions decreased by 48.42 pp and 0.66 pp, respectively. **Conclusion:** Under the VBP policy, patients undergoing the CB35 lens surgery experienced an overall reduction in medical costs while gaining access to premium-feature IOLs. The IOL VBP has proven effective in regulating costs for this specific condition.

C: Healthcare Facilities & Service Delivery

The Analysis and Enhancement of Numerous Adverse Events Associated with the Use of Ultrasonic Knives in a Tertiary Hospital in Wuxi

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Objective: To investigate and retrospectively analyze the incidence and causes of multiple adverse events related to an imported brand of high-frequency surgical integrated system (ultrasound knives) and to improve the management and prevention measures. **Methods:** The reports and manifestations of adverse events in four cases of ultrasonic knife

surgery were analyzed, the causes of adverse events were discussed, and improvement measures were proposed to reduce the risk of such adverse events. **Results:** A Fishbone diagram was used to specifically analyze the risk factors of adverse events of the ultrasonic knife, and the fault was located in the handle. Finally, the main cause of frequent adverse events was determined to be the use of an endoscopic sleeve during the operation. **Conclusion:** By stopping the use of endoscopes and increasing the number of disinfection turnovers to ensure the use of ultrasonic knives, the frequency of adverse events was significantly reduced, and the surgical safety of patients was ensured.

C: Healthcare Facilities & Service Delivery

Evaluation Model of Coronary Artery Calcification in Patients with End-Stage Renal Disease Undergoing Hemodialysis Based on Pulse Wave

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Objective: Coronary artery calcification (CAC) is a prevalent condition among patients with end-stage renal disease (ESRD). This study aims to establish an assessment model for CAC based on pulse wave for hemodialysis patients by collecting pulse wave signals and extracting relevant parameters. **Methods:** Pulse wave in this study was collected in the hemodialysis center of the Department of Nephrology, Beijing Jishuitan Hospital, Capital Medical University. Low-dose computed tomography of the chest was used as the imaging standard to evaluate coronary artery calcification in the study population, and according to the Agaston score rules, the study population was divided into four groups: 0 points, 1–100 points, 101–400 points, and > 400 points, corresponding to no calcification, mild calcification, moderate calcification, and severe calcification. At the same time, the non-fistula radial pulse wave of the study was collected. The collection time of pulse wave was selected as: before dialysis, one hour after dialysis, two hours after dialysis, three hours after dialysis, and 0.5 hours after dialysis. The characteristic parameters of pulse wave at different time periods were extracted, and the risk characteristic parameters were screened out by single-factor binary logistic regression analysis and the evaluation model of CAC for patients with ESRD who receive hemodialysis was established based on random forest. **Results:** The machine learning model based on random forest has good performance (Macro Accuracy = 0.88, Macro Precision = 0.76, Macro Recall = 0.76, Macro F1-score = 0.75, and Macro AUC = 0.95). **Conclusions:** The evaluation model of CAC in the hemodialysis population based on pulse wave was established and verified, and it is feasible for predicting CAC for patients with ESRD who receive hemodialysis, and it has great significance for clinical use to select and adjust treatment.

C: Healthcare Facilities & Service Delivery

Enhancing Medical Equipment Incident Investigations in Hong Kong Public Hospitals: Development of a Biomedical Engineering Checklist

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In Hong Kong public hospitals, over 100 biomedical equipment-related incidents are reported annually. When incidents occur, hospital management and the Biomedical Engineering (BME) team are promptly notified through the well-established Advanced Incident Reporting System (AIRS). Biomedical Engineers then apply their professional expertise to coordinate investigations, propose immediate stopgap measures, and develop long-term preventive actions to ensure patient safety. Timely and effective responses are critical, as poorly managed incidents can lead to recurrence of the

incident, harm to patients and staff, and consequently damage the hospital's reputation. Root cause analysis of medical equipment-related incidents is often complex and challenging due to the wide variety of equipment types and models in hospitals, as well as the involvement of multiple contributing factors such as human error, environmental conditions, and equipment malfunctions. Challenges are further compounded by insufficient records on how the incident happened, limited vendor expertise, delayed error code analysis by overseas manufacturers, and inadequate experience of frontline biomedical engineering staff. These difficulties delayed the identification of the root cause and subsequently deferred the development of effective preventive measures, thereby compromising patient safety. While different medical device adverse event management systems emphasize effective communication and governance at corporate and organizational levels, there has been no technical checklist specifically designed to support biomedical engineering teams in conducting thorough incident investigations. The quality of investigations and the proposed preventive measures often depend on the investigator's experience. To address this gap, the Biomedical Engineering Team of Pamela Youde Nethersole Eastern Hospital developed a user-friendly incident investigation checklist. This checklist outlines all critical information needed during incident investigations and facilitates the formulation of both short-term and long-term preventive measures. This abstract aims to share frontline experiences, summarize lessons learned during incident investigation by developing an incident investigation checklist for the healthcare industry. The goal is to help biomedical engineers in hospitals conduct more effective and comprehensive investigations, thereby enhancing overall hospital safety. This initiative also aligns with broader efforts by the Hospital Authority to improve medical equipment maintenance and incident management, as highlighted by recent reviews and recommendations emphasizing clearer roles, improved communication, and enhanced training for biomedical engineering staff to safeguard patient and staff safety.

D: CE/HTM Capacity Building & Strategy

Interpretation of Group Standard on Specification for Clinical Use in X-Ray Computed Tomography (CT)

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Description: The key special project of the National Key Research and Development Program, "Medical Equipment and Biomedical Materials", aims to guide enterprises to enhance reliability design during the research and development and production of equipment through the formulation of group and industry standards, the formation of technical specifications and common technology systems, and to guide the use, testing and maintenance of medical equipment throughout the entire life cycle in medical institutions. By effectively improving the reliability of the equipment,
Ensure that patients can undergo timely examinations to enhance their experience and satisfaction. Based on this, our team formulated and released the group standard (T/ZHYL 017-2025) "Clinical Use Specifications for X-ray Computed Tomography Equipment (CT)", including contents such as clinical environment configuration, clinical examination preparation, clinical use Settings, and equipment maintenance guarantee. It applies to the clinical operation and use of X-ray computed tomography (CT) equipment in medical institutions of all levels and types.
Goals of the project and final users that will benefit: This group standard mainly targets the problems existing in the clinical use stage of current CT equipment, such as environmental dependence, equipment maintenance and support, operation standardization and radiation safety. By providing detailed regulations on all aspects including the clinical environment configuration, examination preparation, usage Settings and maintenance support of CT equipment, it aims to standardize the clinical operation of CT equipment. Ensure its safe, effective, and reasonable application in medical practice.
Results: The formulation of this group standard (T/ZHYL 017-2025) provides comprehensive and systematic norms for the clinical use of CT equipment, covering multiple key links such as environmental configuration, examination preparation, parameter optimization, and maintenance guarantee. The promotion and implementation of this standard will help reduce equipment failures caused by improper operation or insufficient maintenance. Through intelligent operation and maintenance and parameter adjustment, it will lower equipment wear and medical costs. Promote the establishment

of a standardized and intelligent CT equipment management system. The content of this group standard mainly consists of 8 chapters (1. Scope, 2. Normative References, 3. Terms and Definitions, 4. Abbreviations, 5. Clinical procedure configuration, 6. Clinical examination preparation, 7. Clinical Equipment used, 8. Equipment maintenance and guarantee), among which Chapters 5, 6, 7, and 8 are the core contents.

D: CE/HTM Capacity Building & Strategy

Research on the Construction of an Internship System and Teaching Practice of the Biomedical Engineering Major Based on OBE and PBL

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Objective: To construct the practice system of the Medical Engineering Department of Peking University Cancer Hospital and optimize the course design based on the integration of Outcome-Based Education (OBE) and Problem-Based Learning (PBL), to provide a useful reference for cultivating innovative, compound, and applied talents in the field of medical engineering. **Methods:** This study uses the Delphi method to determine the content of internship teaching and assessment. It integrates the OBE and PBL concepts to optimize the curriculum design and establishes an internship teaching system based on the work foundation of previous years. Moreover, it adopts SPSS 21.0 and Excel 2016 software to conduct a retrospective analysis of students' assessment scores and self-evaluation results. **Results:** This study defined the core components of internship practices and evaluation protocols, established a well-structured pedagogical system, and generated replicable operational frameworks. Quantitative and qualitative analyses demonstrated significant enhancements in student assessment scores ($F = 17.73$, $p < 0.01$) and self-evaluated cognitive competencies within this optimized internship paradigm. **Conclusion:** Combined with the actual situation, working basis, and advanced theory, Peking University Cancer Hospital has carried out fruitful exploration and practice in hospital internship and talent education in the field of medical engineering, and provided research experience for training interdisciplinary talents of medical engineering.

D: CE/HTM Capacity Building & Strategy

Research on Quality Control Management of Medical Devices

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The use of medical devices is a crucial part of the medical process. With the continuous improvement of medical technology, the application of medical devices in the diagnosis and treatment process has gradually increased. Therefore, higher requirements have been put forward for the reliability and safety of medical devices during use. Therefore, how to carry out and improve the quality control management of medical devices has become a top priority. Based on this, after combining the relevant national regulations, relevant literature research, and the actual work of the hospital, this paper will discuss the methods of medical device quality control management from the following three aspects: 1. Conducting research in advance, combining the actual situation, and purchasing on demand. 2. Clear standards, tripartite confirmation, and acceptance according to regulations. 3. Use according to regulations, conduct periodic inspections, and ensure safety. In addition, regular quality testing of medical devices is also an important measure to ensure the safety of their use. Especially for medical devices with a high frequency of use and a high risk of use, preventive maintenance should be strengthened. For medical devices listed in the national mandatory inspection catalog, corresponding testing plans should be formulated in advance and promptly notified to each department to prepare for inspection. Medical devices that have not been tested or have failed the test results shall not be used. At present, the use of medical

devices in the medical field is becoming increasingly widespread, and the progress of the medical industry cannot be separated from the development of medical devices. Therefore, it is necessary to pay special attention to the quality of medical devices, carry out more scientific, reliable, and feasible medical device quality control management work, and ensure the safe use of medical devices.

D: CE/HTM Capacity Building & Strategy

Analysis of the Effect of Different Conditions on the Quality of Computed Tomography CT Images

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CT is a medical imaging technology that is widely used in clinical diagnosis, treatment planning, and disease monitoring, and is particularly valuable in the diagnosis of tumors, vascular lesions, trauma, and infections. When CT is used for scanning under clinical conditions, different CT devices are located in different environments, and different temperatures and humidity, as well as dust, may affect the performance of CT devices, and different clinical protocols and scanning and reconstruction parameters may affect the image performance of CT. The evaluation indices affecting CT image quality mainly include spatial resolution, density resolution, field uniformity, dose, noise, layer thickness, and so on. To address this key technical issue, the data related to CT scanning under different environments and image requirements are collected to analyze and study the impact of different conditions on the analysis of CT image quality. Experimental protocol: The acquisition object is determined to be the classic test module Catphan500, CTP714 layer can measure the subjective spatial resolution, CTP515 can measure the subjective low-contrast resolution, CTP682 layer can measure the objective spatial resolution, layer thickness, CT value linearity, and CTP712 layer can measure the CT value, uniformity. Clinical protocols were selected for four more representative protocols: head, abdomen, chest, and inner ear. Different scanning and reconstruction parameters, such as tube voltage, tube current, collimation, rotational speed, pitch, image layer thickness, dose modulation, and image enhancement, were selected. Different regions of the country and different seasons were chosen to test each brand and model of CT, and then the impact of different conditions on CT image quality was analyzed through the evaluation index of CT image quality. Analysis scheme: The analysis method mainly consists of parameter comparison and correlation analysis, which can do the following related analyses: comparative analysis of systems of the same model in the same season at different sites, comparative analysis of systems of the same model in the same site in different seasons, comparative analysis of systems of the same model in different sites in different seasons, and so on.

D: CE/HTM Capacity Building & Strategy

Challenges and Development Paths of Female Clinical Engineers

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This paper uses a stratified sampling survey method, classified by professional title (Junior/Intermediate/Senior), to investigate a total of 100 female clinical engineers in hospitals in Shanghai (the proportion of the survey population is 5:3:2). Through questionnaire research, we understand the current work status and pressure challenges faced by these 100 female practitioners. The research finds that the special training system, family-friendly policies (flexible childcare system), fair promotion opportunities, and professional academic teams can greatly promote the enthusiasm of female clinical engineering practitioners and effectively promote their careers.

D: CE/HTM Capacity Building & Strategy

Case Study and Management Improvement of Medical Device Adverse Events

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Introduction: In recent years, the Chinese government has revised and updated a series of medical equipment-related laws and regulations, emphasizing carrying out the re-evaluation of medical equipment after listing. It's clearly stipulated that the users of medical devices should timely report and handle the medical equipment adverse events (MDAEs). **Objective:** To sum up the handling methods and management effectiveness of MDAEs according to the new version of "Regulations for the Supervision and Administration of Medical Devices". **Methods:** Three recent typical cases of MDAEs in our hospital were studied and evaluated, and detailed processing and improvement feedback were recorded. **Results:** Several management improvement points were summarized according to these cases in order to avoid the recurrence of similar adverse events. **Conclusion:** The hospital must continue to strengthen the management of MDAEs and promptly evaluate, review, and process when MDAE happens to improve the level of medical equipment management and to guarantee the safe use of medical devices.

D: CE/HTM Capacity Building & Strategy

Construction of Medical Device Quality Control Management System Under the Performance Evaluation Requirements of Tertiary Public Hospitals

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Objective: to reduce the safety risks of medical equipment use, improve the efficiency of medical equipment quality control management, and ensure the reasonable and orderly implementation of medical equipment quality control management. **Method:** Based on the "performance evaluation operation manual for three-level public hospitals" and combined with the actual work of medical institutions, a medical equipment quality control work plan is formulated and implemented, and existing problems are identified and continuously improved. **Result:** A medical equipment quality control management system has been established, the quality control work of medical institutions has been standardized, and the quality control management system and processes have been improved in a targeted manner. **Conclusion:** By establishing a quality control management system, the level of medical equipment quality control management has been improved, the safety and effectiveness of medical equipment have been ensured, and standardization of medical equipment quality control management has been achieved.

D: CE/HTM Capacity Building & Strategy

A New Dimension in Expanding a Clinical/Biomedical Engineer's Career Through Management and Global Collaboration

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Trained as a biomedical engineer with a master's degree, PhD, and several years of postdoctoral research experience, I initially envisioned my career within the academic and technical realms of science and innovation. I found intellectual fulfilment in solving complex problems, assessing new medical technologies, and contributing to scientific literature. However, as I engaged more deeply with the broader healthcare ecosystem, it became increasingly clear that impactful change does not happen solely in laboratories or lecture halls, but it requires vision, structure, and coordination at organizational and policy levels. This realization led me to transition into leadership and management roles in several non-profit organizations central to the field of Clinical Engineering and Health Technology Management, including the Global Clinical Engineering Alliance (GCEA), *Global Clinical Engineering Journal (GCEJ)*, Pul Alliance for Digital Health and Equity (Pul Alliance), the International Federation for Medical and Biological Engineering (IFMBE), and the European Alliance for Medical and Biological Engineering & Science (EAMBES). My involvement in these organisations has allowed me to contribute not just as a biomedical engineer, but as a connector, organizer, and advocate for the profession and its critical role in ensuring patient safety. The decision to take on administrative and organizational responsibilities was driven by a deep desire to help shape the infrastructure that supports the clinical engineering community. I found great joy in the creation of sustainable programs, the facilitation of international initiatives, and the building of platforms that empower professionals across all regions to collaborate, learn, and lead. One of the most rewarding aspects of this work has been the opportunity to network and collaborate with colleagues from around the world. These interactions have brought not only professional insights but also a profound sense of shared mission. Through congresses, working groups, joint publications, and webinars, I have witnessed how global connectivity fuels progress and how diverse experiences and perspectives can converge to solve common challenges in health technology management. Moreover, working alongside some of the giants in our field—visionaries whose decades of dedication have defined Clinical Engineering—has been both a privilege and a source of inspiration. Their mentorship and openness to collaboration have reinforced my belief that leadership is not about hierarchy, but about service: serving a community, a cause, and ultimately, the patients whose safety depends on the systems we help build and improve. My shift into management and organizational leadership has not been a departure from biomedical engineering but an extension of it. By engaging with these global non-profit organisations, I am contributing to the maturation and recognition of our profession. I believe that clinical engineers must have a seat at the decision-making table to ensure technologies are applied safely, effectively, and ethically. This is where science meets strategy, and where our greatest impact could be applied! You can experience similar intellectual fulfilment reported here by engaging with such organizations.

D: CE/HTM Capacity Building & Strategy

Quality Control and Detection Evaluation of Infusion Pumps Based on Real-World Data

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Objective: To explore the factors influencing the quality control test results of infusion pumps in an environment close to real clinical settings, and to provide feedback to the manufacturers of infusion pumps and infusion sets, to further optimize the infusion plan and improve the treatment effect of patients. **Methods:** To make the working state of the

infusion pump during the detection more closely resemble the actual clinical working state, that is, the input end of the infusion pump is connected to drugs, normal saline or distilled water, and the output end is connected to a device with blood pressure changes or simulating blood pressure changes, this study designs a device that simulates human blood pressure changes. This device can simulate normal human blood pressure changes, as well as the states of hypertension and hypotension. In order to investigate the influence of human blood pressure factors and drug factors on the accuracy test of infusion pumps, this study used three brands of infusion pumps, two types of liquid medications, one infusion set, an electronic precision balance scale, a human blood pressure simulation device, and a camera. Three experiments were conducted: the impact of different liquid medications on the measurement accuracy of the infusion pump in an unsimulated blood pressure state, the impact of different liquid medications on the accuracy of the infusion pump in a simulated blood pressure state, and the impact of having or not having a simulated blood pressure state on the accuracy of the infusion pump. Statistical analysis of differences was also performed. **Results:** Under the condition of no blood pressure, there is a statistically significant difference in the measurement accuracy of infusion pumps with different medication solutions; Under the condition of blood pressure, there is a statistical difference in the measurement accuracy of infusion pumps with different medication solutions; Under the same type of liquid, there is a statistical difference in the measurement accuracy of infusion pumps. **Conclusion:** The type of medication and blood pressure status are important factors affecting the accuracy of infusion pump testing. In the actual quality control process, these factors should be fully considered, and the testing process should be standardized. It is suggested that the current quality control testing process for the infusion pump's infusion accuracy be further optimized.

D: CE/HTM Capacity Building & Strategy

Clinical Engineering Capacity Building Based on 3D Modeling and 3D Printing

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Description: Robust clinical engineering capacity is vital for enhancing medical service quality, ensuring patient safety, and catalyzing technological innovation in modern healthcare. The rise of 3D modeling and printing, with their flexibility, precision, and customization, is profoundly transforming clinical engineering practices and offering new avenues for engineer training and development.

This paper explores the diverse applications of these technologies in clinical engineering capacity building. In education and training, 3D modeling and printing create accurate anatomical and pathological models, as well as detailed replicas of medical equipment. Integrated with Virtual Reality (VR) and Augmented Reality (AR), these tools provide immersive, risk-free environments for procedural simulation, significantly improving training effectiveness and knowledge retention over traditional methods, while reducing reliance on costly simulators or cadaveric resources.

For personalized medical devices, the impact is revolutionary. Using patient-specific imaging data (CT, MRI), engineers can design and 3D print custom-fit surgical guides, bespoke implants (e.g., orthopedic, craniofacial), patient-matched prosthetics, and complex surgical instruments. This personalization enhances surgical precision, reduces operating times, minimizes tissue damage, improves patient outcomes, and supports precision medicine by tailoring interventions to individual anatomies.

In medical equipment R&D, maintenance, and lifecycle management, 3D printing accelerates prototyping of new components, allowing rapid design iterations. For legacy equipment with discontinued parts, reverse engineering and 3D printing offer agile on-demand fabrication, extending equipment lifespan, ensuring service continuity, and reducing costs, especially in resource-limited settings. Custom jigs and calibration tools can also be efficiently produced.

The integration of these technologies comprehensively strengthens clinical engineers' core competencies: innovative design based on clinical needs, complex problem-solving, and interdisciplinary collaboration with physicians and designers. It also deepens understanding of material science, digital workflows, and regulatory pathways. However, widespread adoption faces challenges: material biocompatibility and sterilizability, printing accuracy, cost-effectiveness, evolving regulations for patient-specific devices, and the need for skilled personnel and initial investment.

Conclusions: 3D modeling and 3D printing are revolutionary forces, elevating clinical engineering capacity and

offering opportunities to cultivate skilled, versatile talent. Future advancements must prioritize novel materials, optimized printing processes, AI integration for design, and clear industry standards. Systematic integration of these digital tools into clinical engineering, alongside robust collaborations, will sustainably enhance service capabilities, contributing significantly to global healthcare innovation and human well-being.

D: CE/HTM Capacity Building & Strategy

Standardization Study on the Standardized Training System for Clinical Engineers in Medical Institutions

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Objective: This study aims to establish a scientific, systematic, and operable standardized training system for clinical engineers, in order to fill the domestic gap in this field and promote the development of clinical engineering disciplines. By clarifying key elements such as training objectives, content, methods, and assessment, the study seeks to achieve standardization and homogeneity in clinical engineer training, thereby enhancing their professional skills and providing a solid guarantee for medical quality and safety. **Method:** A drafting group consisting of clinical engineering experts from medical institutions, representatives of clinical engineers, and professionals from industry associations was formed to take charge of the drafting work of the system standards. Through online and offline communication with foreign experts, reviewing domestic and foreign literature, standards, and norms, as well as conducting field research and questionnaire surveys on the current status of clinical engineer training in medical institutions of different levels in China, a large amount of data and information was collected. Based on thorough research and considering the actual situation and development needs of medical institutions in China, the first draft of the standardized training system for clinical engineers in medical institutions was constructed, with reference to advanced training concepts and methods both domestically and internationally. Through organizing internal group discussions, expert seminars, and pilot verifications, the framework structure, main content, technical indicators, and other aspects of the standard were repeatedly discussed, revised, improved, and optimized. **Result:** This system standard clarifies the importance of a standardized training system for clinical engineers in medical institutions and provides a systematic, scientific, and standardized guiding framework for their training. It stipulates key elements such as training objectives, content, methods, and assessment, ensuring the systematicness and standardization of the training. At the same time, pilot verifications have demonstrated their feasibility and effectiveness. The formulation of the standard not only aligns with the job requirements of clinical engineers and the laws of talent development but also closely centers around actual clinical needs, emphasizes the cultivation of practical abilities, and focuses on the forward-looking and coordinated nature of the training. **Conclusion:** The "Standardization Study on the Standardized Training System for Clinical Engineers in Medical Institutions" will effectively enhance the professional skills of clinical engineers, standardize their operational behavior, and thus ensure the safe and efficient operation of medical equipment, providing a solid guarantee for medical quality and safety. At the same time, the establishment of this system will also provide a strong talent guarantee for the sustained and healthy development of medical engineering disciplines and promote the comprehensive improvement of medical technology levels. Therefore, this system standard holds significant practical significance and wide application value.

D: CE/HTM Capacity Building & Strategy

Research on the Construction of a Comprehensive Clinical Evaluation System for ECMO under Medical-Engineering Integration

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Objectives: Extra-Corporeal Membrane Oxygenation (ECMO), a critical intensive care support therapy, requires a comprehensive evaluation of its safety and economic efficiency. However, there is a lack of post-market clinical comprehensive evaluation for ECMO. This study aims to establish a clinical comprehensive evaluation framework for ECMO's effectiveness, safety, reliability, and health economics, fill the gap in post-market evaluation, provide innovative ideas for ECMO localization, and promote medical institutions to introduce relevant policies and standards.
Methods: Preliminary indicators were summarized through a literature review, followed by a Delphi method questionnaire survey among 72 experts (52 clinical experts from ICU, neonatology, cardiac surgery, etc., and 20 management experts from medical engineering and administrative departments). The importance of indicators was scored using a Likert scale (1-10), and indicators under the same dimension were ranked. Suggestions for product innovation and ECMO management were proposed based on clinical needs.
Results: Expert Authority: Experts were from 10 provinces, over 90% from tertiary grade A hospitals, with working experience >10 years and intermediate or higher professional titles. The authority coefficient ($Cr \geq 0.7$) confirmed their expertise.
Primary Indicators Ranking: The most concerned primary indicators included reliability (8.96), effectiveness (8.90), and key performance (8.83).
Key Secondary Indicators:

For reliability: backup pump (8.65), backup battery (8.35), and failure rate (8.27);
For effectiveness: physiological function improvement (9.04) and effective weaning rate (8.85);
For key performance: oxygenator and centrifugal pump head (9.17), coating (8.92), and flow/rotation precision (8.85);
For body complications: hemorrhage (9.04), thrombosis (8.96), and neurological complications (8.94);
For mechanical complications: pump head dysfunction (9.37), pipeline issues (9.25), and oxygenator failure (9.21);
For transportation: equipment battery life (8.98), portability (8.96), and anti-vibration capacity (8.96).

Conclusions:

Reliability: Clinical priority requires backup pumps/batteries and failure rate reduction;
Effectiveness: Closely related to patient conditions and clinical operation skills, necessitating enhanced training and guideline compliance;
Key Performance: Differentiators (e.g., oxygenator, pump head, coating) significantly influence procurement decisions;
Safety: Body complications (hemorrhage, thrombosis) and mechanical failures (pump/pipe issues) require strict prevention;
Transportation: Improvements in battery life, portability, and integration are critical;
Economy & Service: Consumable costs and medical insurance coverage affect economic efficiency, while after-sales service and training enhance usability;
Medical-Engineering Integration: Facilitates cross-departmental collaboration, promoting ECMO localization and hospital management improvement.

D: CE/HTM Capacity Building & Strategy

Unity3D-based MRI Virtual Simulation System

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This paper carries out the design and realization of a virtual platform for a superconducting MRI system structure and clinical scanning. The key components of the superconducting MRI imaging system were designed, and the whole process of clinical scanning was simulated, as well as the influence of scanning data on imaging quality. The main research contents are: (1) The MRI imaging principle and the structure of MRI equipment are studied; (2) The overall

design of the superconducting MRI virtual platform was carried out; (3) The virtual scene and key component modeling of the superconducting MRI virtual simulation platform were implemented; (4) Realized the clinical scanning and other functions of the superconducting MRI system in the virtual clinical environment. We have tested the function of the MRI virtual simulation platform and packaged and released the simulation platform in a Windows environment, which can be used on both the WebGL side and the Windows side. The platform realizes a high degree of simulation of the structure of MRI equipment, allowing users to immerse themselves in the disassembly and assembly of key components such as magnets, gradient coils, RF coils, and so on. It also allows the user to experience the routine steps of clinical scanning, which is convenient for people who use the platform to study and research MRI systems. The platform provides a new set of medical imaging virtual devices for the virtual device field and a new way of learning in the MRI field.

D: CE/HTM Capacity Building & Strategy

Comprehensive Analysis of Equipment Failures in Renal Care: Insights from Hospital Incident Reports and Global Surveillance Data

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Millions of patients worldwide are dependent on renal equipment for life-sustaining treatment, making its reliability and safety crucial. This comprehensive study analyses renal equipment-related incidents in healthcare settings through a systematic examination of past incident reports from public hospitals in Hong Kong, supplemented by comparative data from an overseas online surveillance database. Root cause analysis (RCA) was performed on the incidents to identify underlying causes. The analysis identified diverse failure modes, including mechanical degradation, electrical malfunctions, water system failures, software issues, network vulnerabilities, and human factors. The insights gained were considered in a Failure Mode and Effects Analysis (FMEA). Within the framework, risk assessment was performed based on severity, occurrence, and detectability scores to identify high-risk items requiring prioritized mitigation. Key findings reveal that mechanical failures and human factor issues remain the most prominent factors of equipment failure. Human factors analysis exposed knowledge gaps between clinical and technical domains, cognitive overload during multi-device failures, and procedural variations. The increased connectivity, software proliferation, cybersecurity, and software update threats of medical device have also introduced growing risks of operational disruptions and compromised patient safety. This study demonstrates that ensuring renal equipment reliability and safety in modern renal care requires strategies spanning biomedical engineering, information technology, and organizational design. Recommendations span five domains: technical infrastructure improvements; predictive maintenance strategies; integrated monitoring systems for the infrastructure and equipment; organizational improvements addressing human factors; and continuous improvement frameworks.

D: CE/HTM Capacity Building & Strategy

Computational Hemodynamic Characterization of Intracranial Atherosclerotic Plaques in Middle Cerebral Artery Stenosis: A Patient-Specific CFD Approach

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Intracranial atherosclerotic stenosis of the middle cerebral artery (MCA) constitutes a major cause of ischemic stroke, particularly prevalent in East Asian populations. Despite its clinical importance, quantitative characterization of the hemodynamic environment associated with MCA plaques remains limited. This study aims to develop a patient-specific computational fluid dynamics (CFD) framework to systematically evaluate the local hemodynamic alterations induced by MCA stenosis, providing mechanistic insight into stroke risk stratification. High-resolution magnetic resonance angiography (MRA) data were acquired from patients diagnosed with moderate-to-severe unilateral MCA stenosis. The vascular geometries were reconstructed using Mimics and 3-Matic, followed by geometric smoothing, surface repair, and tetrahedral meshing. Blood flow was modeled as an incompressible Newtonian fluid under laminar flow assumptions (Re < 100), with physiological boundary conditions applied based on population-averaged intracranial circulation parameters. Hemodynamic parameters of interest included wall shear stress (WSS), translesional pressure ratio (PR), and wall shear stress ratio (WSSR). Simulations revealed localized elevations in WSS at the plaque throat, with average WSS reaching 1.254 Pa, and lesion-site pressure approximating 14,646 Pa. PR and WSSR exhibited significant variation across degrees of stenosis, indicating their sensitivity to pathological narrowing and utility in quantifying hemodynamic disturbance. Post-processing was conducted using a custom Python-based pipeline for batch analysis and statistical extraction, enhancing both reproducibility and computational efficiency. Visualizations clearly demonstrated the redistribution of hemodynamic forces and the amplification of shear gradients in stenotic regions. This study demonstrates that CFD modeling, grounded in patient-specific vascular geometry, offers a powerful tool for assessing intracranial plaque biomechanics. By quantifying flow-derived metrics with high spatial fidelity, this approach provides clinically relevant biomarkers that may support early diagnosis, risk prediction, and therapeutic decision-making in intracranial atherosclerosis. The integration of CFD into neurovascular diagnostics could inform personalized intervention strategies and contribute to stroke prevention efforts.

D: CE/HTM Capacity Building & Strategy

The Role of MeDevPacks in Advancing Universal Health Coverage (UHC) and Global Medical Device Nomenclature

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As countries accelerate progress toward Universal Health Coverage (UHC), the ability to translate clinical interventions into practical technology requirements becomes essential. While the WHO Universal Health Coverage Compendium (UHCC) offers a structured catalogue of evidence-based interventions and associated health product needs, it cannot directly identify the specific medical devices required due to the complexity of device utilization, contextual variability, and shared use across interventions. To bridge this gap, the World Health Organization developed MeDevPacks—an extension of the Medical Devices Information System (MeDevIS) designed to provide structured, contextualized groupings of medical devices tailored to specific clinical interventions and healthcare delivery settings.

MeDevPacks organizes devices into preconfigured packages such as sets, kits, modules, and consumables. These packages are linked to distinct care environments—primary clinics, surgical centers, emergency units—and reflect real-world device dependencies. For example, a surgical procedure might require a lighting module, a reusable instrument set, and a set of sterile consumables. By categorizing devices in this layered and structured manner, MeDevPacks ensures completeness and relevance while allowing flexibility across diverse healthcare systems.

Importantly, MeDevPacks is central to WHO's response to the 2023 World Health Assembly resolution calling for a universal nomenclature for medical devices. Existing systems such as the European Medical Device Nomenclature (EMDN) and the Global Medical Device Nomenclature (GMDN) provide vital classification standards, but they lack the ability to represent devices in use-case-specific groupings. MeDevPacks fills this gap by introducing healthcare setting ontologies and package-level taxonomies that complement existing nomenclature systems, enabling integration at both device and package levels. This enhanced nomenclature supports smarter procurement workflows, allowing for the requisition of interoperable and complete packages instead of fragmented lists, while also enabling inventory standardization and improved safety monitoring.

Beyond procurement, MeDevPacks contributes to health system strengthening by informing technical education and work-

force development. It enables the design of curricula aligned with real-world clinical packages and supports simulation and digital twin modeling for facility planning and scenario testing. Looking ahead, the structured architecture of MeDevPacks provides a foundation for training and deploying domain-specific large language models (LLMs). These models can offer practical, context-sensitive guidance to biomedical engineers, procurement officers, and healthcare planners—for example, checking completeness of device sets, proposing alternatives in resource-constrained settings, or enabling just-in-time training for complex procedures.

The successful development of MeDevPacks was the result of a collaborative global effort. Experts and consultants—including Niccolò Binello, Giulia Russo, Anita Gadgil, Monty Khajanchi, Olga Pineda Velasquez, Fernando Prieto, Mladen Poluta, Luis Fernandez, Roberto Ayala, Eunice Lorenco, and Sasikala Thangavelu—played key roles in classification, package definition, and domain-specific device selection. The web platform was built by Evidence Prime under the leadership of Artur Nowak, with contributions from Helen Dietl, Kuba Kulesza, Maciej Radym, Eryk Stańdo, and Przemysław Romanik.

In summary, MeDevPacks represents a new layer of digital health infrastructure—one that aligns medical device data with clinical priorities, supports global nomenclature harmonization, and enables the intelligent, equitable use of medical technologies in the journey toward universal health coverage.

D: CE/HTM Capacity Building & Strategy

Comparative Analysis of the Profile of Clinical Engineering Activities in Hospitals in Brazil and Ghana

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The role of Clinical Engineering (CE) in Health Technology Management (HTM) in hospital settings is essential to ensure the safe and reliable use of medical devices. There is a large discrepancy in the role of CE in different healthcare establishments. The differences include the activities performed during the technology life cycle, the professionals involved, the services performed externally and externally, among others. This research aims to highlight the profile of CE activities in hospitals in Brazil and Ghana by applying a virtual questionnaire. A total of 30 participants who work in hospitals were invited to participate in the survey, 18 participants from Brazil and 12 from Ghana. Regarding the training of the participants from Brazil, the breakdown is as follows: 44.4% biomedical engineers, 22.2% technologists, 22.2% other engineers, and 11.1% technicians. Regarding Ghana, 83.3% of biomedical engineers, 0.83% of healthcare professionals, and 0.83% of other engineers.

In Brazil, 55.5% had their own CE teams, 33.3% were outsourced teams, and 11.1% had both. In Ghana, 50% had a hybrid CCE department and 50% had their own hospital, with all participants from public hospitals. Regarding the number of hospital beds, the average in Brazil was 249.14(standard deviation 206.7). In Ghana, the average was 429.9 (standard deviation of 475.2). Regarding the work team, in Brazil, the average number of professionals was 13.22, and in Ghana, it was 10.58. The average number of Brazilian engineers per sector was 3.11, and technicians 7.27, and in Ghana, the average number of engineers was 4.58 and technicians 2.08. In Brazil, the equipment with the highest number of failures was: monitor, infusion pump, pulmonary ventilator, and autoclave. In Ghana, CT scanners, MRIs, autoclave, monitors, and aspirators.

About activities realized internally, in Brazil: all reported inventory and training; 94.4% technology incorporation, maintenance program, calibration, installation, and obsolescence assessment; 88.8% financial management, indicator analysis, and risk management; 83.3% corrective and preventive maintenance and adverse event management internally; 50% qualification. In Ghana, perform internally: 91.6% maintenance and corrective maintenance internally, 75% preventive maintenance; 66.6% inventory; Indicator analysis, financial management, risk management, adverse event management, and qualification were mentioned by only one professional. In Ghana, 75% of hospitals perform some external technical intervention, in Brazil, 88.8%.

In Brazil, 83.3% have a computerized system for management. In contrast, in Ghana, 83.3% do not have a computerized system. Regarding the subjects of greatest interest, both in Brazil and Ghana, the most cited are related to HTM and

equipment maintenance. The challenges highlighted by Brazilian professionals include resource management, misuse of technologies, lack of qualified labor and training, lack of professionals to meet demand, and lack of traceability. In Ghana, 75% pointed to the unavailability of spare parts, followed by the lack of analyzers and simulators, the lack of resources, and the lack of training.

This study confirmed the diversity of the CE sectors and activities performed in Brazil and Ghana. For future work, the researchers aim to expand the research to more professionals in other countries, to consolidate the profile of the CE sectors worldwide and raise awareness of the main challenges in order to develop better practices in HTM.

D: CE/HTM Capacity Building & Strategy

3D Printing in Western and Chinese Medicine: High-Risk Procedure Training and Simulation

By Oliver Chan*

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Western medicine treats disease and dysfunctional ailments as they arise. The foundation of Western medicine is based on Western science. Chinese medicine, on the other hand, provides more preventative care, treats early, and rehabilitation that works to make sure body systems, including the immune and digestive systems, are functioning at their best state. Different from Western medicine, Chinese medicine is based on traditional Chinese five-element and meridian theories, which cover 14 meridians and 670 acupoints. Integrating Chinese medicine with Western medicine has proved effective in treating various diseases, such as COVID-19. However, there is a lack of opportunity for collaboration between these two groups of professionals, which hinders the development of this unique strength of our healthcare system in Hong Kong.

Artificial intelligence is a field of science concerned with building computers and machines that can reason, learn, and act in such a way that would normally require human intelligence or that involves data whose scale exceeds what humans can analyze. 3D printing is an additive construction process whereby layers of material are built up to create 3D components.

In 2023, Pamela Youde Nethersole Eastern Hospital (PYNEH) applied Artificial Intelligence Aided Segmentation for 3D Printing of human organs with Ultrasound (US) visible and tactile reality for western medicine in high-risk procedure training and simulation. In 2021, the Hong Kong Medical Sciences Society (HKMMSS) invented a 3D Printed Copper Acupuncture human model for Chinese medicine training. In 2024, a multidisciplinary team composed of medical physicists, biomedical engineers, Western and Chinese medicine practitioners in PYNEH and HKMMSS has been developing a 3D printing-verified Artificial Intelligence Acupoint Finder (AIAF). It is planned to be installed in the PYNEH Geriatric ward. It provides identification of the 3D positions of acupoints to facilitate exercising various maneuvers for elderly patients with related illnesses and enhance preventive care via Chinese medicine.

Our Product is highly recommended by the assessors of Shenzhen Hospital Accreditation Research Center during the assessment of PYNEH under the China's International Hospital Accreditation Standards (2021 Version). Our Product is not only a physical model, it is a "bridge", a "culture contact", to enable collaboration between Chinese and Western practitioners.

In AIAF, the library was adopted for searching for 670 acupoints and 14 meridians of the human body. To start building an AI acupoint model, a commercial acupuncture training model was scanned using a laser-based 3D surface scanner. Using an optimization method on the scanned data and the captured 3D landmarks, the AI model was created. It has been verified by a group of Chinese medicine practitioners in universities. Initially, ten massage exercise videos were made with the help of AIAF for ten different illnesses. These videos can help users to do correct exercises on the correct acupoints with the AIAF.

Since 2019, models for Thoracentesis (Medical), Vascular Cannulation (Intensive care unit), Robotic Partial Nephrectomy (Surgical), Cranioplasty and Ventricular Drainage (Neurosurgery), Stenting for Brain and Aorta Aneurysms (Radiology) have been developed for Western medicine. Ten massage exercise videos of the digestive system, back pain, headache, face and mouth, heart, gynecology, kidney, and general pain diseases were prepared for Chinese medicine.

In conclusion, 3D Printing and Artificial Intelligence techniques can work together for the good of patients in western and Chinese medicines.

D: CE/HTM Capacity Building & Strategy

Integrating NSF Biosafety Cabinet and CETA Sterile Compounding Standards for Enhanced Healthcare Environmental Safety

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Background: Environmental safety in healthcare facilities requires comprehensive protection of healthcare workers, products, patients, and the environment through integrated management of both laboratory and pharmaceutical environments. As healthcare institutions increasingly focus on patient safety and regulatory compliance, the integration of multiple safety standards becomes critical. This presentation explores the practical implementation of dual certification standards—NSF Enhanced Biosafety Cabinet Field Certification and CETA Sterile Compounding Facility Certification—within a JCI-accredited cancer care facility, demonstrating how integrated approaches enhance overall environmental safety performance. **Objective:** To demonstrate the effectiveness of implementing integrated NSF biosafety cabinet and CETA sterile compounding facility standards in achieving superior environmental safety outcomes while maintaining regulatory compliance across multiple healthcare departments, including pathology, pharmacy, and clinical laboratories. **Methods:** With 17 years of biomedical clinical engineering experience, including extensive biosafety cabinet management and experience in sterile compounding safety fields, an integrated approach was developed around fume hoods and biosafety cabinet systems at Shaukat Khanum Memorial Cancer Hospital. As one of the exceptionally few professionals worldwide holding both rigorous NSF Enhanced Biosafety Cabinet Field Certification (about 656 global certifiers) and CETA Sterile Compounding Facility Certification (about 200–300 global certifiers), this unique qualification combination enabled the development of an integrated methodology. The methodology included: systematic environmental assessments using NSF/ANSI 49 protocols for biosafety cabinet performance testing and ASHRAE 110 for fume hood testing protocols; implementation of USP <797> and <800> standards for sterile compounding facilities; integration of clean room ACPH (Air Changes Per Hour) calculations, particle count monitoring, and air balancing verification under ISO 14644 standards; application of ISO 14971 risk management guidelines; and comprehensive staff training programs covering both certification standards. **Results:** The integrated dual-certification approach achieved significant outcomes: near-zero contamination incidents across all biosafety cabinet systems; successful maintenance of JCI accreditation and ISO 9001:2015 certification; compliance with international standards, including ISO and USP guidelines; and successful implementation across multiple hospital departments, including pathology, operating theaters, and compounding pharmacy. The comprehensive approach enabled effective contamination control while maintaining stringent regulatory compliance standards. The methodology proved particularly effective in the complex environment of a cancer care facility with multiple international accreditations (ASHP, QOPI-ASCO, and CAP), demonstrating the scalability and effectiveness of integrated certification standards. **Conclusion:** The integration of NSF biosafety cabinet and CETA sterile compounding facility standards provides a comprehensive framework for healthcare environmental safety management. This dual-certification approach not only ensures regulatory compliance but also enhances patient safety, healthcare worker protection, product integrity, and environmental safety through systematic contamination control and equipment reliability. The success demonstrated at a major cancer care facility validates this integrated model as a best practice for clinical engineering departments worldwide, particularly in institutions requiring the highest levels of environmental safety and regulatory compliance.

D: CE/HTM Capacity Building & Strategy

Certification of Clinical Engineering Departments and Training Programs in Brazil: Building a National Model with ONA and Abeclin

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Description: This proposal expands the previous ONA-Abeclin certification scope to include internal Clinical Engineering departments and specialization programs. It integrates lessons from the Qualification Seal applied to external services and aligns them with NBR 15.943 and global standards. The model promotes quality assurance in both operational settings and academic training, aiming to professionalize and regulate Clinical Engineering across Brazil.
Goals of the project and final users that will benefit: This proposal expands the previous ONA-Abeclin certification scope to include internal Clinical Engineering departments and specialization programs. It integrates lessons from the Qualification Seal applied to external services and aligns them with NBR 15.943 and global standards. The model promotes quality assurance in both operational settings and academic training, aiming to professionalize and regulate Clinical Engineering across Brazil.
Results: Creation of the GDI International Discussion Group to raise the profile of the clinical engineer and define a minimum curriculum for specialization courses; Proposed indicators for operational and educational quality; Initial validation strategy with pilot departments and academic institutions; Integration with WHO UHC frameworks and use of MeDevIS/MeDevPacks ontology to support global alignment; Ongoing dialogue with national and international regulatory bodies.

E: CE/HTM Challenges & Solutions in LMICs

Research on the Construction of an Evaluation System for the Use and Maintenance Decisions of Emergency Life Support Equipment

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With the intensification of regulatory oversight on medical equipment, industry experts have increasingly focused on the utilization assessment and benefit analysis of large-scale medical equipment. However, the evaluation and benefit analysis of emergency life-support medical equipment has not garnered sufficient attention. Consequently, it is imperative to establish a unified evaluation framework grounded in scientific methodologies and tools for life-support medical equipment. Currently, the assessment of emergency life-support medical equipment predominantly centers on technical and safety performance. Nevertheless, indicators associated with application outcomes and maintenance (such as therapeutic efficacy, ease of use, durability, and maintenance costs) deserve adequate consideration. Researching and evaluating these indicators can enhance the overall performance of medical equipment and guide procurement and utilization decisions within healthcare institutions. To validate the applicability of the evaluation indicators for large medical equipment obtained through extensive literature reviews, infusion pumps, which are a type of life-support equipment, were employed as a case study. It was observed that only the evaluation indicators related to usage and economic benefits demonstrated some data variations. However, the substantial differences in maintenance and repair among various brands of infusion pumps, which generate a large volume of data during daily operations, were not adequately captured by any existing indicators. Consequently, based on an analysis of fault occurrences in emergency life-support equipment at Beijing Obstetrics and Gynecology Hospital, Capital Medical University, from 2017 to 2024, the Analytic Hierarchy Process (AHP) and two rounds of the Delphi method were utilized to construct a comprehensive indicator system. This system evaluates medical equipment holistically across dimensions such as clinical application indicators, equipment management indicators, and hospital operation indicators, thereby establishing a robust evaluation framework, thus providing a reliable reference basis for medical equipment procurement decisions.

E: CE/HTM Challenges & Solutions in LMICs

Vacuum Pressure Swing Adsorption (VPSA): A Transformative

Approach to On-Site Medical Oxygen Generation

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The global demand for dependable and energy-efficient medical oxygen generation has significantly increased, particularly following the COVID-19 pandemic, which highlighted the urgent necessity for decentralized and scalable solutions. Pressure Swing Adsorption (PSA) technology has traditionally been the predominant method for on-site medical oxygen production due to its rapid implementation and cost-effectiveness. However, PSA systems are constrained by their energy efficiency, with power consumption levels ranging from 1.5 to 2.0 kWh/m³, which limits their economic feasibility in resource-limited environments. This paper presents Vacuum Pressure Swing Adsorption (VPSA) as an innovative advancement that utilizes vacuum-assisted desorption to achieve a reduction in energy consumption by 40% to 50% (0.8 to 0.9 kWh/m³), representing a significant advancement in on-site oxygen generation technology. VPSA functions by cyclically adsorbing nitrogen from ambient air at moderate pressure and regenerating the adsorbent under vacuum conditions, thereby minimizing the pressure differential necessary for separation. This method substantially decreases energy requirements while maintaining oxygen purity levels between 90% and 95%, which is comparable to that of conventional PSA systems. The design of VPSA includes optimized adsorbents specifically developed for vacuum cycles, high-efficiency vacuum pumps, and energy recovery systems to further enhance sustainability. The modularity, a successful characteristic of PSA systems, is preserved in VPSA to ensure adaptability across various environments, including tropical regions and high-altitude areas, while addressing challenges such as temperature variations, humidity, and air quality. Essential components comprise advanced vacuum modules, multi-stage filtration systems, and intelligent controls with real-time monitoring capabilities to ensure operational reliability under harsh conditions. Prototype assessments indicate that VPSA systems can achieve adsorption-desorption cycles that are 30% faster than those of PSA, thereby reducing downtime and enhancing oxygen yield. Field trials conducted in remote healthcare facilities demonstrate the system's robustness, with consistent performance at altitudes exceeding 3,000 meters and ambient temperatures ranging from -20°C to 50°C. The decreased energy footprint not only reduces operational costs but also aligns with global sustainability objectives, facilitating the integration of solar or hybrid power solutions for off-grid applications. In summary, VPSA represents a paradigm shift in medical oxygen generation, providing a safer, more economical, and environmentally sustainable alternative to PSA. Its modular design, combined with substantial energy savings, positions VPSA as a cornerstone technology for enhancing access to medical oxygen in underserved regions. This research highlights the potential of VPSA to revolutionize healthcare infrastructure, particularly in low-resource settings, while contributing to climate resilience through diminished carbon emissions. Future research will concentrate on scaling prototypes for industrial production and optimizing adsorbent materials for broader operational ranges involving pressure and vacuum.

E: CE/HTM Challenges & Solutions in LMICs

Cochlear Implant Program Quality in Guatemala: A Biomedical Engineering Approach

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Background and Objectives: In Guatemala, Cochlear Implant Treatment (CIT) for profound hearing loss is constrained by high costs, complex procedures, and limited rehabilitation. Although NGOs offer some aid, its scope is insufficient. A major Guatemalan healthcare institution engaged UNOPS (United Nations Office for Project Services) in August 2018 to procure implants and related support services for paediatric beneficiaries. The requirement established

guidelines for the regulatory aspects to be considered in the definition and procurement of the Cochlear Implant System (CIS), along with related services for surgical assistance, post-implant auditory-verbal rehabilitation, and calibration and maintenance. This article details a robust contractual definition, developed from a biomedical engineering perspective, to ensure quality throughout implementation and rehabilitation, and support proper contract development. **Methodology:** Cochlear Implant Therapy (CIT) for paediatric patients with profound hearing loss necessitated a multidisciplinary approach. Selection criteria encompassed clinical factors like age, hearing loss characteristics, radiological findings, and a psychosocial analysis crucial for rehabilitation success. The biomedical engineer's role involved identifying and systematizing regulatory, operational, and management aspects for implant procurement and related services, including surgical and rehabilitation support, during contract development. This involved engaging stakeholders to identify their specific needs and maintaining a consistent focus on these needs throughout the procurement, implantation, and rehabilitation phases. A key challenge involved harmonizing diverse requirements into a standard protocol while preserving individualized patient care. The methodology also addressed local limitations, including scarce suppliers, an evolving regulatory framework, a shortage of specialized medical personnel, and inadequate surgical and rehabilitation facilities. An essential methodological aspect was tailoring procurement procedures to healthcare professionals' needs, enabling them to select optimal device configurations. Initially, device configuration options, particularly electrode types, were restricted due to regulatory and market availability risks. As the market matured, these options expanded, allowing neuro-otologists more flexibility in tailoring treatment for each patient's specific condition. **Results:** The developed methodology facilitated the successful implantation of 52 paediatric patients across various circumstances. The contractual development period was influenced by two events: the COVID-19 pandemic and a voluntary corrective field action by the CIS manufacturer. The contractual definition, including robust validation, monitoring, accompaniment, and evaluation, aligned all stakeholders to achieve the project's envisioned hearing rehabilitation objectives. It also enabled institutional coding, which continues to allow for the acquisition of CIS and related services. Strategies were defined to address requirements, enabling the implementation of diverse configuration options for the variety of pathologies encountered. Patient's quality of life increased, along with compliance with speech therapy rehabilitation. As a secondary outcome, the project broadened the local market for CIS and related services. **Conclusion:** A properly defined set of requirements across all stages—procurement, contractual development, monitoring, evaluation, and quality assurance—is key to maximizing the potential of CIS interventions and related services. Adapting these requirements to the specific needs of patients is essential for maximizing outcomes in speech therapy rehabilitation. Achieving this requires the essential participation of medical and healthcare personnel to address patients' needs from a comprehensive perspective, with the Biomedical Engineer playing a key role in the presented Guatemala project in understanding and implementing user needs.

E: CE/HTM Challenges & Solutions in LMICs

Mobile Biomedical Equipment Deployment Strategies for Flood and Cyclone-Affected Zones in Bangladesh

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Bangladesh is highly vulnerable to frequent floods and cyclones, which often cause widespread damage to healthcare infrastructure and disrupt essential medical services. During these disasters, the timely availability and deployment of mobile biomedical equipment—such as oxygen concentrators, patient monitors, and ventilators—are vital to maintaining emergency healthcare, especially in remote and severely affected areas. However, Bangladesh currently lacks

a coordinated national strategy to efficiently manage and deploy such equipment during crises, resulting in delays that compromise patient care and increase mortality risks. This study aims to develop effective and sustainable deployment strategies for mobile biomedical equipment tailored to the country's flood and cyclone-prone regions. Using a mixed-methods approach, the research will collect data through surveys and interviews with healthcare professionals, biomedical engineers, and disaster management authorities in high-risk districts, including Khulna, Barishal, and Cox's Bazar. The study will also review best practices from both national and international contexts to identify gaps and challenges in equipment availability, mobility, and maintenance during emergencies. Based on these findings, a practical, scalable framework will be designed to guide the rapid deployment, operation, and management of mobile biomedical devices in disaster-affected areas. The framework will emphasize coordination among government agencies, healthcare providers, Non-Governmental Organizations (NGOs), and other stakeholders to optimize resource mobilization and emergency response. Expected outcomes include enhanced disaster preparedness, improved continuity of emergency healthcare services, and reduced morbidity and mortality during floods and cyclones. Ultimately, this research will contribute to strengthening Bangladesh's health system resilience by ensuring critical biomedical equipment reaches those in need promptly and efficiently during natural disasters.

E: CE/HTM Challenges & Solutions in LMICs

LMIC EHR Project to Serve Last Mile Patients

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Goal

The goal of this initiative is to provide a sustainable EHR solution for LMICs, particularly those serving last-mile patients—typically defined as patients in small villages in poorer countries lacking adequate access to evidence-based healthcare services using clinically appropriate medical devices and digital health tools. Faith-based values drive this effort for a multi-national EHR system in challenging locations.

The EHR is

- Designed for a proactive versus reactive system for Clinics
  - Designed for Preventive Care as well as ongoing normal Episodic Routine care in the Primary setting
  - Designed for Well-being, including Spiritual, Mental, Emotional, and Family care
  - Also designed for connecting to and Referral to Secondary & Tertiary care as needed for patients
- Designed to best connect to national health EHR systems
  - Allowing the government to pay as appropriate
  - Patients to receive the best cost-effective care possible
    - Co-payment system needed in this solution, e.g., Patient, Government, Churches, NGOs, etc.

Potential EHR Solution Managers and Budget

- New development
  - Highly credible Ecuadoran colleagues can assist ($2k/month USD for 2 people) as Full Stack Developers
  - Cloud-based Hosting service, e.g., AWS (paid by a TBD international NGO)
  - Budget of $2.5k per month for developing and then supporting, website and web services
  - A new initial development approach
- Work with existing development
  - Other Colleague organizations for development approach also being considered, e.g., OpenMRS: regenstrief.org, the source of the OpenMRS project https://www.regenstrief.org/real-world-solutions/
  - A partner needs to be chosen to host and store the Data, e.g., India (TBD).

Provider EHR Clients—Needed Roles

- Administrator(s)—locally—highest level of overview of system operation
- Users of the System—local clinical practitioners, e.g., physicians and nurses
- Patients—access to their info and test results
- Allied Health supporting centers—Lab, Imaging, Pharm integrated into system (Interop, partial?)

- Pastors/Ministry Leaders—connected to link with appropriate patients & provide support

Pending Case Studies

- Indonesia
- India
- Haiti

Timetable

- If the initial Solution approach, development, and implementation could begin in 2025
- Hire and Host—2 months to deploy with Android-based Cell Phone platform, so $5k up front
- Ongoing $2.5k / month to enable support
- Fee for Service (FFS)—as data to be managed—service costs will increase for Clients, e.g., $20/month per clinic

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E: CE/HTM Challenges & Solutions in LMICs

Early Accurate Prediction of Thrombosis Risk in Lung Cancer Patients with PICC Based on Multi-Dimensional Biomarkers Dynamic Monitoring

By Li Shen*

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Background: Lung cancer is one of the most common malignant tumors with high incidence and mortality worldwide. Many patients need a Peripherally Inserted Central Catheter (PICC) placement for chemotherapy. However, PICC placement is associated with a risk of thrombosis, which can affect treatment and lead to complications like pulmonary embolism. Early, accurate prediction of thrombosis risk is crucial for improving prognosis. **Methods:** 215 lung cancer patients were prospectively included. Blood samples were collected before PICC placement and on days 1, 5, 9, and 13 after placement to measure the levels of TM, ATIII, DD, IL-1β, and TNF-α. Thrombosis was confirmed by Doppler ultrasound. A prediction model was established using statistical analysis. **Results:** The thrombosis incidence was 25.1% ($n = 54$). In the thrombosis group, TM levels rose gradually, ATIII levels dropped gradually, DD levels increased significantly on day 1 after placement, and IL-1β and TNF-α levels peaked on day 5. Based on these dynamic changes, a prediction model was built, which effectively predicted the thrombosis risk. It had an AUC of 0.87, indicating good performance. The optimal prediction threshold was 0.5 (Youden index), with a sensitivity of 82.1% and specificity of 78.3%. **Conclusion:** Dynamic multidimensional biomarker monitoring enables early, accurate prediction of thrombosis risk after PICC placement in lung cancer patients, offers a basis for clinical nursing, helps develop personalized nursing interventions, reduces thrombosis, and improves treatment outcomes and quality of life.

E: CE/HTM Challenges & Solutions in LMICs

A Review: Prominent Authors in Human Factors Engineering in Aviation—The Brazilian Example

By Anderson Alberto Ramos*

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The study presents a comprehensive and detailed analysis of plane crash scenes, focusing on identifying 24 recurring errors that significantly contribute to the occurrence of these tragic events. These errors encompass a wide range of factors, including technical malfunctions, human mistakes, environmental conditions, and procedural shortcomings. Systematically examining these errors, the research provides valuable insights into the complex interplay of causes leading to aviation accidents.

One key aspect highlighted in the study is the role of human error, a critical factor in aviation safety. Pilots, air

traffic controllers, maintenance personnel, and other stakeholders can inadvertently make mistakes due to fatigue, miscommunication, inadequate training, or stress. The study categorizes these human errors into different types, such as decision-making failures, lapses in attention, and procedural violations, each contributing uniquely to accident scenarios.

Besides human factors, the research also emphasizes technical failures, e.g., mechanical breakdowns, system malfunctions, and design flaws. These issues can arise from manufacturing defects, poor maintenance, or unexpected wear and tear, underscoring the importance of rigorous inspection routines, PM, and technological advancements to minimize the risk of such failures.

Environmental factors also play a significant role in aviation accidents. Weather such as fog, storms, wind shear, and icing can severely impact flight safety. The research analyzes how pilots and systems respond to these challenges and identifies common errors made when dealing with adverse weather. Understanding these interactions is crucial for developing better training programs and improving weather forecasting tools.

Procedural errors, including deviations from established protocols and inadequate communication among crew members and ground control, are examined, revealing that lapses in following standard operating procedures often exacerbate other errors, leading to a chain reaction culminating in accidents. This finding highlights the need for strict adherence to procedures and continuous training to reinforce best practices.

The study also brings attention to researchers who extensively address aviation-related errors, a critical view of both technical and human failures, contributing to a deeper understanding of flight safety challenges. By reviewing the literature and incorporating various expert perspectives, the research is situated within a broader academic and practical context, acknowledging the ongoing efforts to enhance aviation safety worldwide.

The ultimate goal is to understand recurring errors thoroughly to support future surveys and studies to reduce the occurrence of aviation accidents. By identifying patterns and root causes, the study provides a foundation for developing improved safety protocols, training, and technological innovations. These advancements are essential for mitigating risks and protecting the lives of passengers, crew, and people on the ground.

The findings contribute to the continuous improvement of aviation practices and procedures, fostering a culture of safety and accountability. Airlines, regulatory agencies, manufacturers, and training institutions can all benefit from the insights, implementing changes that address identified errors effectively.

Finally, this study serves as a vital resource for the aviation community, combining detailed analysis with practical recommendations, reinforcing the importance of a multidisciplinary approach to flight safety, integrating human factors, technical reliability, environmental awareness, and procedural discipline. Through ongoing collaboration, the aviation industry can continue to advance towards safer skies for everyone.

E: CE/HTM Challenges & Solutions in LMICs

The Application and Discussion of the FMEA Model in the Preventive Maintenance of First Aid and Life Support Equipment

By Zhenzhu Chen, Zhen Chen, Yongjia Zhang, Zhengying Qian*

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Objective: Incorporate the Failure Mode and Effects Analysis (FMEA) model into the quality management of medical equipment in the hospital, and evaluate the effectiveness of the quality management of this model for the quality management of medical equipment. **Methods:** Use the FMEA model to study and analyze the failure modes of hospital emergency life support medical equipment, classify the risk alarm, calculate the Risk Priority Number (RPN), evaluate the severity of the failure mode, and formulate improvement measures. Compare the effects of risk management of emergency life support for emergency life support, and use the χ^2 test to compare the maintenance of medical equipment supporting medical equipment before and after implementation. **Results:** Through the analysis of the FMEA mode, the A-level and B-level preventive maintenance plans for emergency life support medical equipment are formulated. And the number of faults has also been reduced. Among them, the failure example of the ventilator was reduced by 42.95% ($\chi^2 = 33.08$, $p < 0.001$), the example of an anesthetic machine decreased by 31.96% ($\chi^2 = 22.12$, $p < 0.001$)) and the case of a defibrillation monitor was reduced by 46.38% ($\chi^2 = 28.96$, $p < 0.001$), and the differences were statistically significant.

Conclusion: In the preventive maintenance plan of first aid medical equipment, the application of the FMEA mode can effectively improve the integrity rate of emergency life support, and provides more sufficient guarantees for clinical safety use.

E: CE/HTM Challenges & Solutions in LMICs

Application of Clinical Engineering and BIM Methodology for the Integral Optimization of Hospital Projects: The Case of Pangoa Hospital, Peru

By Ana Aldana*, Luis Vilcahuaman

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Background/Objectives: Public investment projects in Peru's health sector frequently face cost overruns, functional misalignments, and delays, largely due to limited integration of medical-technical criteria during early project phases. These deficiencies are exacerbated by the minimal involvement of Clinical Engineering (CE) professionals during conceptualization and design stages, despite their strategic role in ensuring the operational functionality and sustainability of healthcare infrastructure. According to recent assessments, more than ninety percent of national hospitals exhibit deficiencies in medical device (MD) planning and operational readiness. This study investigates the impact of integrating CE practices into Building Information Modeling (BIM) workflows in hospital projects, using the case of Pangoa Hospital as a model for systemic improvement. **Methods:** The technical dossier of Pangoa Hospital (Junín region, Peru) was modeled in Autodesk Revit and Navisworks to Level of Development (LOD) 300, covering architectural, structural, electrical, and sanitary systems. BIM tools were employed to identify clashes and inefficiencies in the design. A Clinical Engineering evaluation was conducted post-modeling, applying World Health Organization (WHO) guidelines and Peruvian health technology regulations. The evaluation addressed spatial compatibility for diagnostic and therapeutic devices, infrastructure readiness for equipment installation, and preventive maintenance feasibility. Additional emphasis was placed on evaluating the clinical workflow logic, energy requirements, and equipment circulation paths using CE criteria from the "Design of Clinical Services" framework. **Results:** The application of BIM tools alone led to measurable improvements: a 10.38% reduction in material quantity take-offs, an 11.11% reduction in projected construction duration, and an 18.69% reduction in estimated costs—translating to savings of over three million Peruvian soles. Nevertheless, the CE assessment revealed critical gaps, including the absence of proper medical gas distribution for certain areas, insufficient electrical capacity for high-consumption equipment, a lack of IT system interoperability (e.g., PACS and HIS), and the absence of designated maintenance access zones. These findings confirmed that despite geometric coordination achieved through BIM, the design lacked functional alignment with clinical service delivery needs. **Conclusions:** BIM provides an essential framework for coordination and digital modeling in hospital projects, yet it is not sufficient to ensure technical-operational readiness. The inclusion of Clinical Engineers from the earliest stages—conceptualization, design, and detailing—is crucial to ensure that infrastructure supports safe, effective, and maintainable health technology. This case study supports the growing body of evidence advocating for regulatory reforms that institutionalize the role of Clinical Engineering in public health investment planning. By combining BIM with CE frameworks, Peru's healthcare infrastructure can move towards intelligent hospital systems that are resilient, patient-centered, and technically sustainable across their full lifecycle.

E: CE/HTM Challenges & Solutions in LMICs

ThyroMeter: A Portable Electrochemical Biosensor for Point-of-Care Detection of Thyroid Hormones (T3, T4 and TSH) in Low-Resource Settings

By Mudunuri Iandhavi*

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Description: In the outpatient departments of rural hospitals and urban clinics alike, thyroid dysfunction often goes undetected—despite its silent but widespread impact on physical and mental health. Patients complaining of fatigue, weight gain, or anxiety are frequently advised to undergo blood tests, but many never return with results. The reason? Delays, high testing costs, or the unavailability of reliable diagnostics. Having witnessed this diagnostic gap firsthand during my clinical rotations in government hospitals, I was drawn to a question: Could there be a faster, more accessible way to screen thyroid function right where the patient stands? This question gave rise to ThyroMeter—a concept for a low-cost, portable electrochemical biosensor aimed at detecting T3, T4, and TSH at the point of care. The envisioned device combines a hormone-specific disposable test strip with a compact, battery-operated reader. Using electrochemical techniques like chronoamperometry and electrochemical impedance spectroscopy, the system detects hormone levels from a drop of capillary blood within minutes. The electrodes are functionalized to selectively bind T3, T4, and TSH, allowing for accurate and independent detection of each biomarker. Unlike traditional immunoassays that require centralized labs, electricity, and trained technicians, ThyroMeter is designed for front-line use: affordable, portable, and easy to operate. It could potentially empower primary health workers in underserved communities to screen patients on-site—reducing the dropout rate between testing and treatment. This presentation outlines the early development journey of ThyroMeter—from identifying the clinical need to designing the sensor architecture and prototyping initial circuits. The device is still under development. I am currently seeking collaboration through innovation ecosystems such as AMTZ, aiming to develop the prototype, validate its performance, and eventually deploy it where it's needed most. **Conclusions:** ThyroMeter is more than a technical proposal; it's a response to a real-world problem faced daily in healthcare. Decentralizing thyroid testing and placing diagnostic power in the hands of primary care providers has the potential to improve disease detection, early intervention, and health outcomes in resource-limited settings. Through this presentation, I hope to gather insights, mentorship, and interdisciplinary collaboration to bring ThyroMeter from concept to clinical impact.

E: CE/HTM Challenges & Solutions in LMICs

Transcription of Medical Corpus with West African Accents

By Keke Mahuvivi Turibio[1,2], Houessouvo C. Roland[1,2], Jossou R. Thierry[1,2], Medenou Daton[1,2]

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In a rapidly evolving medical context, integrating artificial intelligence (AI) into patient consultations offers opportunities to optimize time management and improve the quality of medical documentation. However, existing speech-to-text models, although effective in standard linguistic environments, perform significantly worse when processing speech with West African accents due to their poor representation in training datasets. This project aims to develop a medical audio corpus representative of these accents by recording African participants reading the same medical text at various times of day to capture natural speech variations. The resulting dataset will serve to train or adapt transcription models, notably Whisper (open source) and Dragon (commercial). The goals are to improve transcription accuracy for African speakers and enable low-latency, edge-ready deployment. Initial evaluations will involve fine-tuning Whisper and comparing performance metrics such as Word Error Rate (WER), latency, and background noise robustness against baseline models. This work contributes to linguistic justice and technological equity by improving the inclusiveness of AI-driven medical tools and establishing foundations for standardized multilingual medical datasets.

E: CE/HTM Challenges & Solutions in LMICs

Prediction of Biomedical Test Results from Limited Patient Parameters

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In many low-resource medical settings, healthcare professionals are faced with the challenge of making critical diagnostic decisions with only partial data due to financial constraints, limited laboratory infrastructure, or logistical inefficiencies. Full biomedical test panels, which provide a comprehensive view of a patient's health, are not always accessible in rural clinics or underserved communities. This research investigates the application of artificial intelligence (AI) to overcome this challenge by predicting missing laboratory values based on a reduced set of available test results. The approach involves training machine learning models—including regression algorithms, decision trees, and neural networks—on anonymized and complete biomedical datasets to identify reliable patterns and correlations between available and missing parameters. For instance, using common indicators such as glucose, urea, or creatinine, the model aims to estimate more costly or unavailable tests such as hemoglobin levels, liver enzymes, or lipid profiles. Model performance is evaluated using metrics like root mean square error (RMSE) and the coefficient of determination (R^2), ensuring both accuracy and reliability in clinical use. The system is designed to function in mobile or edge computing environments, making it suitable for deployment in remote and offline contexts. Expected outcomes include reduced diagnostic costs, improved clinical decision-making speed, and greater equity in access to healthcare. By leveraging data-driven predictions, the project contributes to enhancing diagnostic capabilities, promoting preventative care, and supporting adaptive and personalized medicine in environments where comprehensive testing is often unavailable. Ultimately, this work highlights the transformative potential of AI to bridge diagnostic gaps and support equitable healthcare delivery through predictive, intelligent, and data-driven tools.

E: CE/HTM Challenges & Solutions in LMICs

Analysis of Typical Cases of Medical Metrological Acceptance of Infusion Pump

By Yang Li, Zhenwei Du*, Lidong Fan, Li Xu

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Objective: Medical metrology is an important guarantee for the safe and stable operation of medical service equipment. As an important medical service equipment, the medical infusion pump is widely used in the treatment of severe patients in wartime. The stability of its performance parameters plays a key role in wartime rescue. **Methods:** 32 infusion pumps newly purchased in our hospital were selected for measurement acceptance analysis according to the military metrology calibration standard "Technical Specification for Quality Inspection of Infusion Pumps and Injection Pumps (Trial)". **Results:** The flow rate or pressure alarm parameters of most infusion pumps did not reach the standard of military measurement calibration specification during the initial inspection of measurement acceptance. After calibration and the manufacturer's treatment, 32 infusion pumps were finally accepted. **Conclusion:** The measurement and acceptance of medical infusion pumps in strict accordance with the military medical metrology standards can not only reduce the risk of clinical use of equipment, but also guarantee the quality of medical equipment and strengthen the support of military medical service equipment.

E: CE/HTM Challenges & Solutions in LMICs

Clinical Engineering Applications in Hospital Crisis Contexts: A Case Study from Pará in Brazil During the COVID-19 Pandemic

By Niziomar Freitas and Ederson Cichaczewski

Biomedical Engineering Department, UNINTER International University Center, Brazil

Clinical engineering was crucial during the COVID-19 pandemic, ensuring the functionality of healthcare systems amid increased demand and equipment strain. In under-resourced areas, the lack of maintenance and technical staff revealed major vulnerabilities. The case presented in this study highlights the essential role of clinical engineers in restoring and maintaining hospital operations during a critical crisis in Itaituba, Pará, Brazil. In December 2020, at the height of the COVID-19 pandemic, a hospital in Itaituba, Pará, faced a severe operational crisis: its vital departments, such as the Central Sterile Services Department (CSSD) and the laundry, were plagued by instability and intermittent shutdowns of essential equipment, jeopardizing the safety of both patients and staff. An emergency call brought in a clinical engineer, who began a detailed assessment that revealed a critical lack of preventive maintenance. Autoclaves exhibited unregulated pneumatic pressure, door sealing failures, obstructions in the reverse osmosis system, residue in steam generation systems, as well as oxidation and looseness in electrical connections. In the laundry area, washers and dryers were operating precariously due to failures in frequency inverters, programmable logic controllers, chemical dosing systems, and mechanical problems, leading to the return of dirty linens and service interruptions. The challenge was immense: to restore the functionality of this equipment with limited resources and the need for immediate response. The solution adopted was multifaceted: initially, technical interventions focused on the autoclaves were carried out, including pneumatic pressure adjustments, sealing repairs, and cleaning of the reverse osmosis systems, restoring approximately 80% of functionality without the need for parts replacement. In the laundry, washers and dryers underwent adjustments to frequency inverters and logic controllers, along with mechanical repairs and calibration of dosing systems, restoring operability to the departments. Simultaneously, the planning of a systematic preventive maintenance program began, including the hiring of a specialized company for inspections and performance monitoring. In January 2021, in recognition of his performance, the engineer was integrated into the hospital's clinical engineering team, taking the lead in setting up Intensive Care Units (ICUs) and surgical centers—essential in the fight against COVID-19—installing ventilators, multiparameter monitors, and other life-support equipment. His work extended into 2022, playing a crucial role in the implementation of the hospital's water treatment and dialysis systems and the oxygen plant, ensuring the continuity of these vital services. The results were significant: the reactivation of a large portion of the equipment ensured the continuity of hospital services, optimized scarce resources, and reduced future costs. Training of local teams was a key legacy, strengthening technical autonomy and establishing a culture of planned maintenance, thereby enhancing hospital safety. The implementation of new facilities such as the oxygen plant and dialysis system represented a major advancement in the region's healthcare infrastructure. What began as an emergency intervention evolved into a series of continuous improvements, and the professional and institutional recognition of the engineer reaffirmed the essential role of clinical engineering in managing public health crises, establishing it as a strategic pillar for hospital quality and safety.

E: CE/HTM Challenges & Solutions in LMICs

Contributions of the Clinical Engineer in the Management of Technologies During the COVID-19 Pandemic: An Experience Report

By Sabrina Noema da Costa and Ederson Cichaczewski

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In Brazil, the role of the clinical engineer often goes unnoticed in the daily operations of hospitals, being undervalued or mistaken for purely technical maintenance functions. However, during public health emergencies such as the COVID-19 pandemic, the necessity of this professional's active presence in hospitals and temporary care centers became evident, in

order to ensure the safe, effective, and continuous operation of the entire hospital technological infrastructure. This professional plays a strategic role at the intersection of engineering, healthcare, and management, ensuring that medical equipment is available, functioning correctly, and compliant with current standards and regulations. This paper reports the experience of a clinical engineer in managing clinical and medical technologies at a specialized COVID-19 care center. The methodology consists of a case study, in the form of a professional experience report, developed at the COVID-19 Care Center II, located in the city of Macapá, in the state of Amapá. The center was established on an emergency basis through the adaptation of a local maternity hospital, in response to the increasing demand for hospital beds and intensive care support due to the worsening of the pandemic in northern Brazil. The clinical engineer's activities began in May 2020, when he was transferred from the city of Porto Velho to Macapá, with the mission of supporting the setup of the emergency care unit. Among the actions carried out, the complete installation of 10 intensive care unit (ICU) beds stood out, including the physical assembly of hospital beds and the deployment and testing of all equipment that makes up a modern ICU, such as parenteral and enteral infusion pumps, multiparameter monitors, crash carts, defibrillators/cardioversors, and mechanical ventilators. In addition to the installation process, the work also involved training multiprofessional healthcare teams in the proper use of medical equipment, as well as performing both preventive and corrective maintenance. It was essential to ensure that all installations complied with technical standards and regulations established by the National Health Surveillance Agency (ANVISA) and the Brazilian Association of Technical Standards (ABNT), aiming to provide safety for both the operator and the patient connected to the equipment. Ongoing responsibilities included equipment calibration, routine inspections, and on-site technical support. This experience demonstrated that the presence of the clinical engineer is crucial in addressing emergency situations in public health. Their work ensures efficient management of the technological infrastructure, from equipment acquisition to its disposal, directly contributing to the quality of care and hospital safety. Furthermore, it highlights the importance of integrating this professional permanently into healthcare management teams, not only in times of crisis. The clinical engineer's participation in this collective effort was extremely valuable, both technically and personally, and reinforces the need to establish clinical engineering as a strategic area within the Brazilian healthcare system.

E: CE/HTM Challenges & Solutions in LMICs

Application of PDCA Management Method in Standardizing Temporary Procurement of Medical Supplies in a Tertiary Hospital

By Xiwei Li*

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Background: In recent years, refined medical management has highlighted inefficiencies in temporary procurement of medical supplies, often resulting in extended procurement cycles, inconsistent quality, and avoidable costs. This study applied the Plan-Do-Check-Act (PDCA) methodology to standardize temporary procurement in a tertiary teaching hospital, aiming to improve efficiency, cost control, and clinical satisfaction.

Methods: From January to December 2024, the hospital integrated PDCA management into its supply chain workflow:

- **Plan:** Defined responsibilities across procurement, clinical, and finance teams; developed a policy framework; and created digital process maps.
- **Do:** Implement hospital smart operation management platform (HRP)module for procurement, enabling real-time tracking, dynamic demand forecasting, and automated approval routing. Added early price-approval mechanisms for time-limited and elective surgery supplies, a standardized training system (*n*=245 staff, 100% completion), and dynamic emergency procurement protocols.
- **Check:** Established a multi-dimensional assessment system measuring procurement cycle time, preoperative filing

compliance, supply rejection rate, inventory loss rate, and department satisfaction. Conducted joint "PDCA + DRG/DIP" analysis to adjust procurement strategy based on reimbursement patterns.

• **Act:** Developed continuous feedback loops with quarterly audits, corrective action tracking, and supplier performance scoring.

Measured Indicators:

- Procurement cycle time (days)
- Preoperative procurement and price-filing compliance rate (%)
- Comprehensive procurement expenditure (CNY)
- Inventory loss rate (%)
- Supply rejection rate by medical insurance (%)
- Clinical department satisfaction (Likert scale)
- Number of training sessions/staff trained (%)

Results: Following implementation:

• Median procurement cycle time decreased from 6 days to 3 days (–52.3%).

• Compliance rate for preoperative procurement and pricing information filing improved from 68.3% to 95.7% (+27.4 pp).

• Comprehensive procurement expenditure reduced by CNY 3.12 million/year (–14.8%), primarily through bulk pricing and reduced emergency purchases.

• Inventory loss rate decreased from 2.4% to 0.9% (–62.5%).

• Medical insurance rejection rate dropped from 4.6% to 1.1% (–76.1%).

• Departmental satisfaction scores increased from 3.6 to 4.4/5.

• All 245 procurement-related staff completed standardized training, with post-training competency scores averaging 95%.

Discussion: PDCA-based procurement management, supported by digital tools, significantly improved operational efficiency, reduced costs, and strengthened compliance. The closed-loop system addressed pre-existing disorderliness by linking planning to post-implementation evaluation. Collaborative integration of DRG/DIP data enabled better alignment with financial sustainability goals. The model fostered a "triple management" approach—system + digital tools + performance assessment—creating a collaborative supply chain ecosystem.

Challenges included the 9–12-month implementation period, high initial IT investment (~CNY 1.50 million), and variability in staff adaptability. Organizational culture and training intensity were critical success factors.

Conclusion: This standardized PDCA model shortened procurement cycles by half, improved compliance to over 95%, reduced costs and losses, and enhanced clinical satisfaction, while improving supply chain transparency. The approach is scalable and replicable for similar hospitals and offers a foundation for developing full life-cycle medical supply management systems, integrating AI for predictive analytics, and building three-way digital collaboration mechanisms among hospitals, suppliers, and regulators.

F: Digital Health, Connected Devices & AI/IoT

Exploration and Practice of Performance Evaluation System for Large-Scale Medical Equipment Based on Internet of Things Technology in Children's Medical Center

By Chang Su*

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Large-scale medical equipment, as a key indicator of smart hospitals, is crucial for hospital operations. However, they face issues such as high procurement costs, high operational and maintenance costs, and high requirements for operational personnel. To ensure the safe and efficient operation of medical equipment, a reasonable evaluation system is indispensable. This study introduces a platform based on Internet of Things (IoT) technology that connects medical devices and collects data, achieving standardized and structured data processing, and supporting online operational supervision. By using the Delphi method, in conjunction with the principles of full lifecycle, operability, efficiency, fairness, and effectiveness, a performance evaluation index system for large-scale equipment is constructed, including 6 primary indicators and 22 secondary indicators. The platform utilizes DICOM data acquisition boxes to enable efficiency analysis, total cost analysis, benefit analysis, usage evaluation and decision support, data analysis, and reporting functions. This research is still in its early stages, with the future expectation of integrating a wider variety of devices, achieving precise tracking of medical consumables and diagnostic reagents usage management, and having a significant impact on the development decisions of public hospitals.

F: Digital Health, Connected Devices & AI/IoT

Full-Body Pose Reconstruction and Correction in Virtual Reality for Rehabilitation Training

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Existing statistical data indicate that an increasing number of people now require rehabilitation to restore compromised physical mobility. During the rehabilitation process, physical therapists evaluate and guide the movements of patients, aiding them in a more effective recovery and rehabilitation and preventing secondary injuries. However, the limitations of mobility and the high cost of rehabilitation training impede some patients from timely accessing rehabilitation. Utilizing virtual reality for rehabilitation training may offer a potential solution to these issues. Nevertheless, common pose-reconstruction algorithms in the field of rehabilitation mainly rely on images, restricting their applicability in virtual reality. Moreover, existing pose-evaluation and correction methods in the rehabilitation field primarily provide clinical metrics for doctors and fail to offer patients effective movement guidance. In this paper, a virtual-reality-based rehabilitation training method is proposed. Sparse motion signals from virtual reality devices, especially head-mounted displays and hand controllers, are used to reconstruct full-body poses. Subsequently, the reconstructed poses and the standard poses are fed into a natural-language-processing model. This model compares the differences between the two poses and provides effective pose-correction guidance in the form of natural language. Quantitative and qualitative results show that the proposed method can accurately reconstruct full-body poses from sparse motion signals in real-time. By referring to standard poses, the model generates professional motion-correction guidance text. This approach facilitates virtual-reality-based rehabilitation training, reduces the cost of rehabilitation training, and improves the efficiency of self-rehabilitation training.

F: Digital Health, Connected Devices & AI/IoT

Artificial Intelligence Generated Content (AIGC) in Medicine: A Narrative Review

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Recently, the artificial intelligence generated content (AIGC) has been receiving increased attention and growing exponentially. AIGC, generated by generative AI models based on intentional information from human instructions, can quickly and automatically produce large amounts of high-quality content. In the medical field, there is a shortage of medical resources and complex medical procedures. Thanks to its characteristics, AIGC can help address these issues, which has led to its growing attention in medicine recently.
This paper offers a comprehensive review of the current state of AIGC studies in medicine. It first gives an overview of AIGC. Then, based on recent research, it reviews the application of AIGC in medicine from two aspects: medical image processing and medical text generation. It considers and summarizes the basic generative AI models, tasks, target organs, datasets, and contributions of these studies. Finally, it discusses the limitations and challenges of AIGC and proposes possible solutions in relation to relevant studies. The aim is to help readers understand the potential of AIGC in medicine and gain innovative ideas in this area.
This description highlights the importance of AIGC, its application in solving medical problems, and the main contents of this paper, which can be filled in the "Description as noted in the **Abstract** submission" to briefly introduce the abstract's key points.

F: Digital Health, Connected Devices & AI/IoT

A Secured RFID Authentication Protocol in Telecare Medicine Information System

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This abstract (and/or the work summarized herein) will be published in *International Journal of Network Security*. It is reproduced here with the permission of the author for the purpose of record and wider dissemination.

With the continuous development of Internet of Things technology, the demand for radio frequency identification technology is growing day by day. As one of the key technologies in the Internet of Things, the research on radio frequency identification technology security authentication technology is of great significance to the healthy development of the Internet of Things. Research on radio frequency identification technology security authentication technology can solve the security problems encountered in large-scale applications and support the large-scale application of Internet of Things technology. It is not only related to data security and user privacy protection, but also involves the reliability of the system,

international standardization, industrial collaboration, technological innovation, and other levels. We propose a secure radio frequency identification technology authentication protocol in a telecare medicine information system based on Chander et al.'s protocol. GNY logic is used to prove the improved protocol. Meanwhile, we carry out a comparative analysis of performance and efficiency. The results show that the improved protocol has higher security and lower calculation cost.

F: Digital Health, Connected Devices & AI/IoT

Application Progress of Digital Twin Technology in Intelligent Construction of Operating Room

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Digital twin technology, which constructs virtual replicas of patients or surgical environments, is reshaping the intelligent process of modern operating rooms. This review explores the core applications, technological breakthroughs, and future directions of digital twin technology in surgical settings. In preoperative planning, multimodal image fusion (e.g., MRI and CT) enables the creation of three-dimensional models for precise surgical design, pathological response prediction, and personalized treatment optimization. For intraoperative navigation, mixed reality and real-time data feedback systems enhance surgical precision and safety, while Internet of Things technology is used to realize the seamless linkage between devices and data. Additionally, digital twins revolutionize medical education and training through high-fidelity simulators that generate synthetic data for virtual surgical rehearsals. Despite its potential, challenges persist in data privacy, model standardization, and hardware costs. Looking ahead, the integration of AI and 5G will drive digital twin operating rooms toward unmanned operations, personalized workflows, and remote collaboration, positioning this technology as a cornerstone of precision medicine.

F: Digital Health, Connected Devices & AI/IoT

The Application and Risk Management of Digital Health Technology in Home-Based Cardiac Rehabilitation

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Description: Cardiovascular disease remains one of the leading causes of death worldwide, posing significant challenges to public health. As a cornerstone of secondary prevention for cardiovascular diseases, cardiac rehabilitation has proven effective in reducing recurrence rates and mortality. However, traditional rehabilitation models face limitations such as low participation rates, poor adherence, and uneven distribution of medical resources. With advancements in digital health technology, home-based cardiac rehabilitation has overcome many constraints of conventional approaches, enabling patients to receive professional guidance and monitoring at home or in community settings. This article systematically reviews the current applications of digital health technologies in home-based cardiac rehabilitation, including intelligent systems such as wearable ECG monitoring devices, artificial intelligence-driven remote personalized rehabilitation platforms, and immersive technologies like virtual reality (VR). These innovations facilitate continuous monitoring, real-time feedback, and remote guidance, significantly enhancing rehabilitation outcomes. Additionally, the article provides an in-depth analysis of challenges associated with these technologies, aiming to offer clinical practitioners actionable recommendations for technical management and risk mitigation to promote the high-quality integration of digital health in home-based rehabilitation.
Conclusion: Digital health technologies have demonstrated substantial benefits for home-based cardiac rehabilitation,

yet their sustainable development requires coordinated efforts in technological innovation, standardized management, and policy support. Future priorities should focus on three dimensions: improving technical reliability, refining policy frameworks, and optimizing user experience. By consistently prioritizing patient safety and care quality as the core guiding principles, propel home-based rehabilitation driven by digital health technologies toward more intelligent and personalized development.

F: Digital Health, Connected Devices & AI/IoT

Non-Invasive Detection of Multiple Myeloma Using Surface-Enhanced Raman Spectroscopy of Urine Combined with Deep Learning

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Multiple myeloma (MM) is a hematologic malignancy characterized by the malignant proliferation of plasma cells in the bone marrow. It exhibits high heterogeneity, remains incurable, and is prone to relapse. According to the 2024 National Comprehensive Cancer Network (NCCN) guidelines, current MM diagnosis primarily relies on invasive and time-consuming procedures, including bone marrow aspiration, immunofixation electrophoresis, and magnetic resonance imaging (MRI) or positron emission tomography/computed tomography (PET/CT). However, in the context of MM, these conventional methods remain limited in sensitivity, especially for early detection and minimal residual disease (MRD) monitoring. Therefore, there is an urgent clinical need to develop a non-invasive, efficient, and accurate diagnostic approach.

In this study, we propose an intelligent, non-invasive diagnostic framework for MM based on urine samples, integrating surface-enhanced Raman spectroscopy (SERS) with deep learning techniques. Urine samples were collected from 10 newly diagnosed MM patients and 10 healthy controls at the China-Japan Union Hospital of Jilin University. Using gold nanoparticle-enhanced SERS, 100 Raman spectra were acquired per subject, totaling 2,000 spectra. A convolutional neural network (CNN) incorporating an attention mechanism was constructed to classify the spectral data, and model training and evaluation were conducted using five-fold cross-validation.

The CNN model achieved an average classification accuracy of 96.88%, with individual fold accuracies ranging from 95.13% to 98.25%. Receiver operating characteristic (ROC) analysis showed an area under the curve (AUC) of 0.96, with a true positive rate exceeding 0.9 and a false positive rate below 0.1, demonstrating excellent diagnostic performance. Principal component analysis (PCA) revealed clear spectral separation between the MM and control groups, suggesting the presence of distinct biochemical signatures. Compared with traditional classification algorithms, the CNN exhibited superior accuracy and generalization capability, indicating strong robustness.

In conclusion, the AI-assisted SERS technique offers an effective non-invasive diagnostic solution for multiple myeloma. In addition to its high classification accuracy, the approach also demonstrates strong potential for engineering implementation and productization, supporting its feasibility for clinical application.

F: Digital Health, Connected Devices & AI/IoT

Technological Advancements and Clinical Applications of Ultra-High-Definition Surgical Microscopes

By Jin Li*, Bin Li, Jing Tong

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As the demand for precision and safety in surgical procedures increases, ultra-high-definition surgical microscopes have become indispensable in modern surgery. This article presents a comprehensive review of the technological advancements and clinical applications of ultra-high-definition surgical microscopes, with particular emphasis on

innovations in optical systems, light source systems, visualization systems, and multimodal imaging technologies. In comparison to traditional microscopes, ultra-high-definition microscopes, utilizing imaging technologies with resolutions of 4K, 8K, or higher, offer clearer and more detailed views, thereby significantly enhancing the surgeon's ability to identify minute tissue structures, ultimately improving surgical accuracy and safety.

This study's innovation lies in its thorough exploration of the integration of intelligent assistive technologies with ultra-high-definition surgical microscopes, particularly the application of augmented reality (AR) and artificial intelligence (AI) in surgical navigation and decision-making. By integrating preoperative 3D imaging with real-time surgical views, augmented reality technology facilitates precise lesion localization and dynamic navigation, thereby significantly reducing the risk of operational errors. Artificial intelligence, through advanced image processing and data analysis, optimizes the microscope's imaging quality, further enhancing the intelligence level in surgery.

This article also systematically reviews the clinical applications of ultra-high-definition surgical microscopes across various fields, including neurosurgery, ophthalmology, otolaryngology, and spinal surgery, highlighting their unique advantages in minimally invasive surgery, precise navigation, and real-time intraoperative feedback. Despite significant technological advancements, challenges related to the large size of equipment, light control, and data transmission persist. Consequently, this paper proposes future directions for technological advancement, including the miniaturization and modular design of microscopes, along with deeper integration with robotic surgical systems.

In conclusion, ultra-high-definition surgical microscopes, through the integration of advanced optical imaging technologies and intelligent assistive systems, are advancing the development of more efficient, precise, and safer surgical practices. The research presented in this article offers valuable insights for the continued innovation and clinical application of future surgical microscope technologies.

F: Digital Health, Connected Devices & AI/IoT

Usefulness of the 12-Lead ECG Reading Guide AR System for Diagnosis of the Accessory Pathway Location Using Delta Waves

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The widespread adoption of catheter ablation therapy for arrhythmias has increased the demand for healthcare professionals, including clinical engineers, to develop advanced skills in interpreting 12-lead electrocardiograms (ECGs). In Wolff-Parkinson-White (WPW) syndrome, pre-procedural localization of the accessory pathway using delta waves on ECGs is crucial for guiding treatment strategies and improving procedural outcomes. However, many clinicians and clinical engineers find it challenging to memorize the detailed diagnostic flowcharts required for accurate localization, leading to variability in diagnostic accuracy and efficiency. To address this issue, we developed and evaluated an interactive augmented reality (AR)-based ECG interpretation guide designed to assist in localizing accessory pathways in WPW syndrome. The system, known as the Medical AR Support System (MARSS), integrates AR smart glasses (BT-40S, EPSON), bone conduction headphones (Shokz), and voice-activated software to enable hands-free operation. Users are guided through step-by-step diagnostic instructions projected into their field of vision, allowing real-time comparison of 12-lead ECGs with algorithmic guidance based on the Arruda method—a validated approach with reported sensitivity and specificity of 90% and 99%, respectively. We conducted a study involving 15 participants: five experienced clinical engineers and ten less-experienced undergraduate students. Participants reviewed 12-lead ECGs from confirmed WPW cases using the AR system and completed a structured questionnaire assessing diagnostic concordance, interpretation confidence, time to diagnosis, and perceived usefulness. All participants acknowledged the importance of ECG-based localization prior to ablation. While all clinical engineers correctly identified the accessory pathway location, three students failed to do so, primarily due to difficulties in interpreting delta waves and misunderstanding the "±" polarity in the flowchart. However, all students reported faster interpretation times with the AR system compared to traditional methods. The AR system demonstrated clear educational advantages, particularly for students and less-experienced professionals, by enhancing engagement, promoting active learning, and improving conceptual understanding. Some noted drawbacks included a not-so-user-friendly interface and a learning curve associated with AR glasses operation. Nevertheless, the overall response to the system was positive. Looking forward,

integration with artificial intelligence (AI) may enable semi-automated or fully automated ECG interpretation, offering real-time feedback and performance scoring. Furthermore, expanding diagnostic coverage to include arrhythmias—such as atrial tachycardia, premature ventricular contractions, and bradyarrhythmias—could further enhance the system's value in clinical education and practice. In conclusion, the AR-based ECG interpretation guide shows strong potential as both an educational platform and a diagnostic support system. It effectively aids in the localization of accessory pathways in WPW syndrome and represents a promising fusion of immersive technologies and clinical engineering education.

F: Digital Health, Connected Devices & AI/IoT

A Solar-Powered Wearable ECG Monitoring and Early Warning System for Sudden Cardiac Death Risk Detection

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Background: Sudden cardiac death (SCD), an unpredictable natural death caused by cardiovascular diseases (CVD), has been occurring frequently and tends to be younger in recent years, which has constituted a global public health challenge. According to statistics, about 6 million people worldwide pass away each year, accounting for more than half of patient deaths from CVD, and China tops the list with more than 540,000 cases per year. Ventricular arrhythmias, especially Ventricular Tachycardia (VT) and Ventricular Fibrillation (VF), are the main culprits of SCD. Electrocardiogram (ECG), as a diagnostic tool, can accurately capture the abnormal signals of VT and VF, but it is often insufficient to capture the intermittent and transient nature of arrhythmic episodes. Therefore, early detection of VT, VF, and other high-risk arrhythmias and accurate targeting of high-risk groups of SCD not only strengthens the effectiveness of preventive measures but also wins valuable time for patients to save their lives. **Method:** This device adopts TI ADS1292 ECG acquisition module combined with Arduino uno development board, through the self-programmed "abnormal ECG recognition" algorithm, to achieve automatic identification of normal and abnormal ECG and real-time alarm, supporting LED light prompts and serial port display, the use of solar thin film batteries and lithium batteries Solar thin-film battery and lithium battery are used for power supply, which prolongs the battery life of the device. The device is integrated into a close-fitting adjustable vest, which enhances wearing comfort and facilitates prolonged wearing and daily activities. **Results:** Based on 100 "Heart Health Awareness and Smart Wear Acceptance Questionnaires", we completed the design and fabrication of the device to realize the functions of miniaturized hardware, intelligent software, comfortable wear, and sustainable energy, which is especially suitable for daily health monitoring and early warning of people with a high risk of SCD. **Conclusion:** The device integrates advanced sensor technology to achieve real-time, continuous monitoring of patients' ECG signals and sends out an immediate warning signal when potential risks are detected, which is expected to play an important role in future clinical practice and open up new pathways for the prevention and intervention of SCD.

F: Digital Health, Connected Devices & AI/IoT

Proposal for Implementing a Big Data Solution to Address Health Data Management

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The Mexican healthcare system faces challenges such as fragmentation, incompleteness, and inefficiencies in data management, which hinder clinical decision-making, resource allocation, and the development of public

policies. To address these issues, various subsystems are aiming to implement an integrated system that utilizes Big Data, the Internet of Things (IoT), and 5G networks. However, they encounter obstacles, including a lack of interoperability, a shortage of trained personnel, and risks related to data privacy. The goal is to create a unified healthcare data infrastructure that enhances operational efficiency, specifically in resource management, inventory control, and hospital logistics. This infrastructure aims to improve medical accuracy by optimizing diagnostics and ensuring continuity of treatment. Additionally, it seeks to enhance security and personalization through the reduction of clinical errors and tailored patient care. All of these objectives are to be implemented within a legal framework that complies with the Ley Federal de Protección de Datos Personales en Posesión de los Particulares (Federal Law on Protection of Personal Data Held by Individuals; LFPDPPP) and ISO/HL 7 27931:2009 standards. The first phase focuses on data analysis, specifically classifying medical, clinical, and hospital data in accordance with ISO standards. This phase begins with a descriptive analysis that identifies historical patterns. It is followed by a predictive analysis through risk modeling and tracking outbreaks of prevalent diseases. Ultimately, this leads to the development of personalized treatment recommendations. The second phase of implementation involves establishing a Big Data architecture based on the ISO 20547-5:2018 standard. This phase proposes a minimum requirement of 25 TB of storage and 16 GB of random-access memory (RAM). Key considerations include the use of scalable hardware and software, governance of data security, and training for staff and the technological surveillance committee on these issues. Furthermore, the challenge of gradually digitizing physical archives is addressed in accordance with the Federal Archives Law, which mandates retaining physical records for four years. Insights from Moorfields Eye Hospital (UK) and Sheba Medical Center (Israel) have led to the following goals: Enhance decision-making with accurate diagnoses from medical record analysis; improve efficiency by reducing waiting times and costs by 20% to 30%; enable early detection of chronic diseases using AI-powered digital tools; tailor treatment approaches to individual genetic profiles and strengthen patient safety by monitoring medical errors in real time. A timeline of 12–24 months is proposed for the development and implementation of initial stages, with a full transition to a digital system anticipated within 4–5 years.

In developing strategies to generate the necessary actions, the following critical challenges arise and will be addressed throughout the process:

- Data integration, normalization, and cleansing of fragmented information.
- The need for the formation and training of multidisciplinary teams.
- Harmonization with the LFPDPPP for the storage of sensitive data.
- Ensuring compatibility with the current infrastructure.

The adoption of the Big Data framework in healthcare subsystems will enable a transformation that fosters improved quality healthcare based on real-time data, sustainability through resource optimization and long-term cost control, and innovation through research accelerated by the availability of data and analysis and synthesis tools.

F: Digital Health, Connected Devices & AI/IoT

Software Design for Multi-Modal Radiomics Feature Mining and Analysis Based on Artificial Intelligence

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Description: To address the issues of data incompatibility and inability to adjust algorithm parameters that often arise from the use of multiple software in radiomics research, an AI-based radiomics analysis and modeling software has been developed to provide doctors and researchers with a centralized solution for radiomics that supports image preprocessing, feature extraction, feature screening, modeling analysis, and data visualization. The multimodal imaging omics feature mining and analysis software designed in this study mainly includes four modules: data preparation, feature extraction and screening, automatic modeling and classification prediction, and data visualization. This software can process image data, including but not limited to MRI, CT, PET, etc. It uses PyRadiomics to extract radiomics features and has multiple built-in feature selection and dimensionality reduction methods, such as t-test, chi-square detection, mutual information (MI), principal component analysis (PCA), maximum correlation minimum redundancy, Lasso, etc.

The software supports the integration of commonly used machine learning algorithms, including Support Vector Machine (SVM), XGboost (eXtreme Gradient Boosting), Random Forest, Multilayer Perceptron (MLP), etc. The software provides various common chart drawing methods, including feature weight maps, ROC maps (with AUC values), fitted trajectory maps, feature hotspot maps, etc. Open source code is in https://github.com/DarthLeehom/RadiomicsTool/tree/master. The test data used in this study came from the Multimodal Brain Tumor Challenge 2019 dataset (BraTS19), which included MRI images of 335 patients. There were 259 patients with high-grade gliomas and 76 patients with low-grade gliomas, respectively. Each case included MRI sequences of four modalities (T1, T2, T1CE, FLAIR) and a label file. Use this dataset to test software functionality, create 8 sets of analysis models, classify and predict the test set data one by one, and output key performance indicators. Through parameter tuning, further optimize the model performance and verify the usability of the software. **Conclusions:** Researchers can use this software to complete the entire process of feature extraction, screening, and analysis modeling of image data, supporting functions such as algorithm tuning, model evaluation, and data visualization.

F: Digital Health, Connected Devices & AI/IoT

Monitoring and Prevention of Atrial Fibrillation from Machine Learning Biases and the Use of Home Wearable Devices

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Atrial Fibrillation (AFib) stands as one of the most prevalent cardiac arrhythmias globally, significantly impacting public health. In recent years, its diagnosis and management have witnessed remarkable advancements, particularly through the integration of the Internet of Things (IoT), especially consumer-grade wearable devices. Manufacturers like Apple, with their Smartwatch Series, have achieved groundbreaking U.S. Food and Drug Administration (FDA) approvals and certifications for AFib detection, making in-home cardiac monitoring a tangible reality for millions. This technological leap has empowered individuals to participate more actively in their heart health management, facilitating early detection of AFib episodes that might otherwise go unnoticed.

Despite these significant strides, the current landscape of wearable-based cardiac monitoring presents notable limitations. While AFib detection has garnered regulatory approval, the detection of other critical arrhythmias, let alone the diagnosis of acute myocardial infarctions (heart attacks), currently lacks similar endorsements for home-based wearable technologies. This gap highlights a crucial need for further research and validation to expand the diagnostic capabilities of these ubiquitous devices.

Moreover, a critical aspect often overlooked in many research endeavors, particularly in the machine learning (ML) phase of AFib detection studies, is the pervasive issue of data bias. The training datasets used to develop these sophisticated algorithms can inadvertently carry biases stemming from various origins, including sex, age, ethnicity, or differing exposure levels to critical risk factors such as smoking, alcohol consumption, sedentary lifestyles, and chronic stress. When studies exclusively rely on the ECG signal vector as the sole independent variable for AFib prediction, these inherent biases can lead to predictions with alarmingly low sensitivity and specificity, coupled with high rates of false positives and, more critically, false negatives.

The implications of false negatives in cardiovascular health are severe. An undiagnosed or untreated case of AFib can precipitate more severe forms of cardiomyopathy, increasing the risk of stroke and other life-threatening cardiac complications. This underscores the ethical imperative for developers and clinical engineers to meticulously address data bias, ensuring that AI-driven diagnostic tools provide equitable and accurate results across diverse patient populations.

In the realm of the Internet of Medical Things (IoMT), the approval for AFib detection in wearables is partly attributed to the fact that AFib can often be identified using a single Einthoven lead, typically obtained from two sensors on the left wrist of a smartwatch. This approach, while effective for AFib, stands in stark contrast to hospital-grade electrocardiograms (ECGs), which capture 12 Einthoven leads, offering a far more comprehensive view of cardiac electrical activity. While detecting AFib using a home wearable device represents a significant technological and

medical achievement, allowing for convenient monitoring, it prompts a deeper reflection.
AFib can often serve as an initial indicator for the development of other, more severe arrhythmias or the onset of ischemic processes. This raises a fundamental question: Do current smart devices truly offer safe and reliable continuous home monitoring capabilities that extend beyond basic AFib detection to encompass these broader, potentially life-threatening cardiac events? Future developments in wearable technology and the underlying AI algorithms must prioritize not only expanded detection capabilities but also the rigorous validation of data quality and the elimination of inherent biases, ensuring these devices contribute robustly to comprehensive and equitable cardiac care.

F: Digital Health, Connected Devices & AI/IoT

Grad-CAM Guided cGAN for Generating 18F-FAPI PET Images from 18F-FDG PET Images

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Description: Positron Emission Tomography (PET) is an important clinical diagnostic tool in the field of nuclear medicine, widely applied in clinical practice. Tumor cells typically exhibit high glucose metabolism activity, and the FDG tracer can reflect the distribution of cellular glucose metabolism activity in the body. Previous studies have shown that 18F-FDG PET has a high detection rate for various tumors, such as colorectal cancer and lung cancer, but is less sensitive to tumors with low glucose metabolism or atypical metabolic patterns. FAPI targets the unique FAP receptors in the tumor microenvironment, avoiding the metabolic overlap issues of FDG in certain tumors and inflammations. Scholars have confirmed that in diseases like liver cancer, gastric cancer, and pancreatic cancer, 18F-FAPI PET has higher specificity compared to 18F-FDG PET. Therefore, combining information from both tracers can better assist diagnosis, improve diagnostic accuracy, and thus have significant clinical value. The aim of this study is to generate 18F-FAPI PET images from 18F-FDG PET images using deep learning (DL), aiming to reduce the number of PET scans for patients, lower radiation doses, and provide clinicians with more comprehensive and richer information.
In this study, 120 pairs of 18F-FDG and 18F-FAPI PET images from the same patients scanned at different times were collected. First, the images from the two PET tracers were registered to ensure spatial alignment. We then proposed a Grad-CAM-guided 3D cGAN deep learning method (Grad-CAM Guided cGAN, GCG cGAN) that can generate 18F-FAPI PET images from 18F-FDG PET images. To mitigate the gradient vanishing problem and smooth the gradient flow, we used Mean Squared Error (MSE) loss instead of Binary Cross-Entropy (BCE) as the objective function for the GAN. Additionally, an L1 loss function and a Grad-CAM-guided attention mechanism were introduced to provide further guidance for the image transformation. The Structural Similarity Index (SSIM), Peak Signal-to-Noise Ratio (PSNR), Root Mean Squared Error (RMSE), and Normalized RMSE (NRMSE) were calculated to assess the overall image prediction accuracy. The tumor ROI SUV mean was computed, and the correlation between the predicted and real images was plotted.
The results show that the 18F-FAPI PET images generated using the GCG cGAN method are similar to the real 18F-FAPI PET images (SSIM = 0.981, PSNR = 46.02, RMSE = 0.297, NRMSE = 0.570). Correlation analysis indicated a strong correlation between the generated and real 18F-FAPI PET images (slope = 0.73, R^2 = 0.62).
Conclusions: The method proposed in this study to generate 18F-FAPI PET images from 18F-FDG PET images is feasible. This approach can reduce the number of scans, time, and cost for patients, and provide clinicians with more accurate and comprehensive diagnostic information.

F: Digital Health, Connected Devices & AI/IoT

Reasonable Configuration Evaluation and Decision-Making Application Platform Construction for Large-Scale Medical Equipment

By Hongliang Qi*, Weiguang Liao, Hanwei Li, Ye Chen, Hongwen Chen

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Objectives: Establish a large-scale medical equipment rational configuration evaluation and decision-making model and an intelligent application tool based on real-time dynamic full process data. **Methods:** To greatly shorten the development time and have strong portability and compatibility after software design and packaging, the overall development language of the software is Python, version 3.8.4, the interface UI is built using PyQt5 5.15.9, the algorithm library mainly uses scikit learn 1.3.2, and the database uses SQLite 3.35.5. The integrated development environment uses VS Code, which has advantages such as being lightweight and fast running speed. It also provides functions such as auto completion, intelligent perception, static inspection, debugging, and unit testing, as well as the ability to easily switch between Python environments. It is paired with the Anaconda package manager to achieve development environment isolation. Logging and unit testing use the logging and unit test open source modules, respectively, and finally, Pyinstaller is used for software packaging. The software runs on the Windows platform. **Results:** In order to study the practical application of a rational configuration decision evaluation system for large-scale medical equipment data platforms based on real-world data, this study describes and develops a large-scale medical equipment configuration scheme evaluation software. The rational configuration decision evaluation system for large-scale medical equipment is combined with artificial intelligence algorithms based on real-world data to achieve three main functions: applicability evaluation of large-scale medical equipment configuration, rationality evaluation of large-scale medical equipment configuration, and comprehensive analysis and evaluation of large-scale medical equipment configuration. The usability and reliability of the software are verified through practical examples. **Conclusions:** This platform has initially formed a standardized, intelligent, and scalable application system and tools through the analysis of real dynamic data, providing a management loop for the configuration, tracking, traceability, and evaluation optimization of large medical equipment.

F: Digital Health, Connected Devices & AI/IoT

Real-Time Monocular Endoscopic Depth Estimation Based on Synthetic Data and Domain Adaptation

By Hu Yingzi[1,*], Shenglin Liu[2], Qingmin Feng[2], Yongzhi Liu[2], MingXuan Li[3]

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Accurate depth estimation in endoscopic imaging is crucial for precise navigation and lesion localization. However, the constrained space of endoscopic instruments limits the application of conventional depth sensing technologies. In addition, the highly variable appearance and complex morphology of colonic tissues present significant challenges. This study proposes a deep learning-based approach to estimate depth maps directly from endoscopic images. Based on the DepthAnything monocular depth estimation model, domain adaptation fine-tuning is performed using the ZoeDepth framework. To enhance spatiotemporal consistency in depth predictions across endoscopic video sequences, a novel temporal gradient matching loss is introduced. The training dataset is generated from segmented computed tomographic colonography (CTC) data to reconstruct 3D colon surface models. Using a Blender-based simulation pipeline, 8 video sequences comprising 20,000 frames of synthetic colonoscopy images with precise depth annotations are constructed. The proposed method is evaluated against existing approaches, demonstrating real-time performance and improved accuracy in endoscopic depth estimation. This hardware-independent solution provides a promising direction for intelligent endoscopic navigation systems, with potential clinical applications in 3D lesion localization and surgical path planning.

F: Digital Health, Connected Devices & AI/IoT

Multimodal Feature Fusion Using Transformer for Gamma Passing Rate Prediction in Stereotactic Radiotherapy

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Stereotactic radiotherapy requires precise dose delivery due to its use of small target volumes and steep dose gradients, making individualized quality assurance essential. Traditional quality assurance methods based on portal dose image prediction and gamma analysis are widely used in clinical practice but are time-consuming and labor-intensive. This study investigates a deep learning-based method to virtually predict gamma passing rates for treatment beams in stereotactic radiotherapy. To enhance prediction performance, we developed a transformer-based neural network that incorporates a multi-scale fluence image encoder and integrates beam complexity features extracted from the treatment plan, including monitor units, segment area, and aperture modulation. These complementary inputs improve the model's ability to capture both spatial dose distributions and plan characteristics. The model was trained and tested on a multi-institutional dataset using various gamma evaluation criteria (e.g., 2%/2 mm). Results showed that the proposed feature fusion approach significantly improved prediction accuracy compared to models using fluence images alone. This work demonstrates the feasibility of transformer-based virtual quality assurance and its potential to reduce the workload of conventional pre-treatment verification in stereotactic radiotherapy.

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F: Digital Health, Connected Devices & AI/IoT

Development of an Integrated Application System for Ambulatory Blood Pressure, Electrocardiography, and Oxygen Saturation

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Blood pressure (BP), electrocardiogram (ECG), and oxygen saturation (SO_2) are vital physiological parameters. The simultaneous, continuous, and dynamic acquisition of these three parameters in a wearable form, along with subsequent analysis, is of great significance for the assessment of health status and diagnosis and treatment of diseases. In this study, we develop a hardware and software monitoring and analyzing system that can simultaneously collect the three vital signs signals of BP, ECG, and SO_2 over 24 hours dynamically. A PC-based human-computer interaction software platform is constructed and integrated with algorithms for analyzing ambulatory BP, ECG, and SO_2 data. Multiple parameters of BP, ECG, and SO_2 are extracted, including BP load, BP standard deviation, BP variation, spoon BP, atherosclerosis index, heart rate, etc. The system outputs comprehensive BP reports, statistical graphs, trend graphs, and electrocardiogram analysis reports, which can accurately reflect an individual's BP and cardiac status. In order to verify the reliability of the measurement system and the feasibility and accuracy of the analysis system, tests and comparative verifications are conducted. The results show that the system is able to operate stably, perform analytical functions, and output the results effectively, which can detect abnormal data and parameters. It provides the basis for disease diagnosis and treatment, thereby exhibiting practical application value.

F: Digital Health, Connected Devices & AI/IoT

Construction of a High-Reliability Wireless IoT for Medical Devices Based on Wi-Fi 6

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The data generated by a wide variety of medical devices in hospitals plays a crucial role in precision diagnosis, treatment, and refined management. The Medical Device Internet of Things (MD-IoT) connects diverse medical devices with information systems and data platforms through sensing and communication technologies, thereby supporting

data acquisition, interoperability, and comprehensive analytical utilization during medical processes. MD-IoT enables more efficient collection of patient and medical equipment data, accelerates information flow and integration within the hospital, facilitates preventive maintenance of equipment to reduce clinical risks and adverse events, and provides clinical decision support through in-depth data analysis. Additionally, it offers precise support for hospital equipment management.

MD-IoT can be established via wired or wireless approaches. Wireless MD-IoT solutions facilitate device mobility and ease of use. The sixth-generation Wi-Fi technology (Wi-Fi 6) provides longer communication distances, broader bandwidth, and higher data transmission efficiency, making it particularly advantageous for constructing wireless MD-IoT networks of critical care devices such as patient monitors, infusion pumps, and ventilators, which often require cross-ward or cross-department mobility. Wi-Fi 6 is also highly suitable for rapidly deployable mobile hospital MD-IoT systems, enabling swift device integration within short timeframes. Despite the promising applications of Wi-Fi 6 in wireless MD-IoT deployment, the diversity of medical devices poses challenges, as many lack built-in Wi-Fi 6 modules. Therefore, research is needed to develop Wi-Fi 6-enabled intelligent acquisition terminals compatible with various medical device interfaces, as well as multi-protocol parsing and data acquisition/transmission technologies, to achieve reliable Wi-Fi 6-based wireless MD-IoT construction. To address the requirements of rapid deployment and connection, high-speed and stable data acquisition, and secure transmission, this study developed an MD-IoT integration platform and data acquisition system based on Wi-Fi 6. Key breakthroughs include high-stability wireless intelligent acquisition terminals adaptable to medical devices of different categories and brands, as well as technologies of edge-container-based multi-protocol parsing and high-concurrency, high-throughput real-time data processing. A Wi-Fi 6-based hardware, including wireless customer premises equipment (CPE), intelligent access point (AP), and edge intelligent gateway, was developed. Based on the hardware, dual-band (2.4 GHz/5 GHz) transmission/reception selection with time-priority algorithms for data integrity verification and seamless roaming was studied. A multi-protocol parsing software based on the Thrift framework was developed, which can achieve a 50% reduction in parsing time via field-based memory sharing and dynamic link library calls, and enhance system stability by containerized stream computing for high-throughput time-series data.

Based on the developed wireless hardware and software, the MD-IoT system was constructed with the advantages of strong compatibility for rapid/mobile device integration, high-reliability multimodal medical data transmission. The communication latency is less than 12ms, and the protocol parsing time is no more than 500 ms. This Wi-Fi 6-based MD-IoT system lays the foundation for the acquisition, storage, and intelligent analysis of diagnostic and operational data from medical devices, demonstrating a broad application prospect in smart diagnosis/treatment and intelligent risk management of healthcare equipment.

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The Influence of Cybersecurity on Medical Device Exploitation

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This study explores the Influence of Cybercrime on Medical Device Exploitation to assess the impact of cyberattacks on hospital operations and patient safety worldwide, but particularly in Africa. To achieve this objective, we adopted a qualitative, descriptive, and exploratory approach; consulting scientific reports, including documentary reviews; semi-structured interviews; and case studies. The results demonstrated that Africa, because of its lackluster healthcare system, is the target of numerous cyberattacks, which suggests that the continent is extremely vulnerable to the protection of personal data of users and patients collected in hospitals. Furthermore, additional observations revealed that cyberattacks are perpetrated every day on medical devices without anyone realizing it. These findings have significant

implications for increasing awareness of this massive problem, which is minimized and ignored by virtually everyone. In conclusion, this study presents multiple variations and allows us to realize that the cybersecurity aspect of medical devices is not necessarily taken into account in their operation, highlighting the importance of raising awareness in order to take meaningful action. Future research could deepen this topic further by reviewing legal texts and strengthening cybersecurity policies in hospitals.

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Experimental Evaluation of Poc Systems for Monitoring the Operation of Con-Nected Biomedical Equipment and Integration of Cybersecurity Mechanisms in Hospital Environment

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The evolution of increasingly interconnected medical devices is leading to a growing exposure of clinical infrastructures to cyber risks, often lacking adequate levels of IT security. In this scenario, the testing of Proof of Concept (POC) systems for monitoring the operation of biomedical equipment represents an innovative strategy to combine technical-functional management with IT security monitoring. The project is divided into several phases: Mapping of the biomedical network architecture, Definition of performance and safety indicators, Installation of software and hardware sensors for data collection, integrated with the company system and the CMMS (Computerized Maintenance Management System) platform. The system also provided for the adoption of machine learning algorithms for the identification of anomalous behavioral patterns of the devices, enabling the automatic generation of alerts in the event of deviations from the expected operating conditions or attempts at compromise. The use of this POC has allowed early detection of technical criticalities and signs of cyber-attacks, contributing to the safety of critical nodes through automatic isolation and dynamic reconfiguration of the network segments involved. The main results obtained are the reduction of fault detection times, the increase in operational reliability, the improvement of coordination between Clinical Engineering and ICT, and the strengthening of the hospital's cybersecurity posture. The system has proven effective in identifying vulnerabilities resulting from obsolete firmware, incorrect configurations, or unauthenticated devices and has developed a detailed history of diagnostic and maintenance activities. However, critical issues have been identified related to the fragmentation of communication protocols, the need for standardization of interoperability (DICOM, HL7, IEEE 11073, and MQTT), and compliance with current regulations on security and data protection (GDPR, MDR, and NIS2). The experimental adoption of integrated POC systems for operational monitoring and cyber protection of biomedical equipment represents a necessary evolution in the management of clinical and technological risk, but their application requires architectural rethinking, multidisciplinary governance, and targeted investments in digital skills.