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Editor's Corner

A Call for Competence-Driven Healthcare Technology:

The Right to Repair and Clinical Engineering Competency

The debate surrounding "Right-to-repair" has reached clinical engineering, sparking a crucial discussion about technical expertise and patient safety. On one hand, healthcare providers question why they cannot choose service providers for their medical equipment, obtain replacement parts, and manuals given their investment in acquiring and maintaining its performance. On the other hand, the industry raises concerns about the specialized training and qualifications necessary for safe and effective maintenance of sophisticated devices..

This debate hinges on the concept of competency: the ability to perform a task effectively. In healthcare, where lives hang in the balance, ensuring competency should be paramount. Unlike a simple household appliance, medical equipment demands intricate knowledge, experience, specialized tools, and a deep understanding of its intricacies. Therefore, simply owning the device should not grant automatic repair rights. As you can see on the cover page of this issue, we encourage further understandings of professional stewardship characteristics especially as it refers here to engineering competency. The foundation of competency lies in education, discipline boundary, skills sustainability, and compliance with professional credentialing. From the wisdom of the book of Proverbs, the biblical anthology of saying and instructions, ("Discretion will watch over you, understanding will guard you...") to the Latin root "competere", which is a combination of "com" ("together" or "with") and "petere" ("to seek" or "go towards"). Therefore, the literal meaning is seeking or suitable to go together, having competence. Over time, the term evolved generally to represent the ability, capacity, or fitness to perform tasks or function effectively. It is commonly used now to describe a set of skills, knowledge, and attributes that make an individual a capable and qualified practician in a particular field, role, or task. In healthcare, ensuring patient safety necessitates demonstrable competent stewardship, including from the professionals who ensure that patient care medical technology is safe and effective.

As healthcare grows ever more technology-intensive and its reliance on that technology increases, the Clinical Engineering profession competency becomes ever so more vital. Patient who enters the healthcare system for the treatment of their disease or abnormal condition may be unable to understand and to make decisions about the technology that is about to be used during the treatment or management of their condition. Further- more, patients may be unable to fend for him/herself due to receiving medications or anesthetic drugs that render them unconscious, unable to make decisions.

In such situations patients are appropriately expect that members of the healthcare team will ensure that the technology used on them is safe and effective. The care team includes clinical engineering practitioners. While physicians are taking the historical Oath of Ethics known as "Hippocratic oath", engineers are also bound by the "First do no harm" (in Latin Primum non nocere) and by the engineer's creed contained in Professional Engineer ethical oath.[1]

Assessing and maintaining competency requires a multi-pronged approach:

- **Technical knowledge:** Examining expertise in relevant systems, protocols, and troubleshooting.
- **Risk management:** Evaluating the ability to identify and mitigate potential risks associated with equipment operations and maintenance.
- **Problem-solving skills:** Assessing the capacity to diagnose and resolve technical issues effectively.
- **Communication skills:** Ensuring clear and concise communication with stakeholders, including healthcare professionals and patients.

- **Project management:** Evaluating the ability to manage equipment maintenance projects efficiently and effectively.
- **Ethics and professionalism:** Assessing adherence to ethical principles and professional standards.
- **Continuous learning:** Evaluating commitment to ongoing learning and knowledge acquisition.

The methods for measuring competency range from performance assessments and technical examinations to peer reviews and self-assessments. Ideally, the approach should be tailored to the specific context and goals of the organization and the engineering discipline. However, a global baseline of competency is essential to ensure safe patient outcomes.

The debate around "Right-to-repair" ultimately boils down to who should determine competency: the industry or the healthcare provider? We, as clinical engineers, must advocate for competency-based access, demonstrating our value through education, professional credentialing, and ethical practice. This will pave the way for a future where clinical engineering is recognized as a "free" profession[2], empowered to make decisions based on expertise and not external constraints.

Join the conversation! Share your thoughts on the "Right-to-repair" debate and how we can achieve competency-driven healthcare technology management programs. If you're not yet accredited, let us know how we can help you on your journey towards professional recognition. Global Clinical Engineering Alliance and the Global Clinical Engineering Journal will look forward to your response.

We can ensure that patient safety remains the cornerstone of our discipline, and that means, that together we can make it better.

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Have a wonderful and productive 2024!

Dr. Yadin David

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A Landscape Study to Determine the Innovation Mortality Rate in Health Technology Innovations Across the Globe

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ABSTRACT

Introduction: Health technology innovation encompasses many areas, such as medical devices, diagnostics, pharmaceuticals, digital health solutions, telemedicine, health informatics, and more. These innovations aim to enhance healthcare delivery, improve patient outcomes, increase access to services, reduce costs, and advance medical research.

Methodology: We have analyzed health technology innovations reported between January 2011 and December 2022. Regulatory approval for the innovative products was determined based solely on official open-access websites of health agencies, disregarding information from company websites or third-party sources. The search process utilized identified innovation agencies and sources like Primary Health Care (PHC) Tech Challenge, World Health Organization (WHO) compendium, Global Grand Challenges (GGC), and Biotechnology Industry Research Assistance Council (BIRAC). Innovations were thoroughly examined from these sources, focusing on health technologies, and success was gauged through regulatory approval.

Results: The WHO Compendium includes 200 health innovations primarily intended for low-resource settings, with the USA accounting for the highest number, followed by India, the only low- and middle-income country (LMIC) with significant innovations. However, 58% of the listed innovations did not obtain regulatory clearance. Medical devices dominated the listed innovations, while scalable assistive technologies were limited. Global innovation agencies, particularly Grand Challenges, supported many innovations, but the regulatory approval rate remained low. In India, BIRAC supported 92% of the mapped innovations, with a similar trend of low regulatory approval rates.

Conclusion: The study observed the highest number of innovations during 2015-2017, with medical devices being the most prominent category. However, most innovations from both global and domestic agencies were unapproved, raising concerns about regulatory clearance for these health technologies.

Manuscript Highlights: The manuscript presents several important highlights concerning health technology innovation and regulatory approval. It highlights the evaluation of health innovations from 2015 to 2022, focusing on their success rate based on health agency approval. It reveals an uneven distribution of innovations from different countries and emphasizes the need for critical interventions to improve the process. This study emphasizes the significance of innovations in achieving healthcare equity and sustainable development goals.

Keywords – *Health technology innovation, Regulatory approval, Medical devices, WHO Compendium, BIRAC, Global innovation agencies.*

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INTRODUCTION

Innovation is fundamental to progress and development in various sectors, including business, healthcare, technology, and agriculture. It encompasses integrating fresh ideas, concepts, and creativity into tangible and usable products or services that cater to the needs of the public at large. Moreover, innovation is not limited to creating entirely new products; it also involves enhancing and improving existing offerings, resulting in better customer experiences and increased efficiency.[1]

Though various fields have distinct breakthroughs based on their domain, our analysis will be based on the product innovation of health technology innovation across different countries. Healthcare innovation can be as simple as changing a form to check out a patient five minutes faster or as complex as immunotherapy targeting specific cancer cell types. Simple or complex developments that lead to improvements in health outcomes and patient experiences are considered healthcare innovations. Health technology innovation refers to developing and implementing new and improved technologies in the healthcare sector.[2] It involves the application of scientific knowledge, engineering principles, and innovative ideas to create tools, devices, systems, and software that enhance the prevention, diagnosis, treatment, and management of diseases and improve overall healthcare delivery.[3]

In healthcare, innovation holds immense potential for revolutionizing patient care, disease prevention, diagnostics, treatment, and monitoring.[4] The healthcare sector thrives on innovations that can significantly improve health outcomes, enhance access to services, reduce costs, and contribute to advancements in medical research in the real world.[5] Innovations in medical devices, such as implantable devices, robotic surgery systems, prosthetics, and wearable sensors, have substantially impacted patient care and medical interventions. Similarly, diagnostic tools and techniques, like genetic testing, point-of-care diagnostics, imaging technologies, and lab-on-a-chip devices, have revolutionized early detection and accurate diagnosis of diseases, leading to better treatment outcomes.[6]

Despite the remarkable potential of health technology innovations, the innovation process can be arduous and challenging. Many innovators invest significant efforts into transforming their ideas into commercially viable products; however, many of these innovations eventually face failure. This failure could occur at any stage of the innovation process, and the reasons behind it can be multifaceted.[5,7]

It is laborious to think about a product from the initial seed of a concept through its commercialization. Even though many innovators need their innovations to complete this laborious procedure successfully, most fail after some period. Any stage of the invention process might fail.[8,9]

Start-up companies often confront a higher risk of failure, especially during their initial years of operation. The competitive landscape and rapidly evolving consumer needs and preferences can lead to shorter product life cycles, necessitating continuous innovation and adaptation for survival. As a result, organizations must constantly reinvent and improve their products or services to stay relevant in the dynamic market.[10,11]

Considering this, many start-up companies have a significant chance of failing, with many failing after a few years. This is attributed to intense competition and rapidly changing consumer needs, resulting in shorter product life cycles.[12] companies must continuously innovate and improve their products or introduce new ones to survive. Not all innovations are successful, and failing to commercialize them wastes important investments.[5] Acquiring company-level data on innovation failure is challenging. The study focuses on macro-level data at the country level to acquire insights into the information provided. Compared to well-established organizations, start-ups are more prone to failure, with a considerable proportion failing to survive beyond their first few years.[13] This is primarily due to their intense rivalry, exacerbated by the rapidly changing consumer needs. As a result, the market lifespan of items has been considerably reduced, necessitating ongoing innovation and adaptation.[7]

According to studies, the ratio of successfully commercialized discoveries to failed ones could be as low as 1:300.[14] This means that a significant amount of investment in innovation may be squandered. The financial expense of innovation adds another degree of complexity. Innovation activities are frequently expensive, involving research and development (R&D) costs, experimentation, and

market testing. These costs can be enormous, and when combined with the risk of failure, they create a difficult environment for new businesses.[15,16] Innovation mortality refers to the rate at which new products or ideas fail to gain traction in the market or within an organization. It measures the failure rate of innovations or ideas and can be used to evaluate the success of an organization's innovation efforts.

While existing research has primarily focused on the positive impact of innovation on a company's survival, our study takes a different approach. It seeks to understand how innovation has attained the rate of mortality . Due to the numerous micro-level data regarding innovation, this research relies on macro-level data on specific agencies and organizations. By analyzing broader trends and patterns, the study aims to shed light on the relationship between innovation activities and the ultimate failure of health technology innovations.[17,18]

MATERIALS AND METHODS

The methodology includes the mapping of health technology innovations across the various countries in the world. There were pre-defined criteria for including the health technologies. The inclusion criteria include any health technology innovations within a period of January 1, 2011, to December 31, 2022.

We depend on open access to official regulatory agency websites to determine health agency approval. We do not consider the information on the company website or any third-party websites, including newspapers.

The search includes list of already identified innovation agencies across the world, PHC (Primary Health Care) Tech Challenge, which is a search for innovations in a primary healthcare setting, WHO (World Health Organization) compendium of innovative health technologies for low-resource settings (2011 to 2020) and Global Grand Challenges, and Biotechnology Industry Research Assistance Council (BIRAC). Innovation agencies shall be of any entity, i.e., government, private, non-governmental organization, independent, a collaboration with UNDP (United Nations Development Program), charity organization, or any university collaborative agencies. We have selected five innovation agencies in total for this study. Among them, three were global, and two were from India. PHC Tech challenges was a special call for mapping innovations specific to primary health care. The rest are agencies aiming to find and support innovations from different areas.

We identified the website of each of the innovation agencies from a browser. We thoroughly investigated the English-language calls for proposals, grants, current initiatives, and services. We narrowed our search to just health innovations on the websites of individual innovation agencies based on the inclusion criteria. Irrespective of the agency's website, we also searched the health innovations from the "Global Grand Challenges," "WHO Compendium of innovations for low-resource settings," "PHC Tech Challenge," and "BIRAC."

Various innovations were found from the GGC, a family of initiatives fostering innovation to solve key global health and development problems, while the PHC Tech Challenge includes the compendium of health innovations for primary healthcare settings. These innovations are exclusively shown to bring promising health innovations across the globe to support PHC planning, management, and quality improvement. We also identified the health technology innovations from WHO Compendium of Innovative Health Technologies for low-resource settings from the year 2011 to 2020,[19] which consists of commercially available medical products and finally the BIRAC[20] and PHC Tech Challenge in India[21] in where the innovation and the company's name has been identified for the further collection of macro-level data.

The success of an innovation is decided based on the regulatory approval received from health agencies. All the health technology innovations mapped had been cross-verified to check the regulatory approval of the same products.

STATISTICAL ANALYSIS

In this study, a descriptive assessment of the findings was conducted to summarize and present the results clearly and informally. The results of the analysis were represented in the form of summaries, tables, and figures. Descriptive graphs in bar charts, pie charts and histograms were used to provide visual insights into the

data's patterns, trends, and distribution. Tables were also used to identify the trends and to provide comparisons. Bar charts were utilized to illustrate the frequency or distribution of categorical data. Pie charts were also used to present the proportion of each category within a whole to provide an understanding of relative components.

RESULTS

The WHO Compendium represents the list of health technology innovations that are commercially available. The total number of commercially available products are 152 in number, and prototype products mentioned in the compendium are 48. Of 152 products, 114 received approvals from their respective countries of origin. The WHO Compendium identifies the manufacturer-reported information and the evaluation of innovation results. It focuses on health technologies that can potentially improve health outcomes and quality of life, or offer a solution to an unmet medical/health technology need. It acknowledges success stories and raises awareness of the pressing need for appropriate, affordable design solutions. It also promotes innovation in the field of health. This effort aims to promote interaction among ministries of health, procurement officers, donors, technology developers, manufacturers, clinicians, academics, and the public. Ultimately, it ensures greater investment in health technology towards universal access to essential health technologies. The table represents the date of commercialization of the product, country of origin of the product, and category of the product. All these innovations are at 8 to 9 technology readiness levels. This emphasizes that this has entered the regulatory approval pathway, got approved by their respective country's regulatory approval authority, and entered the commercial market. These innovations mentioned here are successful.

The innovations under PHC Tech Challenge are a platform that brings together promising MedTech, digital health, and cold chain innovations for strengthening primary healthcare. The PHC Tech Challenge document was published in 2018 where they mentioned the overall products as 22. It was rolled out to supply a platform that brings together promising MedTech, digital health, and cold chain innovations from across the globe to key stakeholders (government, health agencies, donors, development partners, private sector companies and providers, etc.). PATH India with its partners embarked on a global search for innovators and entrepreneurs in the healthcare sector with the 'PHC Tech Challenge.' The success of a comprehensive PHC program by bringing together all the relevant stakeholders to advance efforts towards improving primary healthcare quality, access, and affordability and introducing transformative solutions/innovations that could be proven and scaled are found in this review.

A group of programs known as Grand Challenges promotes creativity to address significant global health and development issues. Every endeavor is a test of how to use difficulties to direct innovation towards having an effect. The Bill & Melinda Gates Foundation introduced Grand Challenges in Global Health in 2003. The first focus of this initiative was on 14 significant scientific problems that, if resolved, could make substantial progress in preventing, treating, and curing the illnesses and health conditions that contribute most to global health inequity. It was reintroduced in 2014 under the moniker Grand Challenges, reflecting its broadened focus to include problems with global development.[22]

We have considered 10 major Grand Challenges for identifying health innovations. The Majority were country-specific, and few were exclusively for specific innovations (such as Grand Challenges for development).

The Department of Biotechnology (DBT), Government of India, established the BIRAC, a not-for-profit Section 8, Schedule B, Public Sector Enterprise, as an interface agency to support and enable the emerging biotech enterprise to engage in strategic research and innovation, addressing regionally pertinent product development needs. BIRAC, an industry-academia interface, conducts its mandate through a wide range of initiatives that have an impact, such as providing access to risk capital through targeted funding, technology transfer, IP management, and support programs that help biotech companies become more innovative and competitive on a global scale.[20] We have mapped a total of 253 innovations on medical devices from 2012 to 2021. The WHO Compendium included noticeable innovations in the healthcare arena, intending to seek more support and aid for the same.

TABLE 1. Innovation Agencies Considered for Mapping

Sl No	Innovation agency	Country
1	WHO (Innovation compendium)	Global
2	Grand Challenges Global	Global
3	Innovation Agencies	Global
4	PHC Tech Challenge	India
5	BIRAC	India

All the innovations named by WHO, PHC Tech Challenges, were considered. However, innovations mapped from other agencies were included after considering technology readiness levels, scope, and novelty from a global perspective.

We have categorized our findings into three sections.

1. The WHO Compendium listed health innovations.
2. Health innovations supported through global innovation agencies.
3. Health innovations supported by India's major domestic innovation agencies and health innovation calls.

The WHO Compendium listed health innovations

We have mapped a total of 200 health innovations from WHO innovation compendium. The compendium incorporates innovations intended for low-resource settings. The WHO Compendium lists manufacturer-reported data and WHO evaluation findings for health technologies that can enhance the quality of life or health outcomes or address an unmet medical or technological need. It clarifies the benefits and difficulties of using cutting-edge medical technology in low-resource environments. It may be utilized by non-governmental organizations, governments, and other stakeholders to support purchasing choices.

The USA accounts for more than a quarter of the innovations listed by the compendium. India is the only LMIC comprising many health innovations (18 of 200). Innovations from a total of 44 countries were considered for assessment. Of them, 37 countries accounted for less than 5% of health innovations.

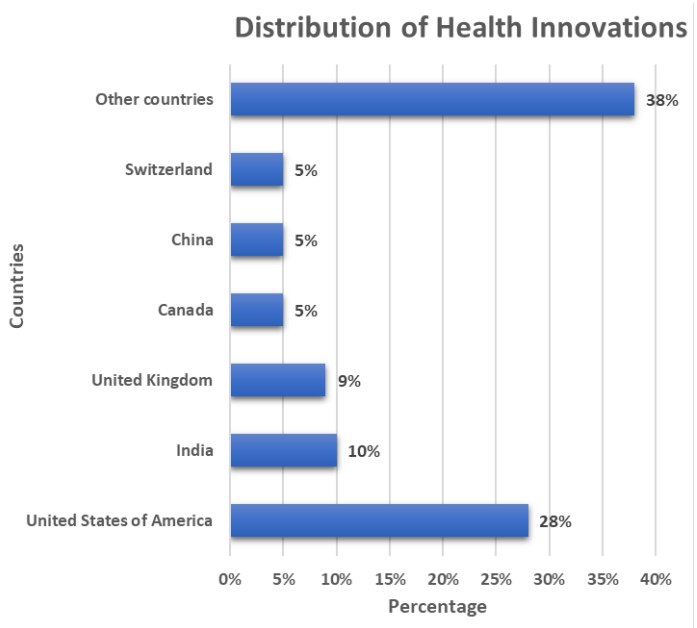

FIGURE 1. Distribution of health innovations with respect to country of origin.

The health innovations from African countries were exceptionally low. The analysis finds that 58% of the health innovations did not obtain regulatory clearance.

Although Canada, China, and Switzerland found a high proportion of regulatory agency approved health innovations, the country-wise approval rate remains the same in absolute numbers.

Medical devices account for nearly three-fourths of the overall health innovations listed in the WHO Compendium (140 of 200). The innovations in scalable assistive technologies were very few (3 of 200). The absolute number of innovations categorized as medical devices was significantly high (86 of 140).

Health innovations supported through global innovation agencies

Medical devices account for the maximum number of health innovations (32 of 67). E-health and assistive devices were the lowest (1 of 67). Regulatory agency approval for innovations mapped from global agencies was significantly low (6 of 67). The regulatory approval for GGC (1 of 43) was significantly low.

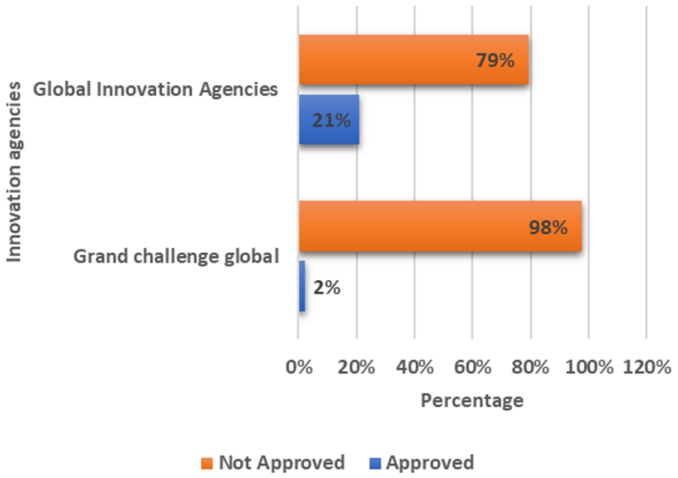

FIGURE 2. Distribution of innovation agency-wise regulatory agency approval status.

The 2015 to 2017 period showed the highest number of innovations supported by innovation agencies. Medical devices were the highest reported health innovation, followed by other technology and digital health. The analysis also found certain process innovations. Process innovations success rate cannot be determined based on health agency approval status.

A deep dive into the health innovations supported by India's major domestic innovation agencies

We have analyzed innovations supported by the major innovation agencies BIRAC, the Ministry of Biotechnology, and the Government of India, and innovations supported through a grand challenge call for PHC Tech Challenge. We have mapped a total of 273 health innovations. BIRAC-supported health innovations accounted for 92% of the total innovations mapped. Our analysis found that around 92% of the health innovations supported by domestic innovation agencies are not receiving regulatory clearance. The highest number of innovations were supported during 2015-2017. Although the reduction is insignificant, the COVID-19 pandemic could be accountable for the low support rate in the subsequent period. Medical devices accounted for the most supported medical innovations (58%). Other technology includes innovations in cold chain, infection control, etc.

The net regulatory agency approval was the lowest for the health innovations supported by global health innovation agencies. Innovations listed in the WHO Compendium, on the other hand, included many regulatory agencies' approved health innovations. Another noticeable finding was that the health innovations from low- and middle-income countries were significantly lower compared to high-income counterparts.

DISCUSSION

The study mapped health innovations supported by six innovation agencies and used regulatory approval to measure success. Surprisingly, over one-third of the supported innovations failed to obtain regulatory clearance. Cross-verifying regulatory agency approval from respective countries was done. Still, some innovations developed in high-income countries for different populations could not be assessed due to a lack of regulatory data. The peak of innovation support was observed during 2016-2018. However, innovations beyond 2021 were not included in the study, except for pandemic-driven ones. While the focus was on medical devices, other categories like digital health and assistive devices were also considered if they played a crucial role in healthcare. Despite this, many innovations lacked supporting documents on regulatory approvals on open websites.

There is currently no widely acknowledged comprehensive definition of innovation, and many fields (such as economics, public health, geography, and sociology) use somewhat different definitions. One of the earliest economists to recognize the importance of innovations to all economic systems, from small businesses to entire countries and the global economy, was Schumpeter. He defined innovation as any modification to the way something is produced, the creation of new goods, the organization of businesses, the entry into a new market, and the "creative destruction" that drives all developments under a capitalist market framework.[1] According to Manuel García-Goñi, innovations in health care can be classified into objects, the relationship to the existing standard, the system affected, the extent of change, and the readiness level. The World Economic Forum, in its latest report, mapped five innovations that could change

TABLE 2. List of Health Innovations and Its Regulatory Agency Approval Status

Innovations Mapped from Global Agencies				
Category of Health Innovation	**Approved by regulatory agencies**		**Not approved by regulatory agencies**	
	Number	**Percentage**	**Number**	**Percentage**
Medical device	5	16	27	84
Digital health	Nil	Nil	15	100
Other technologies	1	7	14	93
Assistive device	Nil	Nil	1	100
E-health	Nil	Nil	1	100

Innovations Mapped from WHO Compendium				
Category of Health Innovation	**Approved by regulatory agencies**		**Not approved by regulatory agencies**	
	Number	**Percentage**	**Number**	**Percentage**
Medical device	86	61	54	39
E-health	13	37	22	63
Other technology	2	13	14	88
Digital health	2	33	4	67
Assistive device	1	33	2	67

Innovations Mapped from India (BIRAC & PHC Tech Challenge)				
Category of Health Innovation	**Approved by regulatory agencies**		**Not approved by regulatory agencies**	
	Number	**Percentage**	**Number**	**Percentage**
Medical device	11	7	146	93
Other technology	2	4	46	96
Digital health	7	16	38	84
Assistive device	2	11	17	89

global health, which include artificial intelligence, 3-D printing, gene editing, virtual reality, and sensor development. Most of the health innovations mapped through the process were found to have some association with the forum-reported innovation domains.[23] David W. Feigal et al., in their paper titled "Impact of the Regulatory Framework on Medical Device Development and Innovation" states that the rate of innovation for regulated items is a function of how quickly research and engineering are developed to make choices about regulations based on

science. New scientific and public health concerns also have a life cycle, from conception to obsolescence, just as breakthrough medical products. Since the two are interwoven, delayed scientific advancement and a lack of a flexible, science-based regulatory decision-making process can hinder growth.[24] The author highlights that the slower the pace of regulatory agencies in approving the innovation, the more it affects the development of innovative medical devices. The World Trade Organization, in its Trade-Related Aspects of Intellectual Property Rights, is an international legal agreement between all the member nations of the World Trade Organization), states that the regulation of medical products has become difficult because of the globalization of product research, manufacturing, and supply as well as the rapid rate of technical and societal change in the setting of limited financial and human resources.[25] The Sixty-Seventh World Health Assembly approved resolution WHA 67.20, "Regulatory system strengthening for medical products," to recognize the value of strong regulatory frameworks. The resolution states that "effective regulatory systems are an essential component of strengthening the health system and contribute to better public health outcomes," "regulators are an essential part of the health workforce," and "inefficient regulatory systems themselves can be a barrier to access to safe, effective, and quality medical products."[26] A study titled "Innovation and Death Rate of Enterprise" identified the mortality rate of companies, where it also aims to analyze how the influence of innovation activities measured through R&D expenditures and the number of resident patent applications on the death rate of companies in member countries of OECD.[27,28]

The evaluation of cutting-edge medical devices is where technological uncertainty is most evident because the regulator must comprehend the scientific principles underlying the operation of the device but fails to have a clear understanding of the information needed to be persuaded of the product's efficacy and safety before the product entered into the regulatory review the line.[29] Addressing the uncertainty over the structure and format of the data necessary for a given medical device's regulatory clearance. The lack of clear guidelines for the protocol for evaluating an innovative product causes content and format uncertainty, which affects how the applicant firm should present and how regulators should evaluate the findings of clinical studies and other tests (like biocompatibility and engineering tests). Without the creation of precise assessment criteria, this form of uncertainty, which always coexists with technological uncertainty for innovative products, may continue.[30] As there may be several reasons why innovation has failed at any stage where we are not accumulating information about the failure, the mortality of innovations is any health innovations that are not commercially available and did not pass through the regulatory authorized channels. A remarkably diverse range of goods fall under medical devices, including pacemakers, coronary stents, and silicone breast implants.[31] Obtaining regulatory approvals for innovations takes much longer than the average approval process of follow-on innovations. This could increase the cost of the approval process. There are many efforts from different parts of the globe to ensure appropriate implementation of the innovations. However, many such efforts fail to deliver the intended benefits to the end user. Government regulations can have dual effects when it comes to promoting health innovations. Ensuring a positive regulatory environment is important, and should consider regulation affects innovation as well as the consequences of technological development for their justification and regulatory design. The OECD report[32] on regulations and innovation states that regulatory reforms should be considered whenever needed to accommodate technological developments. Strict competition policy might restrict the rate of technological process. Competition policy may result in only the approval of innovations from large firms in concentrated industries. As they could finance themselves for the R&D.[32,33] According to the NHS UK, to innovate successfully in the health field, several major problems must be resolved. Budgetary considerations.[33] Hospitals have a notably sluggish adoption rate for technological advancements. One explanation is that their IT staff are already overworked with installing, upkeep, and improving electronic health record (EHR) systems. However, hospitals' unbalanced budgeting and incentive structures might be mainly held responsible.[34,35] Currently, challenges are hindering the progress and widespread adoption of medical innovations, which are crucial for addressing gaps in global healthcare provision. One major obstacle is the slowdown in productivity within healthcare R&D, leading to prolonged timelines for discovering new treatments

for emerging diseases.[36] Consequently, numerous acute and chronic conditions such as cancer, depression, and Alzheimer's still lack groundbreaking cures. Another challenge lies in the comparatively slower diffusion of healthcare innovations compared to other industries. Translating medical innovations from the research stage to practical implementation is often protracted, spanning several decades. This delay can be attributed to the intricate nature of the healthcare innovation ecosystem and the divergent motivations of various healthcare stakeholders involved. Overcoming these challenges is imperative to accelerate medical progress and ensure widespread access to innovative healthcare solutions.[37]

The study had some limitations that affected its scope and data collection. Examining various organizations was limited, potentially leaving out relevant health innovations. Innovations were identified using organization or company names when generic names were unavailable, which might have impacted data accuracy. Additionally, the study faced challenges in identifying health technology innovations and distinguishing between established businesses and start-ups. As a result, certain health innovations, including process innovations and non-medical product categories like digital health, e-health, cold chain, and prototypes, were not considered for health agency approval. Moreover, the study did not assess the outcome of patents granted as a measure of success for health innovations. Moving forward, qualitative research could shed light on factors contributing to the failure of regulatory approval for specific innovations, helping stakeholders address barriers to clearance. This knowledge would assist stakeholders in creating a more supportive environment for health innovation and encourage innovation agencies to provide appropriate assistance for regulatory clearance. Broader consideration of health innovations, including process innovations and non-medical product categories, could enhance our understanding of the health technology landscape's impact on healthcare. Future research should also explore the relationship between patenting and innovation success, recognizing the potential role of intellectual property protection in health technology development and commercialization.

CONCLUSION

This review emphasizes the success of health innovations for the innovations mapped through our pre-defined inclusion criteria. We have considered health innovations mapped from 2015 to 2022 for this study. The distribution of health innovations as per the country of origin showed an uneven pattern and suggested that many innovations were incubated from high-income countries by the global agencies and WHO. The analysis also found specific innovations scaled up from high-income countries but intended for low and LMICs. The success of such innovations could not be determined only through health agency approval status. Health innovation support during the selected time duration showed an uneven pattern in supporting health innovations from the innovation agencies. Medical devices were the highest-mapped category of health innovation. Assessment of success for process innovations and e-health interventions could not be assessed for their success status as they do not require health agency approval. The report found that over three-fourths of health innovations fail to obtain regulatory clearance. This suggests the need for critical intervention interventions in health innovation facilitation by the innovation agencies. Innovations are paramount regarding healthcare equity and achieving the United Nation's sustainable development goals. However, meager support could result in redundant resource wastage. Hence, the global health agencies should streamline the process of innovation support.

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Sustainable Procurement of Medical Devices in an International Context - Part 3

Assessment of Local and Lifelong Use Conditions

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ABSTRACT

Background and Objectives: This article is the third in a series of three manuscripts published in this journal. It aims to describe how sustainable procurement of medical devices (MDs) can be implemented in operational projects in the context of developing countries. It also further details how the biomedical/clinical engineer lead (BCEL) in charge of technical support during the MD procurement process can apply sustainability principles and concepts of value-based procurement.

Material and Methods: Based on the authors' experience of more than 20 years in procurement projects and implementation of MDs, the role of the BCEL will be developed from a theoretical point of view with the description of the second and third pillars of a sustainable purchase following the needs assessment: the assessment of existing conditions along with local capacities and the evaluation of the use conditions during the lifetime of the medical equipment. The application of these principles in operational projects will be further discussed by analyzing literature and lessons learned from projects implemented in developing countries.

Results/Proposal: The BCEL has a key role in the sustainable procurement of MDs to design the technical specifications of the goods, related services, and post-sales conditions to maximize the benefit of the investment. As the specialist can analyze the local existing conditions and capacities while ensuring efficient use of the MDs during their lifespan, they can contribute to a sustainable implementation of MDs in developing countries.

The BCEL shall also be able to analyze the local and international markets to find all possible technological solutions that meet the needs, local conditions, and capacities and ensure quality use during the lifespan of the purchased MD. The BCEL shall have competencies in identifying all the risks related to the use of the MD from the safety risks linked to its installation, use, and maintenance to the sustainability risks linked to obtaining the conditions that guarantee the use of the device and maintaining them as long as possible. Examples of these conditions include the presence of qualified and trained users, availability of maintenance and consumable budgets, availability and maintenance of infrastructure conditions (access, electrical power, water, drainage, medical gasses, etc.), and last but not least, presence of patients requiring a diagnosis or treatment using the purchased MD who were identified during the evaluation of the first pillar: a sound needs assessment.

Conclusion: As an evolution of the BCEL's traditional biomedical and clinical engineering work, he/she shall assume the responsibility to guarantee the sustainability of the MD purchase. This quality assurance and control role is achieved by a sound theoretical background knowledge based on the three sustainable procurement pillars: the needs, existing and lifetime use conditions assessments, the analysis of the local and international markets, and a broad understanding of sustainability risks.

Keywords – *Medical device procurement, sustainable procurement, technical specifications, local conditions, local capacities, lifetime use of MDs, total cost of ownership, health services in developing countries, quality assurance, sustainability, clinical engineer role, international health procurement, value-based procurement.*

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INTRODUCTION

In a previous article,[1] sustainability principles and their importance in MD procurement projects, especially in developing countries, has been described. A theoretical concept with three fundamental pillars was proposed to improve the sustainability in MD procurement projects and address the risk of purchasing MDs that will not be used by local clinical personnel. This concept suggests focusing the technical work of the BCEL on three assessments: (1) the needs, (2) the local conditions and capacities, and (3) the conditions for the lifetime use of the MD. All actions performed during the project are recommended to be coherent with the results of these three assessments linked to the project's objective to facilitate the sustainable outcome of the purchased MDs.

Without specific attention to the sustainable conditions of use, an investment in health technology, including MD purchases, has a high risk of becoming a burden for the local health system.

This article aims to further detail how these pillars for sustainability can be implemented in MD procurement projects within the environment of developing countries. This article will focus on assessing the MDs' local and lifetime use conditions since the needs assessment was already developed in a previous article.[2] The responsibility and recommended actions that the BCEL can take to perform these assessments are discussed and analyzed using examples from implemented projects. In this framework, a convenient approach is to focus on value-based procurement, a novel approach to purchasing that evaluates potential new MDs to maximize overall value for money (including their economy, effectiveness, efficiency, equity, and sustainability), rather than focusing only on the lowest purchase price will also be explored.[3,4]

THE ASSESSMENT OF EXISTING CONDITIONS AND CAPACITIES

The second pillar of sustainability is the assessment of existing conditions and capacities where the MD will be used. This includes the analysis of the following conditions:

- The delivery logistics required to get to the installation site and the installation room from the nearest port/airport and the manufacturing site;
- The customs rules and regulations;
- The installation site infrastructure and installation conditions according to the technical requirements of the MDs to be implemented;
- The local and international rules and regulations on MDs, construction, electrical, fire prevention, health and safety, etc.
- The local capacities are clinical, technical, logistics, financial, etc.
- The availability of the MDs, services, and consumables on the local and international markets is needed to guarantee sustainability.

The result of these analyses is the development of detailed technical specifications for the MDs to be procured, starting from the technological level defined in the needs assessment in line with the analysis of the intended use of the MD, together with an adequate delivery and installation plan translated into requirements to be included in the tender documents.

The technical specifications of the MDs shall be tailored to consider local clinical and technical capacities as well as their working method, standards, and cultural environment. Therefore, a dialogue with the MDs' clinical and technical beneficiaries is essential during assessing the existing conditions and capacities for defining the technical specifications.

EG1 *MDs required to equip a delivery room can be selected in very different ways depending on cultural aspects, including delivery positions and the presence of accompanying relatives. Depending on the local culture, the use of birthing balls, stools, supports from the ceilings together or instead of the classical delivery bed have to be discussed and considered when designing the equipment list and their technical specifications.*[5,6]

Linked to the Incoterms used in the tender and purchasing contract, shipment conditions shall consider the

logistics and safety of the sites. Sometimes, due to urgency or specific logistic complexity, the delivery costs may become higher than the costs of the goods. To minimize the carbon footprint and reduce costs, local suppliers shall be encouraged to participate in the tender processes since ''goods sourced locally have a positive sustainability impact, e.g., eliminating transportation costs.''[7] In most cases, the National Regulatory Authority certification is mandatory to import the goods, and relevant customs bureaucracy shall be managed.

The design of pre-installation requirements represents, for complex equipment, a critical issue since the installation shall comply with the manufacturer's recommendations and local rules and regulations. In most cases, international practices and safety standards for the installation shall be added to local rules and regulations depending on the maturity level of the beneficiary country.

The result of the assessment of the existing conditions are:

1. Detailed technical specification of the MDs;
2. Complete delivery conditions and specifications;
3. Exhaustive organization of the pre-installation responsibilities;
4. Pre-installation requirements;
5. Training requirements for the tender process;
6. Installation requirements for the tender process.

The role of BCEL in the assessment of existing local conditions and capacities

Based on the assessment of the existing conditions: infrastructure, electromechanical installations, clinical and technical capacities, installed and available technologies, local market, intranet-internet connections, etc. the BCEL along with the local stakeholders and within the scope of the project agreement, will design, as summarized in Figure 1:

1. The technical specifications are the detailed requirements for the MD; In this process, the BCEL shall consider the technological level8 and the clinical objectives defined in the needs assessment as well as the installation conditions and, most notably, the local clinical and technical capacities, as well as the lessons learned in previous projects and the local and international market. This process implies a consistent workload depending on how the market analysis can be performed depending on the availability of lessons learned from previous projects. If an up-to-date database of previous successful projects with the same specific technology required for the project is available, the market analysis can be reduced. Suppose a new technology has to be purchased. In that case, the market analysis may require a larger technical effort and contact with potential suppliers and manufacturers, requiring several additional weeks for the specifications design of a single technology. Typically, this process is outsourced by the BCEL to other biomedical engineers who can work remotely while the BCEL focuses on the next steps.

According to the United Nations Office for Project Services (UNOPS)[9] and the United Nations International Children's Emergency Fund (UNICEF),[10] the BCEL could also perform additional sustainability considerations in the planning phase of the project:

- Plan a market analysis to understand and determine:
  - Sustainable solutions that might already exist in the local market;
  - Sustainable solutions that have been implemented internationally;
  - The economic, social and environmental risks/opportunities related to that specific MD;
  - Standards and regulations requirements available for the MD.
- Assess the sustainability risks of the MD and adjust the procurement strategy consequently.

2. The delivery requirements, including temporary storage and transport conditions, safety rules for manipulation and transportation, possibly considering, during tender evaluation, the carbon footprint. For larger equipment, these requirements shall include the access pathway inside the beneficiary's infrastructure to the final installation site, considering the size and weight of the good's packages: the rigging plan. This includes on-site transportation that can become relevant for heavy or large equipment requiring a detailed plan, including health and safety considerations for the workers. Also,

the disposal, recycling, or storage of equipment packaging can also be an important aspect to integrate into the technical specification preparation.

3. The pre-installation responsibilities are linked to the installation site and MD's specific chosen brand and model. The BCEL shall design how to organize the contractual responsibilities between the beneficiary hospital, the supplier, and the international purchasing organization, including, when relevant, the hospital's constructor. The exchange and approval of progressively more detailed technical drawings and the definition of responsibilities for the pre-installation work between all the stakeholders is essential to the success of the implementation. This process shall consider the standards and regulations applicable to the different installation aspects, such as structural capacities, radiation protection, hazardous material management, waste management, etc.

4. The pre-installation requirements which include all technical requirements for a safe installation and use of MDs that need to be specified by the BCEL to support hospital architects and engineers in designing new infrastructures or renovating existing sites[3]; They can be organized as shown in Table 1.

TABLE 1 Pre-installation Requirements, Which Include All Technical Requirements for the Safe Installation and Use Of MDs

Electrical supply	Temperature and humidity
Water hot/cold	Weight
Drainage	Radiation shielding
Medical gasses	Magnetic shielding
Other gasses	Biohazards containment
Network connections	

These requirements are specified when the equipment type is defined and adjusted with the manufacturer's documentation when the specific brand and model is awarded.

5. Human resources (clinical and technical) training requirements. The design of the training requirements is a critical issue, and the BCEL shall consider all available options from simple written instruction of use and maintenance to online training and tutorials or even in-person training by the manufacturer's certified instructor. The BCEL can also consider the possibility of longer training when introducing new technology. For example, the clinical and technical personnel could travel to a clinical or training center where the same equipment model is installed for several weeks of hands-on training. A good practice is to identify the trained personnel and restrict the use and maintenance of the MD only to trained staff. Another recommended strategy is training local technicians to maintain essential MDs, such as hospital furniture and simple equipment commonly found in primary care institutions that benefit a larger population.[11]

6. Detailed installation requirements in charge of the supplier to be included in the tender document. As the last step of the installation design, the BCEL will prepare the final installation requirements to be tendered with the equipment. These requirements shall match the on-site conditions, and the pre-installation works that the beneficiary or a third party eventually takes care of. It is a good practice to include the specific installation requirements in a framework considering environmental protection, health and safety of the installers, as well as human rights and gender equality policies. After installation completion, the supplier may be required to implement a communication plan to enhance the visibility of the project. If so, this activity shall be implemented under the strict supervision of the beneficiary.

The BCEL shall consider the impact of pre-installation works and installation activities on the hospital's clinical workflow and discuss it with the beneficiary before starting the purchasing process. In some instances, the impact can be so unacceptable for the beneficiary that the purchase of the new equipment is rejected, and a different technological solution shall be pursued.

To improve the quality of procurement processes, a standard template of technical specifications for the procurement of MDs with standards, regulations, and sustainability principles is recommended to be available for BCELs within an implementation agency. A peer-review mechanism of technical specifications, delivery, installation, and lifetime use plan by BCELs is also recommended to be incorporated into the procurement processes of MDs. The outcome of the project's implementation can be monitored, and lessons learned can be gathered to benefit future projects.

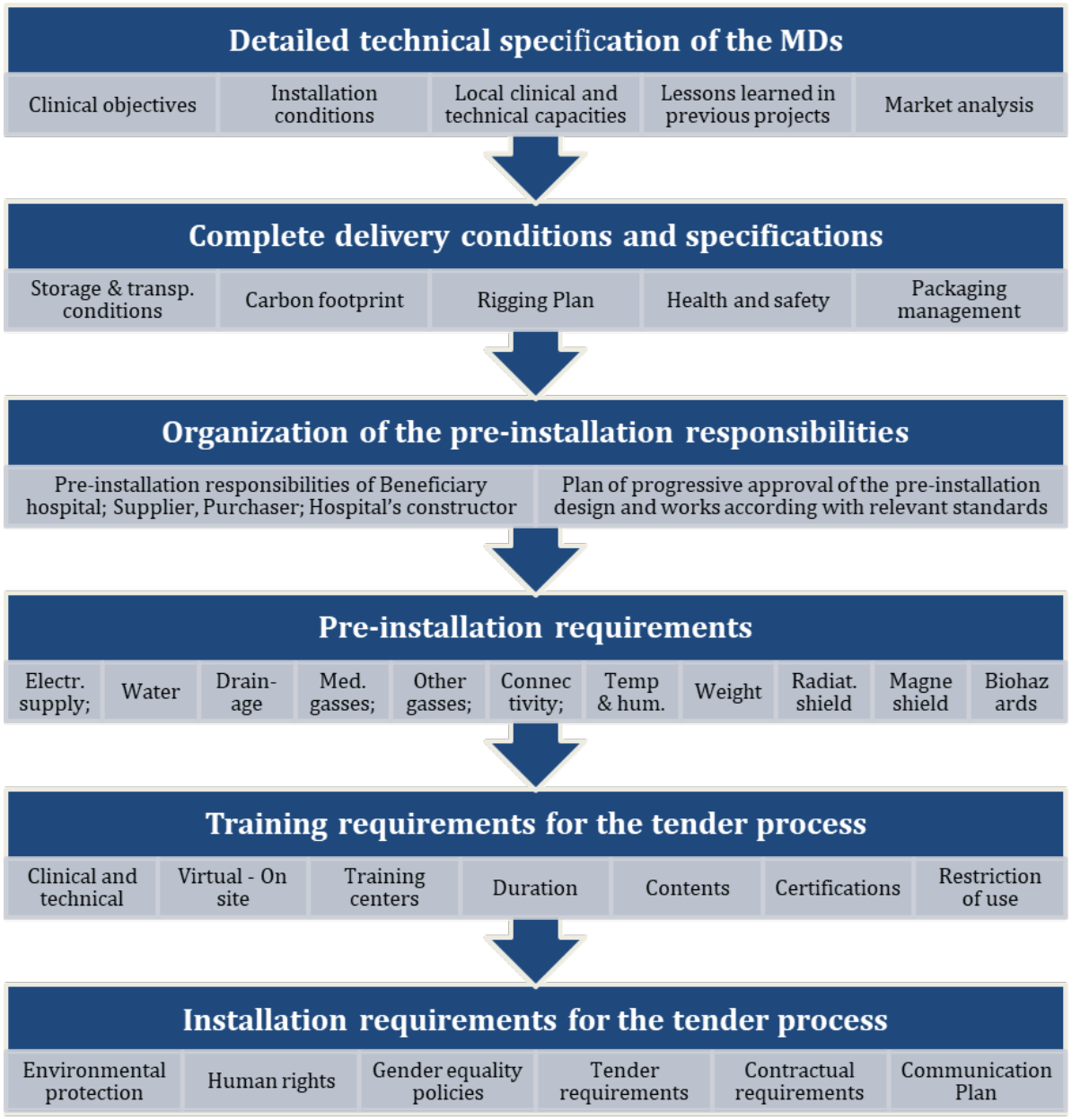

FIGURE 1. The role of BCEL in assessing existing local conditions and capacities.

EG2 *A purchasing project for a few computed tomography (CT) scanners installed in specific hospitals where the clinical engineer has also designed their sustainable use can be further investigated and improved if analyzed nationally. The national distribution of imaging equipment in a network scheme that minimizes the distance to the nearest CT scanner for the population, their connections, and their interactions through local and national PACS/RIS*

The sustainability risks of a weak assessment of existing conditions

A incomplete or absent assessment of the local conditions is, together with a weak needs assessment, the main cause for an unsuccessful project: the equipment is delivered but not used. The opportunity to improve the health system's quality and the investment are lost,

and the equipment becomes a burden to be removed and disposed of. The World Health Organization states, "According to one estimate, only 10–30% of donated equipment becomes operational in developing countries. Reasons for unused equipment include mismanagement in the technology acquisition process, lack of user training, and lack of effective technical support."[12] Other risks associated with a poor assessment of existing conditions can include the following examples·

- An impossibility to deliver, install, test the equipment or train personnel due to poor road conditions, war zones, etc.;
- A lack of services for the safe and effective use of the device: absence of a reliable electrical power source, unavailability of medical gasses, inadequate water quality, insufficient mechanical structure, no protection against radiation or bio risks exposure, lack of information technology, etc.;
- A lack or absence of training and qualified clinical and technical resources to use and maintain the MD;
- A lack or absence of proper accessories and consumables to make effective use of the device;
- Non-compliance of the device to local standards and regulations.[3]

The BCEL shall avoid additional examples of frequent pitfalls and derived lessons learned during the design phase:

1. Absent, insufficient, or wrong pre-installation conditions when the installation works are supposed to start. To prevent this situation, it is possible and useful in some cases to delegate the pre-installation works to the beneficiary hospital even when the beneficiary has a weak technical capacity. In these cases, the supervision of the works and the final approval shall be assumed by the BCEL and the equipment supplier. Only a close follow up of the execution of the pre-installation works can guarantee that the proper pre-installation conditions will meet the requirements.

2. A lack of personnel to be trained: The BCEL shall ensure that the beneficiary users are available and prepared to receive the appropriate training at the planned time. The final users and the final responsibility for maintenance shall be formally designated by the beneficiary authority to receive the training and be available during the training days. Furthermore, recording the training sessions to guide new users and creating a formal document to register who has been trained and is habilitated to use and maintain the equipment correctly is advisable.

3. A lack of specific tools and consumables on the local market. The BCEL shall verify in advance and search for alternatives when a particular tool or consumable is unavailable on the local market.

4. The local supplier representative lacks capacities for installation and post-sales services delivery. The BCEL shall confirm that the local representative of the supplier/manufacturer has been properly trained to install the equipment. The BCEL shall require appropriate certification of local technical people delegated for equipment installation from the manufacturer. In past projects, situations where local representatives could not install the equipment properly and damaged the new equipment during the installation attempt happened. The presence of the BCEL and close supervision of the installation process is recommended, especially for sensitive and high-technology equipment. In case of doubt, a video record of the installation can be useful.

5. During the installation planning, especially in large projects with tens or hundreds of installations, the climate factor has to be considered. The BCEL shall know the difference between the dry and wet seasons in the beneficiary country since some critical delivery operations of managing important loads from trucks to rural sites may be affected by heavy rains.

Working in a developing country environment requires additional flexibility and problem-solving capacities to face some unforeseen issues that arise during the installation. These issues can also be much more complex in a fragile environment.

EG3 *During the installation of a MD in a remote hospital in Haiti, a broken specialized tool represented an issue: the nearest market in the capital was far away, and most probably the specific tool was not available there. An overseas purchase was needed, adding a delay of at least 3-5 days on the overall installation.*

However, it's not all about risks, many opportunities can be analyzed and pursued during the project's design

and implementation. A relevant approach recommended to the BCEL is to constantly seek opportunities to improve the sustainability of the health system through the introduction of technologies.

EG4 *In Jamaica, nurses use most of their work time to manually measure patient vital signs and copy them on paper registers. They report that up to 90% of their time is used to perform similar paperwork. A simple device to monitor and record vital signs in a database can abruptly reduce nurse routine work and help nurses spend more time attending to patient's needs.*

Examples of local conditions assessments

Figure 2 shows the workflow for the pre-installation requirements responsibilities as designed by the BCEL in charge of the procurement project of [32] CT scanners in 2022 in the Philippines. Four main actors were involved: UNOPS organization, the Philippines Department of Health at a national level, the supplier, and the beneficiary hospitals.

Constraints at the beginning of this project were that installation site plans were not all available for every hospital, and it was urgent to implement the project according to certain emergency response programs. Based on the decision that each hospital had to be responsible for complying with the pre-installation requirements, the following operational workflow was designed by the BCEL in charge during the project launch.

In 2008, during a project in Uruguay, a communication plan was proposed by the BCEL and implemented by the project team to inform the recipient health units and the general population of the equipment to be delivered and of their schedule so that the units were prepared for the immediate inclusion of the new technologies in the clinical activities.[13] The Ministry of Health (MSP) implemented a component of the plan through radio messages and local newspaper advertisements. Each supplier implemented a second component under the strict supervision of the MSP. Tender requirements detailed the services required to

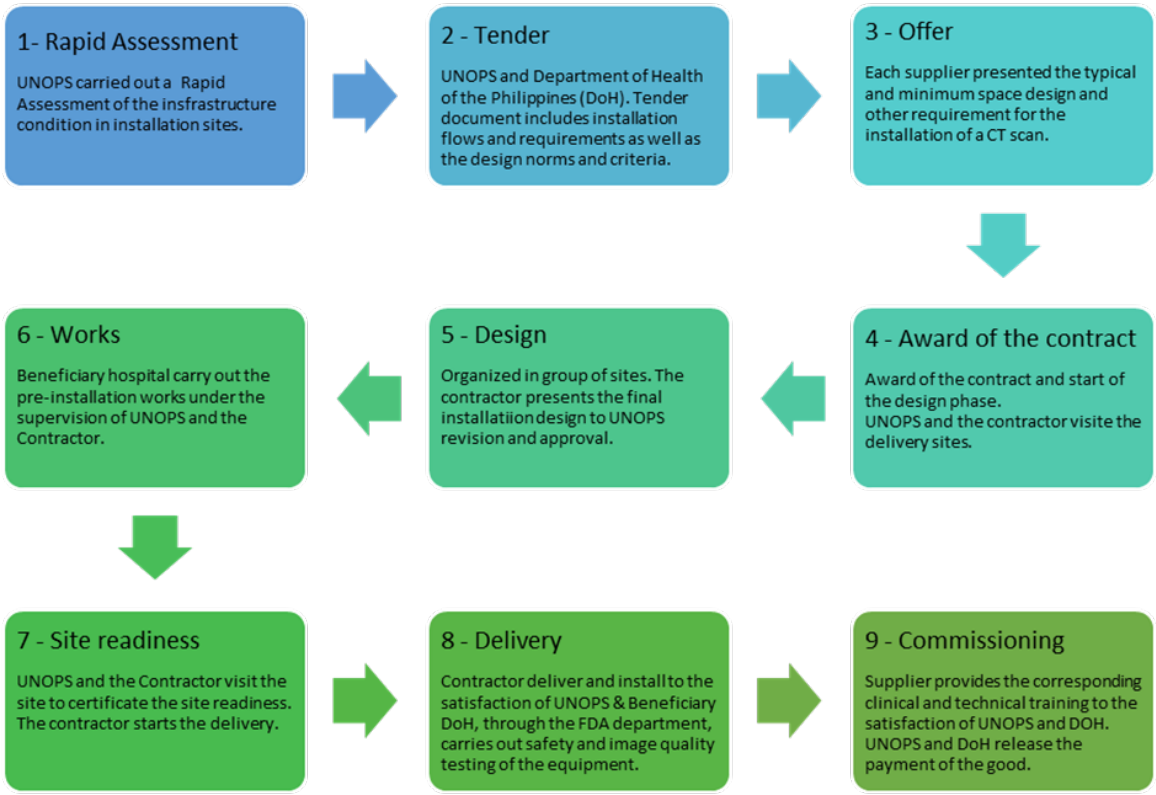

FIGURE 2. Workflow of 32 CTs Installation Process: From the Analysis of Local Conditions to the Definition of the Requirements, Implementation and Use (Klappenbach F. With The Permission Of The Author)

the suppliers: national television advertisements, national written press advertisements, and labels while establishing that the Ministry of Health will keep the rights to all information managed by the supplier, being the supplier forbidden to use it without written authorization.

In many cases, citizens, after a communication campaign on local radios and newspapers, went to the health units to see the new technologies. This process of local conditions assessment to implement the Italian loan for MDs purchase was successfully presented by the Ministry of Health to the Health Commission of the Uruguayan parliament on February 26th, 2008.

ASSESSMENT OF THE LIFETIME USE CONDITIONS

The third pillar of sustainability is the a**ssessment of the lifetime use conditions** of the MD. The result of this analysis is an adequate lifetime use plan. A key factor is to plan the duration of the useful life of the MD. The manufacturers are not used to expose the planned life duration of their goods, but this might change since "manufacturers are required to provide definite expected lifetime for the certification of their product under the new EU medical device regulations (EU MDR 2017/745)."[14] However, the US Food and Drug Administration does not require manufacturers to establish an expected life for a device.[15] The expected minimal life duration of the equipment is an essential element of any purchase since it is relevant to evaluate the total cost of ownership and is the basis of any asset management plan for existing and future technologies.

The role of BCEL in the assessment of lifetime use conditions

While considering the project's constraints such as the available budget, the local conditions, and resources, the BCEL shall explore their awareness and interest with the stakeholders on the purchase's mid- and long-term benefits. The BCEL shall also promote all the actions needed to maintain the equipment during its lifespan and keep the benefits and positive impact of the investment as long as possible.

The BCEL in accordance with the beneficiary, will design and propose, as summarized in Figure 3:

1. The planned lifetime use duration of the equipment. One of the impacts of the life expectancy definition is in the specifications for the materials of the goods. Certain kinds of steel or plastic can increase or reduce the life expectancy of medical furniture or a medical device while simultaneously increasing or reducing its value and purchasing cost. Once the expected duration of the equipment is determined, the BCEL shall revise the technical specifications of the MD to adjust and adapt them consequently to the available technologies on the market.

2. The post-sale services requirements, including warranties, maintenance, consumables contracts, and documentation, are to be provided with the MD.

3. For certain types of equipment, it is recommended to use the financial planning of the total cost of ownership. This costing methodology considers the total cost of a product over its lifetime. In addition to the initial procurement costs, transportation, maintenance, operations, utilities, training, consumables, and waste management costs are also evaluated based on the expected lifetime of the purchased equipment.[16] If the cost of post-sales services or consumables is substantial compared to the cost of the equipment, it is recommended to consider the total cost of ownership during the financial analysis of the purchasing process.

4. When the consumable and maintenance costs are comparable with the equipment cost, other options besides the purchase can be considered by the BCEL such as leasing or renting the equipment by purchasing a certain amount of consumables. These types of contracts may represent a valid strategy alternative to the purchase depending on the market and on the contracting rules of the beneficiary and donors.[17]

5. How to manage the technical documentation accompanying the equipment from the commissioning to the disposal, including all user and maintenance manuals, training and maintenance actions, measures and tests, calibrations etc., shall be planned by the BCEL.

6. Designing the maintenance requirements, including the in-warranty and post-warranty preventive and corrective maintenance requirements according to the complexity of the equipment and the local needs, is an essential duty of the BCEL. Indeed, procuring MDs without a maintenance

plan can be wasteful and reduce the device's lifetime.[18] It is also advisable to include the software updates in the maintenance requirements.

7. It is part of the BCEL role to analyze the availability of spare parts and consumables on the local market and to include appropriate requirements in the purchasing tender conditions to encourage the availability of such goods. The BCEL also needs to confirm with the beneficiaries the availability of a budget for these consumables and their capacity to manage efficiently the purchase of spare parts and consumables.

8. Ideally, when a BCEL plans the lifetime use of the MDs, he/she shall include a plan for its decommissioning and consider the expenses associated when calculating the total cost of ownership.[19]

All the requirements mentioned above, excluding decommissioning, will be included by the BCEL in the tender documents and act as relevant contractual conditions once the device has been received, installed, and commissioned properly.

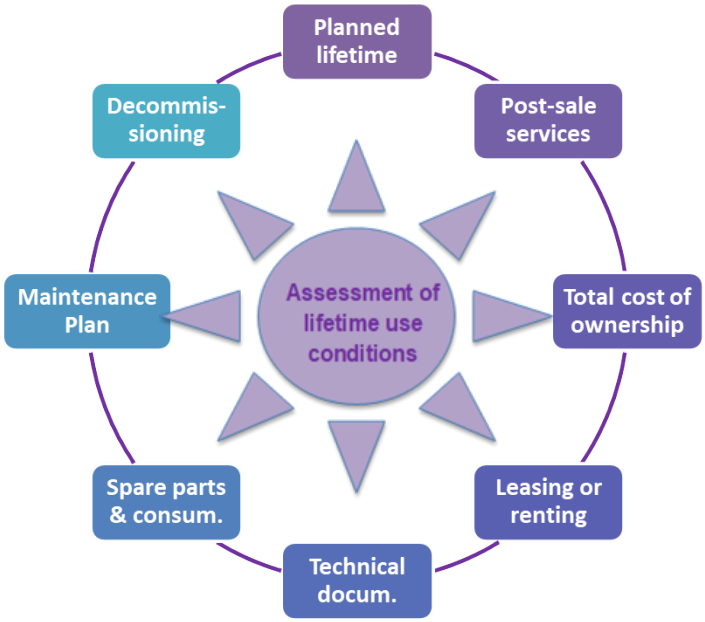

FIGURE 3. The role of BCEL in the assessment of lifetime use conditions.

The sustainability risks of a weak assessment of lifetime use conditions

The risks associated with a poor or absent assessment of the lifetime use conditions may render the MD unusable after some time and thus threaten the sustainability of the project:

- Insufficient planning or lack of financial resources needed to purchase consumables and spare parts to maintain the MD throughout its life expectancy;
- A lack of properly trained clinical and technical staff during the lifetime of the MD;
- An absence of the equipment documentation: contractual warranty, user and service manuals, etc. probably caused by the lack of hand-over of the project's contractual documents regarding warranty and post-sales services to the beneficiary;
- Absent, inadequate, or inappropriate warranty requirements in the tender documents. The manufacturer's default warranty conditions may require to send the equipment to the production site in case of malfunctioning or to demonstrate that the malfunctioning is not due to improper use;
- A lack of managerial capacities to follow up with the supplier regarding maintenance, repairs, and upgrades included in the warranty;
- Unavailability of consumables or spare parts on the local market, which does not allow or makes the use or the repair of the equipment too expensive;
- A premature failure of the purchased MD due to materials inappropriate to the hospital environment where aggressive cleaning agents are frequently used;
- A lack or insufficient program of continuous training on how to use the MD for new users;

SUSTAINABLE RISK ASSESSMENT

The recommended approach to sustainability is to start the project with a proper risk analysis involving the different project's stakeholders. Sustainable risk assessment is performed at the start of the purchasing projects, in the evaluation of the three pillars -needs, existing and lifetime use conditions, and capacities - allows the BCEL to identify the challenges and evaluate the potential risks

related to sustainability that could have an impact on the outcome of the project.

Once the sustainable risk assessment is performed and the specific risks of the procurement project have been identified, a mitigation plan can be prepared. Different risk mitigation strategies to ensure sustainable procurement practices of MD implementation can be applied to different projects, including:

1. Openly discuss the sustainability risk of scarce or improper use of the purchased MDs with the different project stakeholders.
2. Openly discuss sustainability challenges with manufacturers or distributors of MDs during the market analysis.
3. Center the procurement process on the added value of the intended use of the MDs rather than on their possession.
4. Give relevance to the requirements on the supporting services of the goods that can guarantee proper and long-term use of the device.
5. When applicable, choose a procurement process that allows an evaluation of the quality and performance of the MD during the selection phase, discarding the minimum price approach and considering alternatives to the purchase.
6. Ask for a list of reference centers during the selection phase to validate the quality and performance of the bided MD in the mid and long term.
7. Discuss and share experiences with other health technology assessment experts from UN agencies or international institutions on evidence-based procurement of MD.
8. Build within the implementation organization a record of the performances of the MDs and suppliers to build a knowledge database.

CONCLUSION

Sustainable procurement of MDs, especially in developing countries, is of utmost importance[1] The BCEL has a key role and responsibility in assuring the implemented MDs' quality and sustainability. This article further detailed the proposed theoretical background of two fundamental pillars besides assessing the needs[2]: local and lifetime use conditions and capacities analyzes that the BCEL can follow as a guideline to achieve sustainable projects.

It also emphasizes the role of the BCEL as the technical expert conscious of the project's sustainability and responsible for the quality assurance process, raising awareness on the possible issues and discussing solutions with the rest of the team, the beneficiary, and the project's stakeholders to minimize the risks.

Since the BCEL has to work in a multidisciplinary team[20] and be able to dialogue with different stakeholders from various backgrounds, they require expertise to cover all the aspects of the project, from public health to project management, while also considering clinical aspects, hospital design, infrastructure, installation, MDs design and technology.[21]

The assessment of the local capacities and conditions is a key element in the work of the BCEL to:

- Ensure that the technology level is adequate to the site conditions which in developing countries may be challenging because of the lack of adequate infrastructure, stable electrical power supply, controlled working temperature and humidity, accessibility, and
- Ensure that the MD is adequate to the local capacities of use and of maintenance since, in most developing countries those capacities are scarce. Expert professionals, when available, have a high turnover because they are constantly searching for better conditions.

Once the BCEL confirms that the technology design is fit for purpose and adequate to local conditions and capacities, including the design of the support services for delivery, installation, and training, they have to ensure that these sustainable conditions will last during the device's lifetime.

This can be done by planning the intended lifespan of the MD and verifying that the main conditions will remain stable: availability of trained personnel, planned maintenance by trained technical personnel, availability of consumables, adequate electrical supply, etc.

The focus on the lifespan of the MD will bring the total cost of ownership criteria in the evaluation and add the analysis of alternative ways of procuring the goods, such as renting or lending the equipment with a consumable

contract. The benefit procured by using the purchased MD should be the central matter of the procurement process rather than the ownership of the MD. Additionally, to communicate efficiently and integrate the different collaborators' viewpoints, perceived risks, and suggested mitigation measures, the BCEL must know all these aspects to understand and use the appropriate language. When the BCEL is entrusted with an international procurement project, professional preparation, progressive exposure to complex projects, and a peer-review mechanism are recommended.

The BCEL can contribute to accomplishing the desired outcome by first confirming that the project objectives are built on evidence-based data and that the purchase of the MD will indeed improve the health services of the beneficiary country. Then, they must keep a high coherence of all their actions with the desired objectives and outcomes. This coherence needs to be maintained throughout the project, be it during the preparation of the purchasing list and the technologies' specifications or the installation and design of the post-sales services. All these actions must be consistent with the desired outcome, and the local situation, resources, and capacities available on the field must always be considered.

Finally, monitoring the results of a procurement project by visiting the installation sites and recording the use of the MDs within 6 months or one or several years after their commissioning will allow us to understand the impact of the project and learn lessons on the choices made by the BCEL along the way. The public procurement process has the weakness that most, if not all, of the choices have to be made at the very beginning when the requirements of the tender documents are prepared. How these choices will positively impact the use of the MD in the specific local context is a vision that the BCEL can achieve with experience and guidance from peer-review processes and senior experts. Preparing tender requirements is thus equivalent to designing an infrastructure where everything is to be forecasted in advance, giving the BCEL freedom to express their imagination, creativity, and experience during the process.

CONFLICT OF INTEREST

The authors declare no conflict of interest regarding the publication of this paper.

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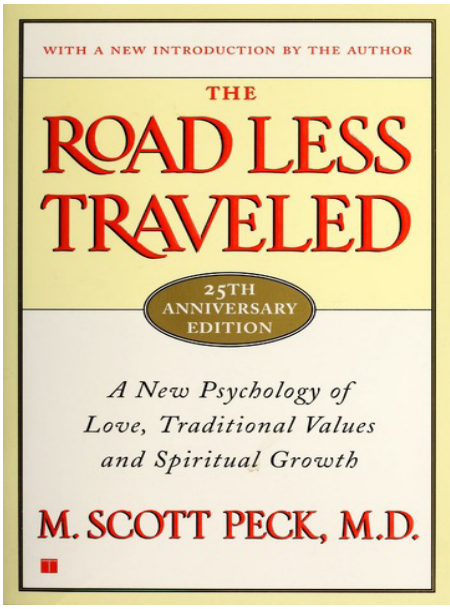
Book Review

Road Less Traveled,(25th Edition)
M. Scoot Peck, M.D.
Publisher: Simon & Schuster
ISBN: 978-0-7432-3825-0 (hard copy)
315 pages
Book price: $18 US at Amazon

By Yadin David
GCEA President

A metaphor for the choices we have experiences, the phrase "the road less traveled" refers to unconventional and uncertain choices made. But why engage with review of a book with such a title here in Clinical Engineering discipline journal?

The first part of this book starts by the author with "*Life is difficult.*" And we, the practitioners working in healthcare delivery, know that first-hand. We also understand that Engineering refers to any type of science concerned with the design, construction and use of machines, systems, and structures. Engineering practitioners come from various backgrounds, cultures, and experiences. Mostly, the field of engineering attracts individuals who are intellectually curious, analytically minded, and passionate about making a difference through technological innovation and problem-solving. What unites them is their passion for creating, overcoming challenges, and making a positive impact on the world. However, from my experience in general, clinical engineering practitioners' shy emotion-associated verbal expression and Dr. Peck, the author, writes in the introduction to his book "… perhaps because it was needed, despite its flaws, there is no question in my mind that as I wrote the book in the solitude of my cramped little office I had help. I really cannot explain that help, but the experience of it is hardly unique. Indeed, such help is the ultimate subject of the book itself." As Dr. Peck continues "…once we truly understand and accept it – then life is no longer difficult." My reason for selecting to write review about THIS book, that most readers will not expect to find in engineering periodical, is that the encouragement and guidance THIS book provides may be helpful to our readers. "When my patients lose sight of their significant and are disheartened by the effort of work we are doing, I sometimes tell them the that human race is in the midst of making an evolutionary leap. "Whether or not we success in that leap…is your personal responsibility", and mine""



This book, *Road Less Traveled* is the best-known work of Dr. Peck, a psychiatrist and best-selling author, educated at Harvard and Case Western Reserve, who helped found the Foundation for Community Encouragement, and published *The Different Drum* and *People of the Lie books.*

The *Road Less Traveled* was first published in 1978 and has since sold over 6 million copies and has been

translated into over 20 languages. It is a description of attributes that make a fulfilled human being, based largely on his experience as psychiatrist and a person.

The book has four parts. In the first, Dr. Peck examine the notion of discipline, which considers essential for healthy emotional, spiritual, and psychological health. He writes about having balance on such notion as delayed gratification and accepting responsibility for oneself actions, dedication to the truth. About Openness to Challenge, the author advises the reader to "continuous and never-ending process of self-monitoring to assure that our communications – not only words that we say but also the way we say them the…" are especially meaningful in the era of texting and instant messaging. In the journey of life, the author advice, mandates negotiation of the curves and corners of our lives where we must continually give up parts of ourselves, but strangely as it seems "…most people choose the alternative and elect to stop by some distance…" creating significant pain. "Giving up" is the essence of balancing and is one of the major forms, according to the author, this book teaches, so the reader may achieve well-balanced patterns of behavior, personality traits and a whole better lifestyle.

In the second part he raises the questions about love, emotional dependency, and explain the term "falling in love". The author states that "we are incapable of loving another unless we love ourselves." And "Love is effortful."

In the third part he writes about spirituality growth, religion and their role in therapy and maturity. "…among the members of the human race there exists an extraordinary variability in the breadth and sophistication of our understanding of what life is about." The author argues that "We must continuously expand our realm of knowledge and our field of vision through the thorough digestion and incorporation of new information" as "The process of expansion of knowledge has been a major theme of this book." Similarly, clinical engineering practitioners must adopt learning as lifelong commitment.

The fourth and final part concerns grace, human spiritual growth, mental health, discussing scientific thinking, and the conscious world around us. The author suggests that "It is hardly remarkable that we sicken and die; what is truly remarkable is that we don't usually sicken very often and we don't die very quickly." Perhaps avoiding giving credit to the role of advances in science and engineering in it. Continuing to explain that "There is a force, the mechanism of which we do not fully understand, that seems to operate routinely in most people to protect and encourage their physical health even under the most adverse conditions." Towards the book's end, under the Miracle of Evolution the author suggests that the human race is in spiritual progression. For ours and our children's future - I hope he is correct.

After reading the book, I felt that I can examine and gain deeper self-knowledge thus attempting to eliminate my shortfalls. Similarly, I felt it may help other trained engineering professionals to better understand their challenges, and if there is path for improvement that they can prescribe to, then it was worth publishing this review of a non-technical book helping everyone to embrace qualities that according to Dr. Peck leads to better health, better relationships, and richer life experiences.

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Healthcare Providers' Readiness to Address Medical Device Cybersecurity within the Irish Healthcare System

By Dara Keeley

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ABSTRACT

Medical devices that can diagnose and treat critically ill patients have become sophisticated and complex. Device manufacturers have been developing these systems to meet market requirements as technology evolves. Combining medical devices and ICT into a distributed medical device IT system can be a solution to incorporating continuous monitoring from the patient bedside to interoperability with a clinical information system. These technology innovations aim to manage patient data and configure medical devices into networked systems that can provide functionality and safety. The implementation of a medical device network solution allows a healthcare provider to take advantage of managing the flow of information to improve clinical work practices and implement a system that can be interoperable with other clinical information systems.

International Electrotechnical Commission (IEC) 80001-1 was developed to assist healthcare providers in identifying and managing the risks associated with medical devices sharing the same IT network with other systems and software. This standard defines roles, responsibilities, and activities in relation to the management of risk with medical devices on an IT network.

This study aims to determine if the standard International Electrotechnical Commission (IEC) 80001-1 is being implemented and determine familiarity with regulations and appropriate standards and guidance for an effective medical device security risk-management program with Irish healthcare providers.

A literature review highlighted the restrictions healthcare providers face in adopting and implementing IEC 80001-1 and the security threats and risks present when integrating medical devices and IT networks. The study research was conducted with clinical engineering members of the Biomedical and Clinical Engineering Association of Ireland (BEAI). This survey targeted BEAI members due to their wealth of experience, knowledge, and skill level in supporting complex medical device systems. An online anonymous survey was created to determine knowledge, awareness, and familiarity with IEC 80001-1 and other medical device security risk-management guidelines.

The study research results revealed low knowledge, awareness, and familiarity among research participants with IEC 80001-1 and guidelines on medical device security risk management. These results were consistent with the literature review that a key to the success of standard adoption is collaboration between stakeholders and a multidisciplinary approach to compliance.

Keywords – *Vital Signs, Physiological Monitor, Medical Device, NEWS, Vital Signs Automation, Medical IT Network, Patient Safety, Cybersecurity Risks, IEC 80001:1 Standard, NIST, AAMI TIR57, NIS Directive, ENISA.*

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INTRODUCTION

Physiological monitoring technology has advanced in the last few years, enabling these devices to be incorporated into healthcare providers' networks. This system can provide real-time centralized management of patient monitors, with patients' vital signs being supervised by clinicians, allowing them to recognize and immediately react to clinical conditions through alarm notifications.[1] This clinical information system can be integrated with other hospital information systems, including a laboratory information system (LIS), patient administration system (PAS), and radiology information system (RIS). The greater automation of a provider's information system can be associated with reductions in patient mortality, complications and costs.[2]

The International Electrotechnical Commission (IEC) developed and released a standard to address risks associated with medical devices that share the same IT network with other peripheral devices and software applications. The standard IEC 80001-1, "Application of risk management for IT networks incorporating medical devices – Part:1 Safety, effectiveness and security in the implementation and use of connected medical devices or connected health software", defines roles, responsibilities, and activities that are necessary for risk management, before during and after connecting medical devices to IT infrastructure.[3] The objective of this standard is to prevent adverse incidents and patient harm in three areas - Safety, Effectiveness, and Security, and requires that a comprehensive risk management program be implemented.

Study Aims

This research study aimed to determine knowledge and awareness of the following within Irish healthcare:

- IEC 80001-1 standard – Application of risk management for IT networks
- incorporating medical devices, defining roles, responsibilities, and activities.
- The restrictions prohibit the adoption of IEC 80001-1 standard and a medical device security risk-management program.
- National Institute of Standards and Technology (NIST) guidelines to secure network-connected medical devices.
- Association for the Advancement of Medical Instrumentation (AAMI) guidance for effectively implementing a medical device security risk-management program.
- A medical device security risk management program.
- Responsibility for implementing and managing a risk management program relating to medical devices incorporated into medical IT networks.
- The National Early Warning Score (NEWS) and the criteria included to calculate the score.
- A digital initiative called Vital Signs Automation (VSA) to capture physiological parameters and automatically calculates the NEWS.

Literature Review

Medical devices have developed over time to become sophisticated and complex systems that can be incorporated into medical IT networks. This digital transformation can provide benefits to a healthcare provider but can also have the potential to be open to cybersecurity threats that can compromise patient safety.[4] In the European Union, medical devices are strictly regulated by safety protocols; however, when a medical device is integrated into an IT network, it becomes a medical IT network.[5] The standard IEC 80001-1 was developed in 2010 to identify and address inherent risks and to assist with managing these risks. It received several iterations to reduce understanding complexity and enable healthcare providers to engage with implementation. The most recent release is IEC 80001-1:2021, which includes significant technical changes to the application of risk management.

Search Strategy

A literature review was undertaken to inform the subject matter and develop a substance review for this thesis. The search criteria are outlined in Table 1.

Physiological Monitor

The World Health Organisation (WHO) defines a medical device as, "a*ny instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the*

TABLE 1. Electronic Search Criteria

Criteria	English Language
Databases	UCD library OneSearch, PubMed, Science Direct, Google, and Google Scholar.
Type	Journals, Books, Websites, Standards, Reports, White Papers, Government Publications and Academic Papers.
Key Words and "Terms" searched	Vital Signs, Physiological Monitor, Medical Device, NEWS, Vital Signs Automation, Medical IT Network, Patient Safety, Cybersecurity Risks, IEC 80001:1 Standard, NIST, AAMI TIR57, NIS Directive and ENISA.

manufacturer to be used, alone or in combination for a medical purpose,"[6] for prevention and screening, diagnose illness, monitor treatments, assist disabled people and to intervene and treat illness, both acute and chronic.

The European Medicines Agency (EMA) defines medical devices as "*products or equipment intended for a medical purpose. In the European Union (EU) they must undergo a conformity assessment to demonstrate they meet legal requirements to ensure they are safe and perform as intended*."[7]

Two new EU laws were enacted in April 2017 relating to medical device regulations (MDR) 2017/745 and in vitro diagnostic medical devices (IVDR) to replace the previous medical device directives. These new regulations aim to address the weaknesses of the previous directives and provide a secure, consistent regulatory framework across all medical devices in the EU market. Clearly defined requirements and specific obligations on stakeholders throughout the supply chain are the main points that stand out with the new regulations.[8]

Patient physiological data from a bedside monitor can be routed to a central station monitor for display, printing, and alarm monitoring. The importance of this workstation cannot be underestimated in allowing clinicians to respond to adverse patient events, reviewing alarm history, and analyzing trend data for research.[9]

The increasing complexity of medical devices, mainly physiological monitors, comes with the ability to monitor multiple vital sign parameters simultaneously with each parameter having the ability to have individual alarms and complex software that can include sub-screens for the clinician to navigate to other devices[10] and systems that include a RIS and LIS.

Clinicians can perform tasks and manage admitting, transferring, and discharging patients, changing alarm limits, storing and retrieving parameter values and trends, and monitoring remote patients.[11] These systems are interoperable with modern electronic health records, enabling patient data to be transferred and populated in real-time.

IEC 80001-1 Standard

The standard IEC 80001-1:2021, "Application of risk management for IT networks incorporating medical devices – Part:1 Safety, effectiveness and security in the implementation and use of connected medical devices or connected health software", defines roles, responsibilities, and activities that are necessary for risk management, before during and after connecting medical devices to IT infrastructure.[3] The standard applies to responsible organizations, medical device manufacturers, and information technology providers. First published in 2010, with the latest revision released in 2021, the standard was considered too complex and complicated to implement and was revised as a process-based approach to overcome reported barriers, such as a lack of alignment between IT and clinical engineering departments within hospitals and a lack of motivation from management to implement the standard.[12] ISO/IEC/TR 80001, under the general title Application of Risk Management for IT Networks Incorporating Medical Devices are outlined in Table 2.

The role of clinical engineering (CE) / Health Technology Management (HTM) departments will have to evolve to meet the needs of healthcare technology risks and needs, in line with objectives and policies. Alwi et al, found that one of the key elements for successfully implementing this standard was the collaboration between CE / HTM and IT departments.[13]

The risk management process has three main phases (Table 3).

With the implementation of this standard's risk management framework, there is a reliance on IT best practices and increasing CE / HTM and IT department convergence. This collaboration is key to ensuring the safe management of medical device IT networks to benefit

TABLE 2. Application of Risk Management

Part 1	Roles, Responsibilities, and Activities
Part 2-1	Step-by step risk management of medical IT networks, practical applications, and examples.
Part 2-2	Guidance for the communication of medical device security needs, risks, and controls.
Part 2-3	Guidance for wireless networks.
Part 2-4	General implementation guidance for Healthcare Delivery Organisations.
Part 2-5	Application guidance for distributed alarm systems.
Part 2-6	Application guidance for responsibility agreements.
Part 2-7	Guidance for Healthcare Delivery Organisations (HDOs) on how to self-assess their conformance with IEC 80001-1.
Part 2-8	Application guidance on standards for establishing the security capabilities identified in IEC 80001-2-2.

TABLE 3. Risk Management Process

Phase 1	Risk assessment to identify application hazards and assess risk for each.
Phase 2	Risk evaluation and control to mitigate identified risk and re-evaluate and develop a report.
Phase 3	Post project and operation to continuously monitor and reassess risk.

staff and patients.[13] ISO published a technical report in 2015, ISO/TR 80001-2-7:2015, guidance for healthcare providers to self-assess conformance to the standard. This includes a Process Reference Model (PRM) and Process Assessment Model (PAM) with assessment questions to assist with identifying strengths and weaknesses of the risk management process.[14] In 2016, a technical report, IEC TR 8001-2-8:2016, was developed to guide healthcare providers and medical device manufacturers in identifying security controls and addressing each security capability for the risk management process.[15]

Standards and Risk Management

The NIST developed a cybersecurity framework (CSF) to enable organizations to protect themselves and continue business operations during an attack. The CSF allows organizations to manage and mitigate cybersecurity risk based on existing standards, guidelines, and practices.[16] As seen in Table 4, CSF is organized into five core functions.

The NIST CSF guides healthcare organizations in managing assets, defining their vulnerabilities, and assisting with fending off a growing number of malicious attacks as new digital transformation projects are incorporated.[17]

TABLE 4. NIST Cybersecurity Framework

1.	Identify physical assets and information to establish a risk management strategy that is tailored to an organisations business function.
2.	Protect the assets and data from malicious attacks or unintentional compromise.
3.	Detect and monitor the environment for security incidents and events.
4.	Respond to attempted or successful attacks.
5.	Recover from the attack and adjust security policies in retrospect.

In 2016, the AAMI published Technical Information Report 57 (TIR57) to provide guidance and assist medical device engineers in integrating cybersecurity risk management into the development of the device so potential threats can be identified and mitigated before placing on the market. TIR focuses on cyber risks and provides steps for identifying and evaluating threats and vulnerabilities, as well as security risk controls and monitoring the ease of use of these controls. The FDA have recognized and approved this standard, reflecting on the requirement for the protection of medical devices as we move toward the transition to digital healthcare.[18]

In 2016, the EU enacted cybersecurity legislation in the form of the Network and Information Systems (NIS) Directive 2016/1148 to enhance cybersecurity across member states. As shown in Table 5, NIS has three parts.

The European Network and Information Security Agency (ENISA) is responsible for cybersecurity and implementing the NIS directive to assist member states in identifying good practices, supporting the EU-wide cybersecurity incident reporting process, guidance with common approaches and procedures, and assisting member states in addressing common cybersecurity issues.[19] ENISA has developed good practice guidelines to manage cybersecurity threats with medical devices.

TABLE 5. NIS Directive

Phase 1	Risk assessment to identify application hazards and assess risk for each.
Phase 2	Risk evaluation and control to mitigate identified risk and re-evaluate and develop a report.
Phase 3	Post project and operation to continuously monitor and reassess risk.

The National Electrical Manufacturers Association (NEMA) developed a voluntary standard in 2008, the Manufacturer Disclosure Statement for Medical Device Security (MDS2), to assist appropriate and responsible persons in assessing security risks in managing medical device security issues. This form allows medical device manufacturers to answer a series of questions covering relevant security capabilities about a medical device and is shared with a healthcare provider.[20]

IEC 27001:2022 was developed for Information Security Management Systems (ISMS) and provided a systematic and comprehensive approach to managing and protecting sensitive information. The standard outlines several requirements that organizations must meet that including developing security policies, performing risk assessments, defining information security roles, managing and maintaining an inventory of assets, training staff to be security aware, developing a business continuity plan, ensuring compliance with GDPR, developing an incident response plan, monitoring the performance of ISMS and restricting access to information to authorized personnel only.[21]

The EU Medical Device Coordination Group developed guidance on cybersecurity for medical devices in 2019 to guide manufacturers on fulfilling all Annex I MDR 745/2017 requirements and IVDR 746/2017 about cybersecurity. Manufacturers must develop products that consider risk-management information security principles and set out minimum requirements concerning IT security measures, including protection against unauthorized access.[22]

Argaw et al. found that building and improving the cyber resilience of a healthcare provider is vital and a shared responsibility. Clinicians and administration staff should be provided with training and practice digital hygiene, while decision-makers should enforce policies that include cybersecurity when making purchasing decisions. Information security teams in hospitals should upkeep security tools to safeguard the provider and patients.[23]

RESULTS AND ANALYSIS

Method

The purpose of this project is to conduct research and determine if the standard IEC 80001-1 "Application of risk management for IT networks incorporating medical devices" is being implemented and determine familiarity with regulations as well as appropriate standards and guidance for an effective medical device security risk-management program with Irish healthcare providers. The online questionnaire was hosted by Qualtrics, which could generate a report based on individual feedback on each question posed.

Question 1, Position

Participants were asked to provide an outline of this current position within clinical engineering, whether working within a hospital setting or working for private enterprise.

Response	Count	Percentage
Working within a healthcare provider	31	79
Working for a private company	8	21
Total	39	100

Question 2, Experience

Participants were asked if they had any prior experience integrating medical devices with medical IT networks.

Response	Count	Percentage
Yes	35	92
No	3	8
Total	38	100

Question 3, Support

This question asked participants whether they support medical devices integrated with medical IT networks.

Response	Count	Percentage
Yes	36	95
No	2	5
Total	38	100

Question 4, Clinical Engineers

Clinical engineers' skills, abilities, and knowledge have expanded to support medical systems that have become more complex with hardware and software technology.

Response	Count	Percentage
Strongly disagree	3	8
Somewhat disagree	1	3
Neither agree nor disagree	4	10
Somewhat agree	7	18
Strongly agree	24	61
Total	39	100

Question 5, Responsibility

Who maintains and supports your organization's medical device systems and IT networks?

Response	Count	Percentage
Clinical Engineering	3	8
IT Department	4	11
Both Clinical Engineering and IT	29	81
Total	36	100

Question 6, Standards

The importance of standards cannot be underestimated, particularly as they relate to healthcare and patient safety.

Response	Count	Percentage
Strongly disagree	5	14
Somewhat disagree	0	0
Neither agree nor disagree	2	6
Somewhat agree	4	11
Strongly agree	25	69
Total	36	100

Question 7, IEC 80001-1

Participants were asked to indicate knowledge and awareness of IEC 80001-1 standard – "Application of risk management for IT networks incorporating medical devices, defining roles, responsibilities and activities."

Response	Count	Percentage
Not at all aware	7	19
Slightly aware	9	25
Moderately aware	17	47
Very aware	1	3
Extremely aware	2	6
Total	36	100

Question 8, NIST Guidelines

Participants were asked to indicate familiarity with NIST guidelines to secure network-connected medical devices.

Response	Count	Percentage
Not at all familiar	13	36
Slightly familiar	5	14
Moderately familiar	13	36
Very familiar	2	6
Extremely familiar	3	8
Total	36	100

Question 9, AAMI Guidelines

Participants were asked to indicate their level of knowledge and awareness of The AAMI guidance for implementing an effective medical device security risk-management program.

Response	Count	Percentage
Not at all aware	8	22
Slightly aware	12	33
Moderately aware	11	31
Very aware	2	6
Extremely aware	3	8
Total	36	100

Question 10, Security

Participants were asked whether a medical device security risk-management program concerning a medical IT network was implemented within your organization.

Response	Count	Percentage
Yes	8	22
No	13	36
Don't know	15	42
Total	36	100

Question 11, Implementation

Participants were asked if IEC 80001-1 standard – "Application of risk management for IT networks incorporating medical devices" was implemented within your organization.

Response	Count	Percentage
Yes	4	11
No	10	28
Don't know	22	61
Total	36	100

Question 12, Responsibility

Participants were asked who is responsible for implementing and managing a risk management program for medical devices incorporated into medical IT networks.

Response	Count	Percentage
Clinical Engineering	1	3
IT Department	3	10
Both Clinical Engineering and IT	12	39
Multidisciplinary Team	15	48
Total	31	100
Total	36	100

Question 13, Restrictions

Participants were asked what they feel are the restrictions prohibiting the adoption of IEC 80001-1 standard and a medical device security risk-management program. Three responses were categorized from research as the main barriers and restrictions to adopting this standard.

Response	Strongly disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Strongly Agree	Total
Standard is complicated to understand	0	5	13	11	2	31
Lack of management support to provide resources	1	2	4	16	8	31
Clinical Engineering and IT Department are not aligned	1	1	0	16	14	32

Question 14, NEWS

Participants were asked to indicate their level of knowledge and awareness of the NEWS and the criteria included to calculate the score.

Response	Count	Percentage
Not at all aware	6	19
Slightly aware	6	19
Moderately aware	7	24
Very aware	6	19
Extremely aware	6	19
Total	31	100

Question 15, Digital NEWS & VSA

Participants were asked to indicate knowledge and awareness of a digital initiative called VSA to capture physiological parameters such as oxygen saturation, blood pressure, pulse rate, heart rate and temperature by automatically calculating the NEWS used to track whether a patient's condition is deteriorating.

Response	Count	Percentage
Not at all aware	10	32
Slightly aware	5	16
Moderately aware	8	26
Very aware	2	7
Extremely aware	6	19
Total	31	100

CONCLUSION

Strengths

A benefit of the survey would be generating a greater awareness among the participants that standards are available for cybersecurity risk management of medical devices and a national initiative, digital NEWS – VSA, being implemented across acute hospital settings—confirmation of the barriers to adopting IEC 80001-1 correlated with the study results.

Implications of the Research Study

Highlighted by the research findings were the barriers to implementing this standard, with participants surveyed agreeing that the lack of management support to provide resources and a lack of alignment of the clinical engineering and IT departments were the main restrictions to adoption. The literature review highlighted the inherent cybersecurity threats when integrating a medical device into a medical IT network. Healthcare providers and appropriate stakeholders must adopt and implement a cybersecurity risk management program, mainly IEC 80001-1, and ensure compliance to minimize an adverse event or incident.

Recommendations and Future Research

The research study results highlight the lack of knowledge, awareness, and adoption of standard IEC 80001-1 "Application of risk management for IT networks incorporating medical devices" and a low level of familiarity with regulations as well as appropriate standards and guidance for an effective medical device security risk-management program with Irish healthcare providers. The following recommendations are required at the local healthcare

provider, regional hospital group, and national level for adoption and implementation to be successful:

- Education with the appropriate internal and external stakeholders on the importance of standards and their adoption, focusing on IEC 80001-1. The development of a training resource and identifying with the Health Service Executive (HSE) and healthcare providers management to provide resources in the development of expertise and coordinate the availability of personnel to provide education.
- Enable adoption and implementation of IEC 80001-1 more easily by removing the historical barriers to adoption. HSE management provides guidance and governance to healthcare providers, enabling a simple pathway to compliance.

Increased and close collaboration between all stakeholders is essential for standard adoption and implementation success.

Conclusion

Medical devices integrated into healthcare providers' IT networks have become more prevalent over the last few years, specifically physiological monitoring. This integration and converging of medical systems with traditional IT networks have transformed the IT architecture and introduced additional risks that may have a bearing on the safety and security of this medical IT network. This was highlighted recently in the HSE with WannaCry ransomware attack in May 2017, and the major ransomware cyberattack suffered in May 2021, causing all the IT systems nationwide to be shut down.

IEC 80001-1 standard was developed to assist healthcare providers in applying risk management and system security to minimize patient safety and infrastructure threats by defining roles, responsibilities, and activities. The NIST provides guidelines to secure network-connected medical devices. The AAMI guides healthcare providers in implementing an effective medical device security risk-management program. This study research highlights the barriers to adoption of IEC 80001-1. It makes recommendations to ensure compliance with the implementation of this standard, particularly with the increasing number of digital transformation projects being realized across acute hospital settings in Ireland.

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