Journal of Medical Devices Technology
jmeditec.utm.my

Review Article

A Review of Medical Device Procurement at National Level: Integrating Support Systems for Clinical Engineers Towards Efficient, Transparent and Standardized Procurement Processes

Maheza Irna Mohamad Salim[1], Rania Hussein Ahmed Al-Ashwal[1], Tian Swee Tan[1], Tomy Abuzairi[2]

[1]*Department of Biomedical Engineering & Health Science, Faculty of Electrical Engineering, Universiti Teknologi Malaysia, Johor, 81310, Malaysia*
[2]*Department of Electrical Engineering, Universitas Indonesia, Depok, Indonesia*

ARTICLE INFO

Article History:
Received 21 October 2024
Accepted 24 November 2024
Available online 30 December 2024

Keywords:
Medical Device Evaluation,
Procurement,
Clinical engineers,
Support tools

ABSTRACT

This study explores the role and the key support system required by clinical engineers in enhancing national-level medical device procurement to ensure efficiency, safety and standardization. Using WHO's 2022 data from 11 South-East Asian countries as a foundation, the review identifies critical gaps in the national-level procurement infrastructure, particularly in the availability of regulatory support, standardized procurement processes and technical specifications to support the national level procurement practice. These deficiencies highlight the need for a robust framework that supports clinical engineers in making informed, evidence-based procurement decisions. The study also emphasizes the importance of Health Technology Assessment (HTA) and Clinical Evidence Databases (CED) as essential tools for evaluating the safety, effectiveness and long-term performance of medical devices. In addition to technical evaluation, the research highlights the necessity of standardized procurement guidelines and detailed technical specifications to reduce variability in device quality and ensure compliance with national and international standards. The role of continuous education and training is also examined, stressing that clinical engineers must stay updated on advancements in medical technology, regulatory requirements and sustainability practices to effectively support procurement processes. By continuously upgrading their knowledge and skills, clinical engineers can ensure that procurement decisions are aligned with the current best practices and healthcare priorities. Collaboration among key stakeholders including governments, regulatory authorities, manufacturers and clinical engineers is identified as crucial for establishing transparent, efficient, and equitable procurement systems. Regulatory bodies must ensure that all devices meet stringent safety and performance standards, while manufacturers need to provide accurate technical data and engage in sustainable production practices. Governments, in turn, play a critical role in centralizing procurement processes, standardizing guidelines and facilitating partnerships across the public and private sectors. This research concludes that by effectively putting clinical engineering support systems in place, national procurement strategies can be significantly enhanced. It is hoped that this integration will not only streamline procurement processes but also improve healthcare delivery and patient outcomes in ensuring that devices procured at the national level meet the highest standards of safety, quality, and sustainability.

INTRODUCTION

In the year 2022 the World Health Organization (WHO) has published a statistic on medical device procurement in the South-East Asian region. The statistic is as a part of WHO's ongoing efforts to support its member countries in strengthening health systems through efficient and transparent medical device procurement processes (WHO, 2022a). It is also one of the WHO's initiatives to ensure that medical devices meet the necessary quality standards and are procured through

* Maheza Irna Mohamad Salim (maheza@utm.my)
Department of Biomedical Engineering & Health Science, Faculty of Electrical Engineering, Universiti Teknologi Malaysia, Johor, 81310, Malaysia

transparent and efficient systems which ultimately will improve patient care and safety across the region (WHO, 2022a; WHO, n.d.; WHO, 2022b). The published data focuses on the procurement processes for medical devices within the 11 countries in this region and provides insights into the regulatory frameworks, national procurement systems and availability of essential resources for the process. The key elements of a support system for medical device procurement as outlined by WHO in the statistics are:

- National Procurement Processes: The availability of a centralized or coordinated procurement at the national level
- National List of Approved Medical Devices: A standardized list of medical devices that have been vetted and approved for procurement
- National Guidelines, Policies, or Recommendations: A clear set of guidelines and policies that provide a framework for the procurement process.
- Technical Specifications for Medical Devices: Detailed technical specifications that outline the required standards and features of medical devices.

These support systems are necessary to ensure that medical device procurement is efficient, safe, and aligned with national healthcare priorities. A centralized procurement process allows for cost savings and consistency in quality (Diaconu et al., 2017) (Ferraresi et al., 2021). The national list of approved devices for procurement is necessary to guarantee that only thoroughly evaluated and safe devices are purchased (WHO, 2022b), (Zamzam et al., 2021). Additionally, the availability of clear national guidelines will standardize procurement practices and ensure they meet the regulatory and ethical standards which will reduce device variability and improve treatment outcomes (Trindade et al., 2019). On the other hand, the availability of detailed technical specifications of medical devices ensure that procured devices meet the required safety and performance criteria, which is especially essential for complex or high-risk medical equipment (Trindade et al., 2019) (Hinrichs-Krapels et al., 2022) (Lingg et al., 2016). These elements form a robust support system that enhances healthcare delivery and minimizes risks associated with poor procurement practices.

The WHO statistics on medical device procurement across 11 countries reveals significant disparities in the support systems available for clinical engineers in those countries. The statistics show only 2 countries have a full support system in place for medical device evaluation and procurement which encompass all essential elements listed in the WHO data. The majority of the other countries are lacking a full support system, with one or more key components missing from their procurement infrastructure.

This absence can lead to challenges in maintaining standardized and effective procurement practices, which are vital for ensuring consistent healthcare outcomes. The data also has highlighted several systemic gaps in the support structures that clinical engineers rely on for medical device procurement across various regions. Collectively, these deficiencies can complicate the responsibilities of clinical engineers, leading to potential inefficiencies and quality issues in medical device procurement (Diaconu et al., 2017) (Hinrichs-Krapels et al., 2022) (Lingg et al., 2016). Additionally, previous studies have also echoed the importance of these systems and highlighted challenges such as inadequate planning, lack of specialist expertise and the need for interdisciplinary collaboration to overcome procurement barriers (Diaconu et al., 2017) (Lingg et al., 2016). This data is crucial and will be the basis of discussion in identifying gaps and opportunities to enhance the role of clinical engineers, especially in the procurement of medical devices.

Another major concern is the inconsistent implementation of national-level procurement processes which in turn, make the centralized procurement process to be either absent or fragmented. This lack of centralized coordination can result in inefficiencies, as well as variability in the quality of devices procured, which ultimately affects healthcare delivery (Diaconu et al., 2017). The lack of comprehensive national guidelines and policies on medical device procurement is another challenge. Clinical engineers rely on these guidelines to navigate complex procurement processes and ensure consistency and quality in the devices acquired. In regions where such guidelines are missing or underdeveloped, clinical engineers face increased uncertainty, which can lead to inconsistencies in procurement practices (Rahmani et al., 2022).

This study aims to gather information on the support systems required by clinical engineers to make informed decisions in the evaluation and procurement of medical devices based on insights from previous studies. Additionally, it explores how these support systems can be integrated by the collective efforts from government, medical device regulatory authorities, manufacturer and clinical engineers towards the efficient, transparent, and standardized procurement processes

REVIEW METHODOLOGY

The review is designed to systematically explore the WHO statistics for national-level medical device procurement in the South-East Asian Region, the insights of essential support tools needed by clinical engineers (CEs) for informed, evidence-based procurement decision-making based on previous studies and the integration of these tools to enhance procurement processes at the national level.

To achieve these objectives, a comprehensive search strategy has been employed across recognized academic and industry databases, including PubMed, Scopus, Google Scholar, and Web of Science. The search utilized a combination of specific keywords, such as "medical device procurement," and "support tools" for “clinical engineers". Boolean operators (AND, OR, NOT) were used to refine the search results and ensure that only relevant literature is retrieved.

The inclusion criteria for this review will focus on peer-reviewed journal articles, conference papers and authoritative reports published that address the issues. The article selection process will involve three stages: title and abstract screening, full-text review, and reference list review to identify additional relevant studies. Once the articles are selected, data extraction was focused on gathering key information such as the study's objectives, methodology, findings, and relevance to the research questions.

RESULTS AND DISCUSSION

Summary of article selection process

The comprehensive search across PubMed, Scopus, Google Scholar, authority report and Web of Science yielded an initial pool of 98 articles. Following a systematic selection process that

included title and abstract screening, full-text review, and reference list review, 42 articles were excluded for reasons such as lack of relevance to the research objectives, insufficient methodological rigor, or duplication. The final set of 56 references was chosen based on their alignment with the study's inclusion criteria, focusing on peer-reviewed journal articles, conference papers and authoritative reports addressing national-level medical device procurement and support tools for clinical engineers. The selected articles span a range of publication years, methodologies and geographical contexts, providing diverse insights into the challenges and strategies within this field. These studies formed the basis for identifying key themes, including the critical role of clinical engineers, existing tools and frameworks and gaps in current procurement practices.

Essential Support Systems for Clinical Engineers in Making Informed, Evidence-Based Decision Making for Medical Device Evaluation and Procurement.

The effective evaluation and procurement of medical devices by clinical engineers require a comprehensive support system that encompasses various tools and frameworks. These tools ensure that procurement decisions are informed, evidence-based, standardized and aligned with both clinical and regulatory requirements. Table 1 outlines the key support tools identified in previous studies that are essential for clinical engineers in making informed decisions during the medical device procurement process.

From table 1, it is important for Clinical engineers to have a robust support system to effectively evaluate and procure medical devices, which includes a combination of evidence-based tools, standardized processes, ongoing training, post-market monitoring, and cost management mechanisms.

Health Technology Assessment (HTA) and Clinical Evidence Database (CED) are essential tools to provide information on the safety, effectiveness, and long-term performance of medical devices (Diaconu et al., 2017; Lingg et al., 2016; Chen, 2022; Park et al., 2019). HTA is a multidisciplinary process designed to evaluate the properties, effects and impacts of health technologies including medical devices to support evidence-based decision-making in healthcare (Greenwood et al., 2014) (Park et al., 2019). In contrast, CED benefitting big data analytics and focuses on collecting and organizing real-world clinical data, such as patient outcomes and device performance to assess the long-term safety and effectiveness of medical devices or treatments (Batko & Ślęzak, 2022). HTA examines various dimensions and focused mainly to: clinical effectiveness; cost-effectiveness; safety, organizational implications of introducing new technologies.

The clinical effectiveness assessments in HTA focus on how well a medical device performs in real-world clinical settings to ensure that it achieves its intended health outcomes (Facey et al., 2015). Other than the device's clinical performance, the cost-effectiveness analysis in HTA evaluates the economic aspects by considering both the financial costs and the health benefits provided by the medical device (Chen, 2022). Safety is another critical component where HTA examines potential risks and adverse effects to ensure that the benefits of the technology outweigh its risks (Ghazinoory et al., 2021). Organizational impact is also evaluated to ensure that the integration of new devices into healthcare systems does not disrupt the existing clinical workflows. Other than that, the necessary infrastructure and training availability are also evaluated to ensure that those elements are in placed for new technology introduced (Farah et al., 2024).

Table 1: Support Tools Required by Clinical Engineers for Informed, Evidence based Decision making of medical device evaluation and procurement

Support Tools	Justifications	Reference
Health Technology Assessment (HTA) Tools	HTA tools provide evidence-based assessments of medical device safety, effectiveness, and value, crucial for informed procurement decisions	(Diaconu et al., 2017) (Greenwood et al., 2014) (Chen, 2022) (Park et al., 2019) (Farah et al., 2024) (Facey et al., 2015) (Ghazinoory et al., 2021)
Clinical Evidence Databases	Access to databases that track real-world clinical performance, such as implant survival rates, ensures evidence-based decisions and quality assurance.	(Lingg et al., 2016) (Facey et al., 2015) (Mukasa & Kovacheva, 2022)
Standardized Procurement Guidelines	Clear guidelines to standardize procurement, ensuring alignment with regulatory and ethical standards, reducing variability, and improving outcomes	(Hinrichs-Krapels et al., 2022) (Lingg et al., 2016) (Akyar, 2012) (Rahmani et al., 2022)
Technical Specifications and Quality Assurance Tools	Detailed specifications ensure devices meet required standards, which is essential for high-risk or complex equipment, reducing risks and ensuring safety.	(Diaconu et al., 2017) (Hinrichs-Krapels et al., 2022) (Bucciol et al, 2020) (Trindade et al., 2019) (Altayyar, 2020)
Training and Collaboration Platforms	Continuous training and collaboration help keep clinical engineers updated on procurement best practices, ensuring informed and up-to-date decision-making.	(Zamzam et al., 2021) (Greenwood et al., 2014) (Haleem et al, 2022) (David and Judd, 2020)
Life-Cycle Costing Tools	Accurate estimation of life-cycle costs, including maintenance and training, ensures that all expenses are considered, preventing hidden costs and inefficiencies.	(Diaconu et al., 2017) (Zamzam et al., 2021) (Seo et al, 2022)

Maintenance Management Systems	Maintenance management systems ensure that equipment operates within manufacturer specifications, reducing downtime and ensuring patient safety	(Zamzam et al., 2021) (Seo et al, 2022)

Other study has also highlighted the functions of hospital-based HTA particularly within Italy's decentralized healthcare system as a cost-containment tool in selecting less expensive devices. Additionally, the research also reported that centralized procurement could effectively reduce unit prices, particularly for less expensive devices. The study also emphasizes the need for evidence-based policies to balance innovation and economic sustainability in healthcare (Callea et al., 2017). For clinical engineers, HTA and CED provide essential evidence and insights that guide informed decision-making during the evaluation and procurement of medical devices. By benefitting HTA and CED, clinical engineers can assess the overall value of a device, considering not only its clinical performance but also its economic viability, safety and ethical considerations (Diaconu et al., 2017). This comprehensive approach helps reduce the risk of procuring ineffective or unsafe technologies. Furthermore, HTA and CED also ensures that procurement decisions made by clinical engineers are aligned with broader healthcare goals such as improving patient outcomes, optimizing all resources used in the healthcare setting and maintaining equitable access to medical devices. Incorporating HTA and CED into procurement processes allows clinical engineers to make informed and evidence-based as well as sustainable decisions that align with both clinical and organizational priorities (Greenwood et al., 2014).

Standardized procurement guidelines are often referred to as Procurement Policies and Procedures, Procurement Frameworks, or Standard Operating Procedures (SOPs) for procurement. These guidelines establish a structured approach for acquiring goods and services and ensuring that procurement activities are consistent, transparent, and compliant with regulatory standards across an organization or industry (Akyar, 2012). In healthcare, standardized procurement guidelines may also be referred to as Healthcare Procurement Standards or Medical Device Procurement Guidelines which emphasize the focus on maintaining quality, safety, and efficiency in the acquisition of medical devices at hospital level up to the national level (Lingg et al., 2016; Rahmani et al., 2022). Additionally, countries like Canada, the United Kingdom, Spain, Italy, Australia, and Turkey have adopted varying degrees of centralization in their medical equipment procurement processes with a common emphasis on standardizing criteria such as price, quality, and value for money. While Canada and Australia primarily utilize decentralized procurement at regional or hospital levels, there is a trend towards greater centralization for improved efficiency. The UK operates a highly centralized procurement system through the NHS, focusing on cost-effectiveness and sustainability. Spain and Italy blend regional decentralization with standardized criteria to ensure consistency across regions. Turkey's procurement remains decentralized at the hospital level but is overseen by the Ministry of Health, with a focus on cost-effectiveness, quality and supporting domestic production. Across these countries, the standardization of procurement criteria is key to ensuring that medical equipment is procured effectively and efficiently (Rahmani et al., 2022).
Unlike standardized procurement procedures, which outline the process and steps for acquiring medical devices, technical specifications focus on the specific characteristics and requirements of the devices themselves to ensure that the right product is selected and effectively integrated into the healthcare environment (Bucciol et al, 2020). Medical device technical specifications are crucial for ensuring that devices meet safety, quality, and performance standards. Altayyar et al also emphasizes that the safety and performance of medical devices are governed by essential principles that guide their design and manufacturing. These principles include ensuring that any risks associated with a medical device are minimized and that the benefits outweigh the risks. Manufacturers are responsible for implementing risk management processes to identify and mitigate potential hazards throughout the device's lifecycle and all the safety compliance can be referred to in the technical specification (Altayyar, 2020). Medical device technical specifications incorporate safety elements by detailing the design, materials, and performance requirements that align with established safety standards. It also provides detailed criteria that guide procurement decisions, support compliance with regulatory requirements, and facilitate the maintenance, repair, and proper use of the devices. Technical specifications also ensure compatibility of the device or its accessories with existing systems and help manage costs by offering a clear understanding of the device's features and operational requirements particularly for complex or high-risk devices (Hinrichs-Krapels et al., 2022; Trindade et al., 2019). A significant shortfall in the availability of technical specifications needed to support the procurement of medical devices may complicate the task of clinical engineers. In many cases, even when technical specifications exist, they are not publicly accessible, limiting the ability of clinical engineers to access critical information necessary for making informed procurement decisions. This lack of transparency and access to detailed technical specifications can introduce risks during the procurement process, further complicating the efforts of clinical engineers (Inagaki et al., 2023; Di Virgilio et al., 2024).

Technological advancements are transforming healthcare by expanding knowledge and accelerating the delivery of critical medical services (Jamal et al., 2009). While these advancements create new opportunities, they also introduce challenges that require clinical engineers to always update their knowledge to perform their essential role in development, evaluation, installation, integration, performance assurance and risk mitigation of medical devices. Recognized by the World Health Organization (WHO) as key practitioners, clinical engineering professionals must be equipped with up-to-date knowledge and skills to navigate the complexities of healthcare technology through continuous training (David and Judd, 2020). The availability of training and collaboration platforms will enhance decision-making by keeping clinical engineers up to date with best practices and technological advancements to ensure that they are well-prepared to navigate the complexities of procurement (Zamzam et al., 2021; Greenwood et al., 2014). To ensure that training platforms effectively reach clinical engineers, several strategies can be implemented. Digital learning platforms, such as e-learning systems and mobile apps could provide on-demand access to courses and resources and

make on the job training flexible and convenient. Manufacturer and Medical device regulatory authorities could foster partnership with professional bodies to offer training as part of the clinical engineers continuous professional development (CPD) programs, with mandatory and accredited training. Those partnerships will ensure access to industry-leading resources and up-to-date regulatory knowledge (Mahdavi et al, 2023; Haleem et al., 2022; Borycki and Kushniruk, 2023).

Another important support tool for clinical engineers is the life-cycle costing (LCC) tool, which assesses the full financial impact of medical devices throughout their entire lifecycle. LCC calculates the sum of all costs associated with a device from acquisition to disposal, including direct costs like purchase and maintenance, as well as indirect costs such as downtime and compliance. By considering the complete lifecycle of a product, LCC helps clinical engineers make informed decisions that optimize cost-effectiveness and resource allocation (Diaconu et al., 2017; Zamzam et al., 2021). This kind of economic evaluation of a product across its lifetime will help clinical engineers to choose the best investment plan on the basis of the least cost (Kambanou, 2020; Chang et al, 2022). Many studies also highlighted that life cycle costing for medical devices is a critical strategy for ensuring that devices are replaced and maintained efficiently to guarantee patient safety and cost-effectiveness. Developing life cycle costing (LCC) for medical devices involves identifying all stages of the device's life cycle and collecting detailed cost data for each stage (Chang, 2018; Seo, 2022; Thomas and Chalkidou, 2016). It also involves evaluating devices based on factors like age, maintenance costs, part discontinuation, and failure rates. These factors are used to determine the optimal time for device replacement, balancing the total costs of maintenance with the potential risks posed by device degradation. Implementing a consistent and standardized life cycle calculation method ensures that high-risk medical devices are managed effectively, reducing the risks associated with device failure and enhancing overall healthcare outcomes (Kambanou, 2020).

Last but not least, the medical device maintenance management system (MMS) is a centralized platform that helps healthcare facilities to efficiently manage the maintenance of medical devices throughout their lifecycle (Zamzam et al., 2021). It tracks device inventory, schedules preventive maintenance, generates and monitors work orders, and ensures compliance with regulatory standards. Some MMS are also incorporated with real-time performance monitoring and vendor management. According to WHO, MMS is a tool that can improve the overall medical equipment management at the facility level (WHO, 2011). Another author outlined the use of information fusion technology to enhance medical device MMS and quality control with key features including predictive maintenance which uses data to anticipate and prevent device failures. Quality control framework can also be integrated to ensure the medical devices meet safety and performance standards (Li et al, 2022). The system integrates data from multiple sources to provide a comprehensive view of device performance and maintenance needs and incorporates risk assessment to manage potential hazards in real-time for immediate issue response. Together, these features will improve the reliability, safety, and efficiency of medical devices in healthcare environments. On the other hand, The MediLog (Fairuz et al, 2024) is a simple example of MMS with functions for managing medical device loans and statuses and equipped with features like real-time data management, device tracking, user-friendly interfaces, cloud integration, and loan management. MediLog's use of barcode scanning, cloud-based data storage, and a simple interface facilitates efficient device tracking and status updates, which are essential for any MMS.

Integrating the Support Tools of Clinical Engineers for Medical Device Procurement at National Level: The Role of Government, Medical device regulatory authorities, manufacturer and Clinical Engineers

To effectively implement the centralized medical device purchasing at the national level, various stakeholders including government bodies, medical device authorities, manufacturers, and clinical engineers must collaborate and align their roles to ensure the process is efficient, safe, and compliant with regulatory standards.

Role of National Government

National governments are responsible for localizing and implementing WHO's recommendation within their healthcare systems. Governments could adapt these global standards to suit their specific needs and contexts and align them with the national healthcare priorities. The government also plays a critical role in supporting, setting up and managing the national level purchasing framework to ensure a cost-effective procurement. The strategy includes establishing policies, regulations and standards that align with international best practices such as those recommended by WHO (Rahmani et al., 2022). Governments are also responsible for ensuring that centralized procurement processes are transparent, efficient and equitable across all healthcare facilities (Nemec et al, 2023). Centralizing procurement processes would allow for economies of scale and better control over the quality and pricing of medical devices. Such systems, either led by the governments or regional bodies will enable reduced costs by pooling demand and standardizing processes across healthcare institutions. For example, in some European countries, centralized purchasing bodies are established by the government to handle procurement at the national or regional level to ensure that all public healthcare institutions benefit from the same negotiated prices and terms (Nemec et al, 2023; Callea et al, 2017). Additionally, the governments must also allocate resources for implementing national procurement systems and ensuring that clinical engineers have access to the necessary tools such as Health Technology Assessment (HTA), life-cycle costing mechanisms and maintenance management systems (MMS) (Callea et al, 2017). Governments can also facilitate partnerships between public and private sectors and incentivizing manufacturers to take part in the centralized procurement systems. A few successful national procurement systems have demonstrated their ability to centralize purchasing for not only streamlining the procurement processes, but also being able to reduce costs and ensure consistent quality of medical devices and healthcare supplies (Uyarra et al, 2014). For example, the United Kingdom's NHS Supply Chain operates a highly centralized procurement system by leveraging bulk purchasing to achieve significant cost savings while ensuring access to a standardized and high-quality equipment across all NHS facilities (Rahmani et al, 2022). In Canada, the Provincial Health Services Authority (PHSA) manages procurement for healthcare facilities in British Columbia and is able to improve supply chain efficiency and

standardizing pricing across the province (Snowdon and Saunders, 2022; Zhang et al, 2022). Similarly, Health Purchasing Victoria (HPV) in Australia centralizes procurement for public health services to ensure compliance with regulations and standards as well as additional focus on sustainability. Turkey's Ministry of Health oversees procurement of medical devices in the country with a centralized guidelines that support domestic production and cost control. Spain operates an interregional medical device procurement system where autonomous regions collaborate on bulk purchasing initiatives based on standardized and agreed criteria. South Korea's Public Procurement Service (PPS) centralizes procurement and utilizes an efficient e-procurement system to enhance purchasing transparency, accountability and global sourcing for high-quality medical devices. Overall, common elements of success across these systems include: centralization for bulk purchasing; standardization to maintain consistency in medical device quality; transparency in decision-making; integration of technology through digital platforms; and collaboration across regions or sectors.

These factors enable national procurement systems to deliver cost-effective, high-quality healthcare supplies to ultimately improve patient outcomes (Diaconu et al, 2017; Rahmani et al, 2022).

Role of Medical Device Regulatory Authorities

Medical device regulatory authorities (RA) are responsible for ensuring that all medical devices procured at the national level meet the stringent safety, quality and performance standards set by the country (Rahmani et al, 2022). RAs are responsible for overseeing the entire lifecycle of medical devices from procurement to post-market surveillance and ensuring that devices remain safe and effective after entering the market (Jefferys, 2001). RA's also maintain and update the national list of approved medical devices which involves vetting devices for inclusion based on the device's HTA and CED (Diaconu et al, 2017). Additionally, RA's could support evidence-based decision-making during the procurement process by providing access to HTA and CBE reports to ensure that procurement decisions are based on solid evidence of safety and efficacy. RAs could foster a close collaboration with manufacturers to define and enforce technical specifications and to ensure conformity to safety and performance standards (Altayyar, 2020; Jefferys, 2001).

Developing and enforcing procurement policies that align purchasing decisions with national health priorities is also critical especially to design frameworks that also embed the elements of transparency in competitive bidding processes (Gianfredi et al, 2021). Ethical practices must be embedded in the system to prevent conflicts of interest and ensure procurement decisions are made in the best interest of public health rather than commercial incentives (Rahmani et al, 2022). To streamline the approval process for new medical devices, procedures that reduce delays must be incorporated in the framework while still ensuring rigorous evaluation with fast-track approvals available for essential devices in times of urgent need. A specific example of a fast-track approval process for medical devices can be seen during the COVID-19 pandemic where the U.S. Food and Drug Administration (FDA) implemented its Emergency Use Authorization (EUA) program to expedite the approval of essential medical devices, such as ventilators, diagnostic tests and personal protective equipment (PPE) (USFDA, 2020).

RA's play a critical role in facilitating centralized procurement by fostering collaboration with government agencies to save cost and ensuring consistent medical device quality across healthcare facilities. Through aggregated demand, regulatory bodies help negotiate better pricing and terms with manufacturers. A notable example of centralized procurement facilitated by regulatory bodies and government collaboration is the European Union's Joint Procurement Agreement (JPA) for medical countermeasures. During the COVID-19 pandemic, the European Commission in collaboration with national health authorities, coordinated the procurement of essential medical devices, including ventilators, testing kits, and PPE to ensure equitable access across EU member states. By pooling demand at the EU level, the centralized procurement process has led to better negotiation power with medical device suppliers which resulted in cost savings and consistent quality standards across healthcare facilities in participating countries (European Commission, 2024). This approach not only streamlined the procurement process but also would be able to address the disparities in access to critical medical supplies throughout the region during a time of crisis.

To ensure smooth procurement processes at national level, RA's are also responsible to manage supply chain risks by identifying potential disruptions and ensuring the consistent availability of high-quality medical devices (Di Virgilio et al, 2024). Report shows that many RAs have demonstrated effective management of supply chain risks and market dynamics in various scenarios. During the COVID-19 pandemic, agencies like the U.S. FDA and the European Medicines Agency (EMA) have expedited approvals for alternative suppliers and new technologies to mitigate shortages of essential medical devices such as ventilators and personal protective equipment (PPE) to ensure consistent availability in response to global supply chain disruptions (USFDA, 2020; EMA, n.d). Similarly, after Brexit the UK's Medicines and Healthcare products Regulatory Agency (MHRA) have monitored market dynamics to prevent disruptions in medical device supplies to the UK and facilitate temporary market authorizations and work closely with manufacturers to ensure a smooth transition to new regulatory frameworks (MHRA, 2021). In China, the National Medical Products Administration (NMPA) streamlined the approval process for imported medical devices particularly during the pandemic, to address fluctuating demand and maintain a steady supply of advanced medical technologies (NMPA, 2020). These examples highlight how RAs adapt to challenges and ensure the continuous availability of high-quality medical devices during times of crisis and transition.

Role of Manufacturers

Manufacturers play a critical role in ensuring the success of procurement of medical devices at national level. They must work collaboratively with governments and medical device regulatory authorities to ensure that their devices meet national standards and are included in the national procurement system (Rahmani et al, 2020; Bucciol et al, 2020). Suppliers are responsible for complying with both national and international regulatory requirements to ensure that medical devices are safe, of high quality, and perform effectively throughout their lifecycle. They must also ensure that medical device technical

specifications are available and accessible to clinical engineers. In addition to regulatory compliance, manufacturers are increasingly required to incorporate sustainability practices into their operations. This includes addressing sustainability issues which are increasingly becoming a regulatory and market priority. Suppliers need to integrate these principles into their production processes to meet the growing expectations of healthcare providers and regulatory authorities (Ghadimi and Heavy, 2014). For example, manufacturers are now focusing on lifecycle extension of single-use medical devices through reprocessing and remanufacturing. This approach minimizes waste and promotes a circular economy by extending the lifespan of devices such as sensors (Medical Product Outsourcing, 2023). Additionally, green manufacturing practices, such as reducing energy consumption and waste in production are largely being adopted to minimize the environmental impact of medical device production (McGain et al, 2017). This involves aligning with the Triple Bottom Line (TBL) framework, which emphasizes environmental, economic, and social sustainability (Bradford et al, 2024).

Manufacturers also play a crucial role in supporting clinical engineers through continuous training on the proper use, maintenance and integration of their devices by benefitting the elearning technology and partnership with professional bodies related to clinical engineers (Sony et al, 2023; David and Judd, 2020). Furthermore, manufacturers must engage in data sharing and provide access to clinical evidence databases to enable clinical engineers to make informed decisions during the procurement process. To facilitate national-level purchasing, manufacturers need to be transparent about device costs, life-cycle management, safety and performance in ensuring that devices are maintained and replaced at optimal times to prevent failures (Weng, 2020).

Role of Clinical Engineers

Clinical engineers are at the forefront of evaluating, procuring and managing medical devices (Zamzam et al, 2021). They rely on support tools such as HTA, CED, technical specifications and standardized procurement guidelines to make informed and evidence-based decisions (Diaconu et al, 2017). Clinical engineers play a vital role in ensuring that the devices procured at the national level meet the necessary clinical and organizational requirements. They assess the long-term viability and safety of devices, perform cost-effectiveness analyses and ensure that the devices could be integrate seamlessly into healthcare environments without disrupting workflows. Clinical engineers also ensure that devices are maintained according to manufacturer specifications using maintenance management systems (MMS), thereby enhancing device reliability and safety over their lifecycle (Verga et al, 2023).

To ensure successful delivery of all tasks, clinical engineers must equip themselves with updated knowledge and skills through ongoing education and training (Altmiller and Pepe, 2022). This continuous learning keeps them informed about the latest advancements in medical technology, regulatory changes, and industry standards. With this knowledge, they can make well-informed decisions during the procurement process to ensure that only devices meeting the highest standards of safety, functionality, and sustainability are selected. Their technical expertise is crucial for evaluating medical devices, assessing compatibility with existing systems, and ensuring optimal performance. Additionally, clinical engineers must stay current with regulatory updates, including those related to device safety, sustainability practices, and data privacy, to guide procurement decisions that comply with both national and international standards. In addition to regulatory knowledge, clinical engineers are increasingly involved in promoting sustainability in medical device procurement. By understanding eco-friendly materials, energy-efficient manufacturing processes, and lifecycle impacts, they help ensure that the devices selected not only fulfill healthcare needs but also contribute to environmental goals (Hoveling et al, 2024). Moreover, their role in collaborating with stakeholders, including manufacturers, suppliers, and healthcare providers, ensures that procurement decisions are aligned with technical requirements and broader healthcare objectives. Hence, clinical engineers' commitment to continuous learning, technical proficiency, and collaboration is vital in supporting successful national-level medical device procurement, ensuring that it aligns with regulatory, sustainability, and healthcare priorities.

CONCLUSION

In conclusion, the success of national-level medical device procurement hinges on the collaboration of multiple stakeholders, including governments, regulatory authorities, manufacturers and clinical engineers. The WHO recommendation for medical device procurement provides a robust guideline for establishing transparent, efficient and standardized procurement processes. However, the successful implementation of this framework requires the active participation of clinical engineers, who play a vital role in evaluating, selecting, and maintaining medical devices. Clinical engineers must be equipped with the necessary support tools, including HTA, clinical evidence databases, and standardized procurement guidelines. These tools help them make evidence-based decisions that prioritize safety, effectiveness and sustainability. Furthermore, continuous education and training are essential for clinical engineers to stay informed about the latest advancements in medical technology and regulatory changes, ensuring that they can effectively contribute to procurement processes. Regulatory authorities must also play a proactive role by ensuring that medical devices meet stringent safety and quality standards and by facilitating centralized procurement systems that offer cost savings and consistent quality. Manufacturers, on the other hand, must focus on transparency in providing technical specifications, incorporating sustainability practices, and supporting clinical engineers through training and data sharing. By fostering collaboration among these stakeholders and ensuring that clinical engineers have access to the necessary tools and training, the WHO recommendation can be effectively implemented, leading to more efficient, safe, and standardized medical device procurement processes that ultimately enhance healthcare delivery and patient outcomes.

ACKNOWLEDGEMENT

The authors would like to thank Universiti Teknologi Malaysia for supporting the study.

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